ELECTRICAL LABORATORY- TEST REPORT
MEDICAL ELECTRICAL EQUIPMENT
Part 2-10: Particular Requirements for Basic Safety and Essential Performance of nerve and muscle stimulators

Test Report N°.....	ITC/TEST/NN/1510/03
Date of issue.....	15-01-2016
Sample date in.....	16-10-2015
Date of performance.....	16-10-2015 to 24-12-2015
Applicant.....	Mr. Dilkash Mohammed
Customer.....	Johari Digital Healthcare ltd G-582-583, EPIP zone, Bornanda, Jodhpur-342008, India
Sample description.....	WinStim Plus Combo Therapy
Sample Condition.....	Ok
Customer reference.....	N/A
Trade mark / Manufacturer...	
Model / Type / Reference....	WS4U/ Ver: 3.X / Sr. YYMMW4UXXX
Ratings.....	24 V DC adaptor/2.5 Amp
Test method(s).....	IEC 60601-1:2005+AMD:2013 & IEC 60601-2-52:2015

Overall verdict	**Pass**	☒
	Fail	☐

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Possible test case verdicts:

- Test case does not apply to the test object ..... N/A
- Test object meets the requirement ..... P (Pass)
- Test object does not meet the requirement ..... F (Fail)

General remarks:

- " See enclosure ## " refers to additional information related to this report in the annexes section
- " See table ## " refers to a table appended to this report in the annexes section
- " See figure ## " refers to an image, picture or drawing appended to this report in the annexes section

General product information:

Pictures of Specimen received:

Testing Engineer
Dharminder Chauhan

Technical Manager
Naveen Chopra

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Copy of marking plate

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
7.	**201.7**	**ME EQUIPMENT identification, marking and documents**		
7.1.1		**USABILITY of the identification, marking and documents**		
		The MANUFACTURER shall address the RISK(S) of poor USABILITY, including those associated with identification, marking and documents, through a USABILITY ENGINEERING PROCESS complying with IEC 60601-1-6		P
7.1.2		**Legibility of markings**		
		The marking required by 7.2, 7.3, 7.4, 7.5 and 7.8 shall be CLEARLY LEGIBLE under the following conditions:		
		- For warning statements, instructive statements, safety signs and drawings on the outside of ME EQUIPMENT, from intended position of the person performing the related function.	Provided	P
		- For fixed ME Equipment; when the ME EQUIPMENT is mounted in its position of NORMAL USE.		N/A
		- For TRANSPORTABLE ME EQUIPMENT and for STATIONARY ME EQUIPMENT that is not Fixed ME EQUIPMENT;.		N/A
		- for marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts: when viewed from the intended position of the person performing the related function.		N/A
7.1.3		**Durability of markings**		
		The marking 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 legible during the expected service life of the ME EQUIPMENT.	In Compliance (Refer Table C)	P
7.2		**Marking On The Outside Of ME EQUIPMENT or ME EQUIPMENT parts**		
7.2.1		**Minimum requirements for marking on ME EQUIPMENT and on**		

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		interchangeable Parts		
		If the size of the ME EQUIPMENT, an ME EQUIPMENT PART or an ACCESSORY, or the nature of its ENCLOSURE, does not allow affixation of all marking 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 the ACCOMPANYING DOCUMENTS. Where no marking of the ME EQUIPMENT is practicable, these marking may be affixed to the individual packaging.	Provided	P
7.2.2		**Identification**		
		ME EQUIPMENT shall be marked with		
		– the name or trademark and contact information of the MANUFACTURER;	Provided	P
		– a MODEL OR TYPE REFERENCE;	Provided (WS4U)	P
		– a serial number or lot or batch identifier; and	Provided (YYMMW4UXXX)	P
		– the date of manufacture or use by date, if applicable.		N/A
		Detachable components of the ME EQUIPMENT shall be marked with:	List of the detachable parts has been provided by the manufacturer Refer table B	
		– the name or trademark of the MANUFACTURER; and		P
		– a MODEL OR TYPE REFERENCE;		P
		Software that forms parts of a PEMS shall be identified with a unique identifier, such as revision level or date of release/issue. The identification shall be available to designated persons.	In compliance	P
	201.7.2.2	The MEDICAL BED shall be marked with the name or trademark and address of the MANUFACTURER, MODEL OR TYPE REFERENCE and means to allow traceability		

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		The detachable components s hall be marked with the name or trademark and address of t he MANUFACTURER, MODEL OR TYPE REFERENCE and means to allow traceability unless mis-identification does not present an unacceptable RISK.		
	201.7.2.2.101	**Marking of maximum PATIENT weight and SAFE WORKING LOAD**		
		The MEDICAL BED shall be marked with the corresponding maximum PATIENT weight (see 201.9.8.3.1) and SAFE WORKING LOAD (for symbol see Figure 201.105).		
		Detachable parts of a MEDICAL BED of a mass of more than 20 kg Shall be marked with symbol ISO 7000-1321 (2004-01): .		
		Marking for machine washable MEDICAL BEDS by a n automatic washing system		
		MEDICAL BEDS intended for use with an automatic washing system shall be marked with the following text to distinguish them from MEDICAL BEDS which cannot tolerate such cleaning methods: “Caution, for cleaning purposes this bed can be used with automatic washing systems.”		
	201.7.2.2.103	**Marking for MEDICAL BEDS intended for jet stream washing**		
		MEDICAL BEDS Intended for use with jet stream washing s hall be marked with the following text: “Caution, for cleaning purposes this bed can be used with jet stream washing.”		
	201.7.2.2.104	**Width of carriage of BED-LIFT**		
		If a BED-LIFT has an adjustable width carriage, the range shall be marked, e.g. by linear measurement indicator fixed to the adjustable parts		

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
	201.7.2.2.105	**Marking of replacement mattresses**		
		MEDICAL BEDS shall be marked with following sentence as a warning " Incompatible MATTRESSES can create HAZARDS. Read Instructions for use" or use a symbol as appropriate on a Prominent place on the MATTRESSES SUPPORT PLATEFORM indicating the compatible SIDE RAIL		
	201.7.2.2.106	**Marking of Detachable SIDE RAILS**		
		MEDICAL BEDS shall be marked with following sentence as a warning " Incompatible side rails can create HAZARDS. Read Instructions for use" or use a symbol as appropriate on a Prominent place near the attachment point of the SIDE RAIL, indicating the compatible SIDE RAIL		
7.2.3		**Consul ACCOMPANYING DOCUMENTS**		
		When appropriate symbol ISO 7000-1641 may be used to advise the OPERATOR to consult the ACCOMPANYING DOCUMENTS.		P
7.2.4		**ACCESSORIES**		
		ACCESSORIES shall be marked with:		
		– the name or trade-mark and contact information of their MANUFACTURER		P
		– a MODEL OR TYPE REFERENCE;		N/A
		– a serial number or lot or batch identifier; and		P
		– the date of manufacture or use by date, if applicable.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging.	In compliance	P
7.2.5		**ME EQUIPMENT intended to receive power from other equipment**		
		If ME EQUIPMENT is intended to receive its power from other electrical equipment in an ME SYSTEM and compliance with the requirements of this standard is dependent on that other equipment, one of the following shall be provided:		N/A
		– the name or trademark of the manufacturer of the other electrical equipment with a MODEL OR TYPE REFERENCE		N/A
		– placing safety sign ISO 7010-M002		N/A
		– using a special connector style that is not commonly available on the market and listing of the required details in the instructions for use.		N/A
7.2.6		**Connection to the SUPPLY MAINS**		
		ME EQUIPMENT shall be marked with the following information:		
		-The RATED supply voltage(s) or RATED voltage range(s) to which it may be connected.	Provided (Rated voltage Range: (100-240 V AC)	P
		- nature of supply		P
		- RATED frequency range in hertz	Provided (50 Hz)	P
		- For CLASS II ME EQUIPMENT, symbol IEC 60417-5172	Provided symbol	P
7.2.7		**Electrical input power from the SUPPLY MAINS**		
		The RATED input power of mains powered STIMULATOR shall be the maximum power averaged over any period of 5 s under the specified operating conditions set out by the		

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		manufacturer.		
		The RATED input from the SUPPLY MAINS shall be marked on the ME EQUIPMENT. The RATED input shall be given in:		
		- amperes or volt-amperes, or	2.5 Amp DC	P
		– if the power factor exceeds 0,9, in amperes, volt-amperes or watts.		N/A
		In the case of ME EQUIPMENT for one or several RATED voltage ranges, the RATED input shall always be given for the upper and lower limits of range or ranges, if the range(s) is/are greater than ± 10 % of the mean value of the given range.		
		In the case of range limits which do not differ by more than 10% from the mean value, marking of the input at the mean value of the range is sufficient.		N/A
		If the rating of ME EQUIPMENT includes both long-time and momentary current or volt-ampere ratings, the marking shall include both long-time and most relevant momentary volt-ampere ratings, each plainly identified and indicated in the Accompanying DOCUMENTS.		N/A
	201.7.2.101	**Output**		
		ME EQUIPMENT capable of delivering outputs in excess of 10 mA or 10 V averaged over any period of 1 s shall be marked near the electrode connections with symbol No. 10 of Table D.2 of the general standard.		P
7.2.8		**Output Connectors**		
7.2.8.1		**Mains power output**		
		For MULTIPLE SOCKET-OUTLETS that are integral with ME EQUIPMENT.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
7.2.8.2		**Other Power Sources**		
		output connectors of ME EQUIPMENT intended to deliver power shall be marked with the following information: - RATED output voltage; - RATED current or power (when applicable); - Output frequency (When applicable)		N/A
7.2.9		**IP classification**		
		ME EQUIPMENT or its parts shall be marked with a symbol, using the letters IP followed by the designations described in IEC 60529.	Provided (IP20)	P
7.2.10		**APPLIED PARTS**		
		All APPLIED PARTS shall be marked with the relevant symbol.		P
		The degree of protection against electric shock as classified in 6.2 for all APPLIED PARTS shall be marked with the relevant symbol		P
		For DEFIBRILLATION-PROOF APPLIED PARTS, symbols IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336 shall be used as applicable		N/A
		- There is no such connector, in which case the marking shall be on the APPLIED PART; or		N/A
		- The connector is used for more than one APPLIED PART and the different APPLIED PARTS have different classifications, in which case each APPLIED PART shall be marked with the relevant symbol.		N/A
7.2.11		**Mode of operation**		
		For ME EQUIPMENT intended for non-CONTINUOUS OPERATION, the DUTY CYCLE shall be indicated using an appropriate marking giving the maximum activation (on) time and minimum deactivation (off) time.	CONTINUOUS OPERATION	N/A

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7.2.12		**Fuses**		
		Where the fuse-holder is an ACCESSIBLE PART, the type and full rating of the fuse shall be marked adjacent to the fuse-holder.		N/A
7.2.13		**Physiological effects (safety signs and warning statements)**		
		ME EQUIPMENT producing physiological effects that are not obvious to the OPERATOR and can cause HARM to the PATIENT or OPERATOR shall bear a suitable safety sign. .		P
7.2.14		**HIGH VOLTAGE TERMINAL DEVICES**		
		HIGH VOLTAGE TERMINAL DEVICES shall be marked with symbol IEC 60417-5036 ϟ		N/A
7.2.15		**Cooling conditions**		
		Requirement for cooling provisions for ME EQUIPMENT shall be marked.		N/A
7.2.16		**Mechanical stability**		
		For requirements of ME EQUIPMENT with a limited stability.	See Clause 9.4	P
7.2.17		**Protective packaging**		
		If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly.		N/A
		The permissible environmental conditions for transport and storage shall be marked on the outside of the packaging.		N/A
		Where premature unpacking of ME EQUIPMENT or its parts could result in an acceptable RISK, the packaging shall be marked with a suitable safety sign.		N/A
		The packaging of ME EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile.		N/A
7.2.18		**External pressure source**		
		Adjacent to each input connector, the		

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		ME EQUIPMENT shall be marked with:		
		– the RATED maximum supply pressure from an external source, and		N/A
		– the RATED flow rate if required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.		N/A
7.2.19		**FUNCTIONAL EARTH TERMINALS**		
		A FUNCTIONAL EARTH TERMINALS shall be marked with symbol IEC 60417-5017	Class ll ME Equipment	N/A
7.2.20		**Removable protective means**		
		ME EQUIPMENT has alternative applications that require the removal of a protective means to use a particular function, the protective means shall be marked to indicate the necessity for replacement when the relevant function is no longer needed. No marking is required when an interlock is provided.		N/A
7.2.21		**Mass of MOBILE ME EQUIPMENT**		
		MOBILE ME EQUIPMENT shall be marked with its mass including its SAFE WORKING LOAD in kilograms.	Not a mobile equipment	N/A
7.3		**MARKING on the inside of ME EQUIPMENT OR ME EQUIPMENT PARTS**		
7.3.1		**Heating elements or lampholders**		
		The maximum power loading of heating element or lampholder designed for use with heating lamps shall be marked near the heater or in the heater itself.	No heating element or lamp holders used	N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
7.3.2		**HIGH VOLTAGE parts**		
		The presence of HIGH VOLTAGE parts shall be marked with symbol IEC 60417-5036. or with safety sign.		N/A
7.3.3		**Batteries**		
		The type of battery and the mode of insertion shall be marked.	Ni-MH battery used	P
7.3.4		**Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES**		
		Fuses and replaceable thermal CUT-OUTS and OVER-CURRENT RELEASES that are accessible only by the use of TOOL shall be Identified either by specification adjacent to the component, or by a reference to information in the ACCOMPANYING DOCUMENTS.		N/A
7.3.5		**PROTECTIVE EARTH TERMINALS**		
		PROTECTIVE EARTH TERMINALS SHALL be marked with symbol IEC 60417-5019		N/A
7.3.6		**FUNCTIONAL EARTH TERMINALS**		
		FUNCTIONAL EARTH TERMINALS shall be marked with symbol		N/A
7.3.7		**Supply terminals**		
		Terminals for supply conductors shall be marked adjacent to the terminals unless it can be demonstrated that no unacceptable RISK an result if connections are interchanged.	Detachable supply cord is provided for connection	P
		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 the appropriate code from IEC 60445		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		If marking for connection to a three-phase supply is necessary, it shall be according to IEC 60445	Single phase supply present	N/A
7.3.8		**Temperature of supply terminals**		
		If any point within a terminal box or wiring compartment intended for connection of the power supply conductors for PERMANENTLY INSTALLED ME EQUIPMENT attains a temperature of more than 75°C during NORMAL USE and NORMAL CONDITION at the maximum ambient operating temperature as indicated in the technical description, the ME EQUIPMENT shall be marked with the following or an equivalent statement: "For supply connections, use wiring materials suitable for at least X° C." Where "X" is greater than the maximum temperature measured in the terminal box or wiring compartment in NORMAL USE and NORMAL CONDITION. It shall be CLEARLY LEGIBLE after the connections have been made.		N/A
7.4		**Marking of controls and instruments**		
7.4.1		**Power switches**		
		Switches used to control power to ME EQUIPMENT or its parts, including mains switches shall have their "on" and "off" positions.	In Compliance	P
		– marked with symbols IEC 60417-5007 (2002-10) and IEC 60417-5008 (2002-10) symbols 12 and 13)		P
		– indicated by an adjacent indicator light; or		N/A
		– Indicated by other unambiguous means.		N/A
		If a push button with bistable position is used:		
		– it shall be marked with symbol IEC 60417-5010 (2002-10)		N/A
		– the status shall be indicated by an adjacent indicator light		N/A

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		– the status shall be indicated by other unambiguous means.		N/A
		If a push button with momentary on position is used		
		– it shall be marked with symbol 60417-5011 (2002-10)		N/A
		– the status shall be indicated by an adjacent indicator light		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.		N/A
		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 indicated device,		N/A
		- an indication of the direction in which the magnitude of the function changes.		N/A
		A control device or switch that brings the ME EQUIPMENT into the "stand-by" condition may be indicated by use of symbol IEC 60417-5009 (2002-10)		N/A
7.4.3		**Units of measurement**		
		Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to ISO 80000-1.		P
7.5		**Safety Signs**		
		For the purpose of this clause, 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.		P
7.6		**Symbols**		
7.6.1		**Explanation of symbols**		
		The meanings of the symbols used for marking shall be explained in the	Provided in instruction	P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		instructions for use.	manual	
7.6.2		**Symbols from Annex D**		
		Symbols required by this standard shall conform to the requirements in the referenced IEC OR ISO publication.	In Compliance	P
7.6.3		**Symbols for controls and performance**		
		Symbols used for control and performance sconform to the requirements of the hall IEC or ISO publication where the symbol is defined, when applicable.		P
7.7		**Colours of the insulation of conductors**		
7.7.1		**PROTECTIVE EARTH CONDUCTOR**		
		A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green and yellow coloured insulation.		N/A
7.7.2		**PROTECTIVE EARTH CONNECTIONS**		
		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		**Green and yellow insulation**		
		Identification by green and yellow insulation shall only be used for:		
		- PROTECTIVE EARTH CONDUCTORS (see 8.6.2)		N/A
		- CONDUCTORS as specified in 7.7.2		N/A
		- POTENTIAL EQUALIZATION CONDUCTORS. (see 8.6.7)		N/A
		- FUNCTIONAL EARTH CONDUCTORS. (see 8.6.8)		N/A

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7.7.4		**Neutral conductor**		
		Conductors in POWER SUPPLY CORDS intended to be connected to the neutral conductor of the supply system shall be coloured "light blue" as specified in IEC 60227-1 or in IEC 60245-1.		N/A
7.7.5		**POWER SUPPLY CORD conductors**		
		Colours of conductors in POWER SUPPLY CORDS shall be in accordance with IEC.	In compliance	P
7.8		**Indicator lights and controls**		
7.8.1		**Colours of indicator lights**		
		The colours of indicator lights and their meaning shall comply with Table 2		N/A
7.8.2		**Colours of controls**		
		The colour red shall be used only for a control by which a function is interrupted in case of emergency.		P
7.9		**ACCOMPANYING DOCUMENTS**		
7.9.1		**General**		
		ME EQUIPMENT shall be accompanied by documents containing at least the instructions for use and a technical description.	In Compliance	P
		The ACCOMPANYING DOCUMENTS shall identify the ME EQUIPMENT by including, as applicable, the following; -name or trade-name of the MANUFACTURER and an address to which the responsible organization can refer; -MODEL OR TYPE REFERENCE	In Compliance	P
		The ACCOMPANYING DOCUMENTS shall specify any special skills, training and knowledge required of the intended OPERATOR or the RESPONSIBLE ORGANIZATION and any restrictions on locations or environments in which the ME EQUIPMENT can be used.	Provided	P

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		The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education training and any special needs of the person(s) for whom they are intended.		P
7.9.2		**Instructions for use.**		
7.9.2.1		**General**		
		The instructions for use shall document		
		- The use of the ME EQUIPMENT as intended by the MANUFACTURER,	In Compliance	P
		- The frequently used functions.	In Compliance	P
		- Any known contraindication to the use of the ME EQUIPMENT and		N/A
		- those parts of the ME EQUIPMENT that shall not be serviced or maintained while in use with a PATIENT.		N/A
		Where the PATIENT is an intended OPERATOR, the instructions for use shall indicate:		
		– the PATIENT is an intended OPERATOR;		N/A
		– a warning against servicing and maintenance while the ME EQUIPMENT is in use;		N/A
		– which functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		N/A
		– which maintenance the PATIENT can perform (e.g. changing batteries).		N/A
		The instructions for use shall indicate:		
		– the name or trademark and address of the MANUFACTURER;		P
		– the MODEL OR TYPE REFERENCE.		P
		The instructions for use shall include all applicable classifications specified all markings specified in 7.2, and the explanation of safety signs and symbols		P

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7.9.2.2		**Warning and safety notices**		
		The instructions for use shall include all warning and safety notices	In Compliance	P
7.9.2.3		**ME EQUIPMENT specified for connection to a separate power supply**		
		If ME EQUIPMENT is intended for connection to a separate power supply, either the power supply shall be specified as part of the ME EQUIPMENT or the combination shall be specified as an ME SYSTEM. The instructions for use shall state this specification.		N/A
7.9.2.4		**Electrical power source**		
		The instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement or such an additional power source.		N/A
7.9.2.5		**ME EQUIPMENT description**		
		The instructions for use shall include:		
		- a brief description of the ME EQUIPMENT;	Provided	P
		- how the ME EQUIPMENT functions; and	Provided	P
		- the significant physical and performance characteristics of the ME EQUIPMENT.	Provided	P
		The instructions for use shall include information on the materials ingredients to which the PATIENT or OPERATOR is exposed if such exposure can constitute an acceptable RISK.		N/A
		The instructions for use shall specify any restrictions on other equipment or NETWORK/DATA COUPLINGS other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected.		N/A
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	Provided	P

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		installation instructions are to be found. - Contact information for persons designated by the MANUFACTURER as qualified to perform the installation.		
7.9.2.7		**Isolation from the SUPPLY MAINS**		
		if an APPLIANCE COUPLER or Mains PLUG or other separable plug is used as the isolation means to satisfy 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		**Start-up PROCEDURE**		
		The instructions for use shall contain the necessary information for the OPERATOR to bring the ME EQUIPMENT into operation including such items as any initial control settings, connection to or positioning of the PATIENT, etc.	Provided	P
7.9.2.9		**Operating instructions**		
		The instructions for use shall contain all information necessary to operate the ME EQUIPMENT in accordance WITH its specification	Provided	P

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7.9.2.10		**Messages**		
		The instructions for use shall list all system messages, error messages and fault messages that are generated, unless these messages are self-explanatory.	Provided in the instruction manual	P
7.9.2.11		**Shutdown Procedure**		
		The instructions for use shall contain the necessary information for the OPERATOR to safely terminate the operation of ME EQUIPMENT.	Provided	P
7.9.2.12		**Cleaning, disinfection and sterilization**		
		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 - list the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT parts or ACCESSORIES can tolerate.	Provided	P
7.9.2.13		**Maintenance**		
		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.	Provided	P
		The instructions for use shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the ME EQUIPMENT.		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
7.9.2.14		**ACCESSORIES, Supplementary equipment, Used material**		
		The instructions for use shall include a list of Accessories, detachable parts and materials that the MANUFACTURER has determined are intended for use with the ME Equipment.		P
7.9.2.15		**Environmental protection**		
		The instructions for use shall provide advice on the proper disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE.		N/A
7.9.2.16		**Reference to the technical description**		
		The instructions for use shall contain the information specified in 7.9.3 or a reference to where the material specified in 7.9.3 is to be found	Provided	P
7.9.2.17		**ME EQUIPMENT emitting radiation**		
		For ME EQUIPMENT emitting radiation for medical purposes, when appropriate, the instructions for use shall indicate the nature, type, intensity and distribution of this radiation.		P
7.9.2.18		**ME EQUIPMENT and ACCESSORIES supplied sterile**		
		The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile shall indicate that they have been sterilized and indicate the method of sterilization.		P
		The instructions for use shall indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		N/A
7.9.2.19		**Unique version identifier**		
		The instructions for use shall contain a unique version identifier such as its date of issue	Version no. has been provided in the instruction manual	P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
7.9.3		**Technical description**		
7.9.3.1		**General**		
		The technical description shall provide all data that is essential for safe operation, transport and storage and measures or conditions necessary for installing the ME EQUIPMENT, and preparing it for use. This shall include:		P
-		the information required in 7.2;	Provided	P
-		the permissible environmental conditions of use including conditions for transport and storage.	Provided	P
-		All characteristics of the ME EQUIPMENT, including ranges, accuracy, and precision of the displayed values or an indication where they can be found.	Provided	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,		N/A
-		information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency.		P
	-	The technical description shall specify the parameters mentioned in item a) of 201.7.9.2.101 along with the range of load impedances for which these parameters are valid.		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
7.9.3.2		**Replacement of fuses, power supply cords and other parts.**		
		The technical description shall contain, as applicable, the following.		
		- the required type and full rating of fuses used in the supply mains external to permanently installed ME EQUIPMENT, if the type and rating of these fuses are not apparent from the information concerning RATED current and mode of operation of ME EQUIPMENT.		N/A
		- for me equipment having a non-DETACHABLE POWER SUPPLY CORD, a statement as to whether the POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL		N/A
		- instructions for correct replacement of interchangeable or detachable parts that the MANUFACTURER SPECIFIES as replaceable by SERVICE PERSONNEL;	Provided	P
		- where replacement of a component could result in an unacceptable RISK, appropriate warnings that identify the nature of the HAZARDS, and if the MANUFACTURER specifies the component as replaceable by SERVICE PERSONNEL, all information necessary to safely replace the component.	Provided	P
7.9.3.3		**Circuit diagrams, component part lists, etc.**		
		The technical description shall contain a statement that the MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibrations instructions, or other information that will assist SERVICE PERSONNEL, to repair those parts of ME EQUIPMENT that designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.	In compliance	P
7.9.3.4		**Mains isolation**		
		The technical description shall clearly identify any means used to comply with the requirement of 8.11.1		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.	**201.8**	**Protection against electrical HAZARDS from ME EQUIPMENT**		
8.1		**Fundamental rule of protection against electric shock**		
		The limits specified in 8.4 shall not be exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL CONDITION OR SINGLE FAULT CONDITION.	See clause 8.4	P
8.2		**Requirements related to power sources**		
8.2.1		**Connection to a separate power source**		
		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 and all relevant requirement of this standard shall apply, or the combination shall be considered as an ME SYSTEM.		N/A
8.2.2		**Connection to an external d.c. power source.**		
		If ME EQUIPMENT is specified for power supplied from an external d.c. power source, then a connection with wrong polarity shall not lead to the HAZARDOUS SITUATIONS described in 13.1. The ME EQUIPMENT, when connection is subsequently made with the correct polarity, shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE. Protective devices, that can be reset by anyone without the use of a TOOL are	No external, only Internal DC battery source has been provided	N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		acceptable the ME EQUIPMENT returns to NORMAL CONDITION on reset.		
8.3	**201.8.3**	**Classification of APPLIED PARTS**		
		The APPLIED PARTS of STIMULATORS shall be TYPE BF or TYPE CF APPLIED PARTS	TYPE BF APPLIED PARTS	P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.4.		**limitation of voltage, current or energy**		
8.4.1		**Patient CONNECTIONS intended to deliver current**		
		The limits specified in 8.4.2 do not apply to currents that are intended to flow through the body to PATIENT to produce a physiological effect during NORMAL USE.		P
8.4.2		**ACCESSIBLE PARTS and APPLIED PARTS**		
a)		The currents from, to or between PATIENT CONNECTIONS shall not exceed the limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT.	(Refer table D)	P
b)		The LEAKAGE CURRENTS from, to or between ACCESSIBE PARTS shall not exceed the limits for TOUCH CURRENT specified in 8.7.3 c) when measured as specified in 8.7.4.	(Refer table D)	P
c)		The limits specified in b) above do not apply to the following parts if the probability of a connection to a PATIENT, the instructions for use instruct the OPERATOR not to touch the relevant part and the PATIENT simultaneously:		
		- accessible contacts of connectors;		P
		- contacts of fuse holders that are accessible during replacement of the fuse.		N/A
		- contacts of lampholders that are accessible after removal of the lamp;		N/A
		- parts inside an ACCESS COVER that can be opened without the use of a TOOL, or where a tool is needed but the instructions for use instruct any operator other than SERVICE PERSONNEL to open the relevant ACCESS COVER.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
d)		The voltage and energy limits specified in (c) above also apply to: - internal parts, other than contacts of plug, connectors and socket-outlets, that can be touched by the test pin inserted through an opening in an ENCLOSURE;		N/A
	-	- internal parts that can be touched by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening in the top of an ENCLOSURE.		N/A
e)		Where an ACCESS COVER that can be opened without the use of a TOOL gives access to parts that are at voltages above the levels permitted by this subclauses	Requires use of tool	N/A
8.4.3		**ME EQUIPMENT Intended to be Connected to a Power Source by Plug**		
		ME equipment or its parts intended 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 stored charge does not exceed 45 µ C.	In Compliance (Refer Table D)	P
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, or, if, this value is exceeded, shall not have a stored charge exceeding 45 µC.		N/A
8.5		**Separation of Parts**		
8.5.1		**MEANS of PROTECTION (MOP)**		

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.5.1.1		**General**		
		ME EQUIPMENT shall have two means of protection to prevent APPLIED PARTS and other ACCESSIBLE PARTS from exceeding the limits		P
		Each MEANS OF PROTECTION shall be categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION		P
		Components and wiring forming a MEANS OF PROTECTION shall comply with the relevant requirement.		P
8.5.1.2		**MEANS OF PATIENT PROTECTION (MOPP)**		N/A
		Solid insulation forming a MEANS OF PATIENT PROTECTION shall comply with the dielectric strength test.		-
		Creepage distances and air clearances forming a MEANS OF PATIENT PROTECTION shall comply with the limits.		-
		Protective EARTH CONNECTIONS forming A MEANS of PATIENT PROTECTION shall comply with the requirement and tests.		-
		A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MEANS OF PATIENT PROTECTION. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same NOMINAL capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MEANS OF PATIENT PROTECTION).		-
		Where the working voltage across a barrier forming a MEANS OF PATIENT PROTECTION is less than 42,4 V peak a.c. or 60 V d.c., a single Y1 capacitor is acceptable for two MEANS OF PATIENT PROTECTION		-

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.5.1.3		**MEANS OF OPERATOR PROTECTION (MOOP)**		
		Solid insulation forming a MEANS OF PROTECTION shall: - comply with the dielectric test - comply with requirement for insulation CO-ORDINATION		P
		Creepage distances and AIR CLEARNCES forming a MEANS OF OPERATOR PROTECTION shall; - comply with the limits specified - comply with the requirement for insulation co-ordination.		P
		PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION shall either;		-
		- comply with the requirements of 8.6; - comply with requirements and tests.		N/A
8.5.2		**Separation of parts**		
8.5.2.1		**F-TYPE APPLIED PARTS**		
		The PATIENT CONNECTIONS(S) of any F-TYPE APPLIED PART shall be separated from all other parts, including the PATIENT CONNECTION(S) of other APPLIED PARTS, by means equivalent to one MEANS OF PATIENT PROTECTIOIN FOR A WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE and shall comply with the specified limit for PATIENT LEAKAGE CURRENT with 110% of the MAXIMUM MAINS VOLTAGE applied.		P
		A single F-type APPLIED PART may include multiple functions, in which case separation between such functions is not required.		N/A
		If there is no electrical separation between PATIENT CONNECTION of the same or another function then these PATIENT CONNECTION are treated as one APPLIED PART.		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		Where multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS is as defined by the MANUFACTURER		N/A
		The classification as TYPE CF or defibrillation-proof applies to the whole of one APPLIED PART		N/A
		Any protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and the ENCLOSURE for the purpose of providing protection against excessive voltages shall not operate below 500 V r.m.s.		N/A
8.5.2.2		**Type B-APPLIED PARTS**		
		The PATIENT CONNECTION(S) of a TYPE B 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, unless.		P
	-	- the metal ACCESSIBLE PART is physically contiguous with the APPLIED PART and can be regarded as a part of the APPLIED PART; and		N/A
		- the RISK that the metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT		P
8.5.2.3		**Patient leads or patient cables**		
		Any connector for electrical connections on a PATIENT lead that;		
		- is at the end of the lead or cable that is remote from the PATIENT		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		- contains a conductive part that is not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE. Shall be co constructed so that the said part cannot become connected to earth or possible hazardous voltage while the PATIENT CONNECTIONS(S) contact the PATIENT		N/A
8.5.3		**MAXIMUM MAINS VOLTAGE**		
		The MAXIMUM MAINS VOLTAGE shall be determined as follows:		
		- for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, including INTERNALLY POWERED ME EQUIPMENT that also has a means of connection to a SUPPLY MAINS, the MAXIMUM MAINS VOLTAGE is the highest RATED supply voltage; unless this is less than 100v, in which case the maximum mains voltage is 250 V;	Voltage range : (100-240 V AC) Single phase	P
		- for poly phase ME EQUIPMENT, the MAXIMUM MAINS VOLTAGE is the highest RATED phase to neutral supply voltage.		N/A
8.5.4		**Working Voltage**		
		The WORKING VOLTAGE for each MEANS OF PROTECTION shall be determined as follows:		
		- The input supply voltage to the ME EQUIPMENT shall be the Rated voltage or the voltage within the RATED voltage range results in the highest measured value.	In compliance	P
		- For d.c. voltage with superimposed ripple, the WORKING VOLTAGE is the average value if the peak to peak ripple does not exceed 10% of the average value or the peak voltage if the peak-to-peak ripple exceeds 10% of the average value.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		- the WORKING VOLTAGE for each MEANS of PROTECTION forming DOUBLE INSULATION is the voltage to which DOUBLE INSULATION as a whole is subjected.		N/A
		- for working VOLTAGE involving a PATIENT CONNECTION not connected to earth, the situation in which the PATIENT is earthed is regarded as a NORMAL CONDITION.		N/A
		- The WORKING VOLTAGE between the PATIENT CONNECTIONS(S) of an F-TYPE APPLIED PART and the ENCLOSURE is taken as the highest voltage appearing across the insulation in NORMAL USE including earthing of any part of the APPLIED PART.		P
		- For DEFIBRILLATION-PROOF APPLIED PARTS, the WORKING VOLTAGE is determined without regard to the possible presence of defibrillation voltages.		N/A
		- in the case of motors provided with capacitors where a resonance voltage can occur between the point where a winding and a capacitor are connected together on the hand any terminal for external conductors on the other hand, the WORKING VOLTAGE shall b equal to the resonance voltage.		N/A
8.5.5		**DEFIBRILLATION-PROOF APPLIED PARTS**		
8.5.5.1		**DEFIBRILLATION protection**		
		Arrangements used to isolate the PATIENT CONNECTION(S) of a defibrillation-proof applied part from other parts of ME EQUIPMENT shall be so designed that:		
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 voltage measured between the points Y_1 and Y_2 do not appear on:		N/A

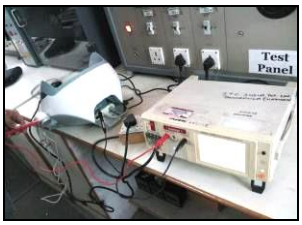
60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		- The Enclosure, including connectors in PATIENT leads and cables when connected to the ME EQUIPMENT.		N/A
		- any SIGNAL INPUT/OUTPUT PART;		N/A
		- metal foil for test on which the ME EQUIPMENT is placed and which has an area at least equal to the base of the ME EQUIPMENT;		N/A
		- PATIENT CONNECTIONS of any other APPLIED PART (whether or not classified as a DEFIBRILLATION-PROOF APPLIED PART); or		N/A
		- any unused or disconnected connections of the APPLIED PART under test or any function of the same APPLIED PART. ME EQUIPMENT that is completely BODY-WORN (e.g. a Holter monitor) is exempt from this requirement.		N/A
b)		following exposure to the defibrillation voltages, and any necessary recovery time stated in the ACCOMPANYING DOCUMENTS, the ME EQUIPMENT shall comply with relevant requirements of this standard and shall continue to provide BASIC SAFETY AND ESSENTIAL PERFORMANCE.		N/A
8.5.5.2		**Energy Reduction Test**		
		Defibrillation-proof APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS shall incorporate a means so that the defibrillator energy delivered to a 100Ω load is at least 90% of the energy delivered to this load with the ME EQUIPMENT disconnected.		N/A
8.6		**Protective earthing, functional earthing and potential equalization of ME EQUIPMENT.**		
8.6.1		**Applicability of requirements**		

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.6.2		**PROTECTIVE EARTH TERMINAL**		
		The PROTECTIVE EARTH TERMINAL of ME EQUIPMENT shall be suitable for connection to an external protective earthing system either by a PROTECTIVE EARTH CONDUTOR in an POWER SUPPLY CORD and, where appropriate, by a suitable plug, or by a FIXED PROTECTIVE EARTH CONDUCTOR. `	Class ll ME EQUIPMENT	N/A
		The clamping means of the PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors of POWER SUPPLY CORDS shall comply with the requirements. It shall not be possible to loosen the clamping means without the aid of a 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 a 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		**Protective earthing of moving parts**		
		Any PROTECTIVE EARTH CONNECTION shall not be used for a moving part unless the MANUFACTURER demonstrates that the connections will remain reliable during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
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
		For PERMANENTLY INSTALLED ME EQUIPMENT, the impedance between the PROTECTIVE EARTH TERMINAL and any part that is PROTECTIVE EARTHED shall not exceed 100 mΩ,		N/A
		For ME EQUIPMENT with an APPLIANCE INLET the impedance between the earth pin in the appliance inlet and any part that is PROTECTIVELY EARTHED shall not exceed 100 m Ω		N/A
		For ME EQUIPMENT with a NON-DETACHABLE POWER SUPPLY cord the impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 m Ω		N/A
		Additionally, the impedance between the protective earth pin in the MAINS PLUG of any DETACHABLE POWER SUPPLY CORD supplied or specified by the MANUFACTURER, when attached to the ME EQUIPMENT, and any part of the ME EQUIPMENT that is PROTECTIVELY EARTHED shall not exceed 200 mΩ,		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

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.6.5		**Surface coatings**		
		Conductive elements of ME EQUIPMENT that have surface coatings of poorly conducting material such as point, and between which electrical contact is essential to a PROTECTIVE EARTH CONNECTION, shall have coatings removed at the point of contact unless an investigation of the joint construction and the manufacturing process has demonstrated that the requirement for impedance and current-carrying capacity are assured without the removal of the surface coating		N/A
8.6.6		**Plugs and sockets**		
		Where the connection between THE SUPPLY MAINS and the ME EQUIPMENT or between separate parts of ME EQUIPMENT that can be operated by persons other than SERVICE PERSONNEL is made via a plug and socket device, the PROTECTIVE EARTH CONNECTION shall be made before and interrupted after the supply connections are made or interrupted. This applies also where interchangeable parts are PROTECTIVELY EARTHED.		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 requirement apply.		
		- the terminal shall be accessible to the OPERATOR with the ME EQUIPMENT in any position of NORMAL USE.		N/A
		- Accidental disconnection shall be avoided in NORMAL USE.		N/A
		- The terminal shall allow the conductor to be detached without use of the TOOL.		N/A
		- The terminal shall not be used for a PROTECTIVE EARTH CONNECTION.		N/A
		- The terminal shall be marked with symbol		N/A
		- The instructions for use shall contain information on the function and use of the		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		POTENTIAL EQUALIZATION CONDUCTOR.		
8.6.8		**Functional earth terminal**		
		A functional Earth Terminal of ME EQUIPMENT shall not be used to provide a PROTECTIVE EARTH CONNECTION.		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. In such a case, the ACCOMPANYING DOCUMENTS shall state that the third conductor in the POWER SUPPLY CORD is only a functional earth.		N/A
8.7		**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		
8.7.1		**General requirements**		
		a) The electrical isolation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 8.7.3.	In Compliance	P
		b) The specified values of the EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions		
-		at operating temperature and following humidity preconditioning treatment, as described in 5.7;	In Compliance, Tested for 48hr at temp:25°C±2°C and RH: 93%±3%.	P
-		after any required sterilization PROCEDURE (see 11.6.7);		N/A
-		in NORMAL CONDITION and in the SINGLE FAULT CONDITIONS specified in 8.7.2	In Compliance	P
-		with ME EQUIPMENT energized in stand-by condition and fully operating and with any switch in the MAINS PART in any position;		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
-		with the highest RATED supply frequency;	In Compliance	P
-		with a supply equal to 110 % of the highest RATED MAINS VOLTAGE.	In Compliance	P
8.7.2		**Single Fault Conditions**		
		The allowable values specified in 8.7.3 apply in the SINGLE FAULT CONDITIONS specified in 8.1 b) except	In Compliance	P
-		where insulation is used in conjunction with a PROTECTIVE EARTH CONNECTION, short circuit of the insulation applies only in the circumstances specified in 8.6.4 b);		N/A
-		the only SINGLE FAULT CONDITION for the EARTH LEAKAGE CURRENT is the interruption of one supply conductor at a time;		N/A
-		LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT are not measured in the SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION.		N/A
8.7.3		**Allowable values**		
a)		The allowable values specified in 8.7.3 b), c) and d) apply to currents flowing through the network of Figure 12 a) and measured as shown in this figure (or by a device measuring the frequency contents of the currents as defined in Figure 12 b)). The values apply to d.c. and a.c. and composite waveforms. Unless stated otherwise they may be d.c. or r.m.s.		P
b)		The allowable values of the PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in Table 3 and Table 4. The values of a.c. apply to currents having a frequency not less than 0,1 Hz.	 Refer Table E)	P

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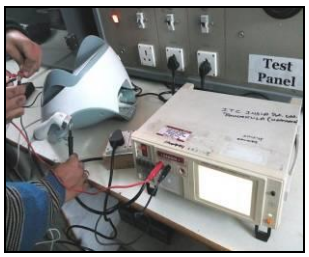
c)		The allowable values of the TOUCH CURRENT are 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION.	 (Refer Table E)	P
d)		The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.		N/A
		For PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit that supplies only this ME EQUIPMENT, a higher value of EARTH LEAKAGE CURRENT is allowed.		N/A
e)		Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT shall exceed 10 mA r.m.s. in NORMAL CONDITION or in SINGLE FAULT CONDITION when measured with a non-frequency-weighted device.		N/A
f)		*. The allowable values of LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.		N/A
8.7.4		**Measurements**		
a)		The EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured after the ME EQUIPMENT has been brought up to operating temperature in accordance with the requirements of 11.1.3 c).	TOUCH CURRENT, PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT are measured at ambient temperature.	P
b)		Where examination of the circuit arrangement and the arrangement of components and material of the ME EQUIPMENT shows no possibility of any HAZARDOUS SITUATION,	In Compliance	P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.7.4.2		ME EQUIPMENT specified for connection to a SUPPLY MAINS is connected to an appropriate power source		
		For single-phase ME EQUIPMENT, the polarity of the supply is reversible and tests are conducted at both polarities	In Compliance	P
		INTERNALLY POWERED ME EQUIPMENT is tested without any connection to a measuring supply circuit.		N/A
8.7.4.3		**Connection to the measuring supply circuit**		
a)		ME EQUIPMENT provided with a POWER SUPPLY CORD is tested using this cord		P
b)		ME EQUIPMENT provided with an APPLIANCE INLET is tested while connected to the measuring supply circuit via a DETACHABLE POWER SUPPLY CORD having a length of 3 m or a length and type specified in the instructions for use.		P
c)		PERMANENTLY INSTALLED ME EQUIPMENT is tested while connected to the measuring supply circuit by the shortest possible connection.		N/A
d)		Measuring arrangement		
1)		APPLIED PARTS, including PATIENT cables (when present), are placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.		N/A
2)		If an isolating transformer is not used for LEAKAGE CURRENT measurements (e.g. when measuring LEAKAGE CURRENT for very high input power ME EQUIPMENT), the reference earth of the measuring circuits is connected to protective earth of the SUPPLY MAINS.		N/A
8.7.4.5		**Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection**		
a)		CLASS I ME EQUIPMENT is tested according to Figure 13. CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9 is tested as if it were CLASS I ME EQUIPMENT.	CLASS II ME EQUIPMENT	--
b)		ME EQUIPMENT has more than one PROTECTIVE EARTH CONDUCTOR (for example, one connected to the main ENCLOSURE and one to a separate power supply unit), then the current to be		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		measured is the aggregate current that would flow into the protective earthing system of the installation		
c)		For FIXED ME EQUIPMENT that can have connections to earth through the building structure, the MANUFACTURER specifies a suitable test PROCEDURE and configuration for measurement of EARTH LEAKAGE CURRENT.		N/A
8.7.4.6		**Measurement of the TOUCH CURRENT**		
a)		ME EQUIPMENT is tested according to Figure 14, using an appropriate measuring supply circuit.		
		Measure with MD between earth and each part of the ENCLOSURE(S) that is not PROTECTIVELY EARTHED.		N/A
		Measure with MD between parts of the ENCLOSURE(S) that are not PROTECTIVELY EARTHED.		N/A
		In the SINGLE FAULT CONDITION of interruption of any one PROTECTIVE EARTH CONDUCTOR (when applicable, see 8.1 b)), measure with MD between earth and any part of the ENCLOSURE(S) that is normally PROTECTIVELY EARTHED.		N/A
		INTERNALLY POWERED ME EQUIPMENT is investigated for TOUCH CURRENT but only between parts of the ENCLOSURE, not between the ENCLOSURE and earth unless 8.7.4.6 c) applies.		N/A
b)		If ME EQUIPMENT has an ENCLOSURE or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm x 10 cm is applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE.		P
		The metal foil is shifted, if possible, to determine the highest value of the TOUCH CURRENT		P
		The metal foil should not touch any metal parts of the ENCLOSURE that are possibly PROTECTIVELY EARTHED; however, metal parts of the ENCLOSURE that are not PROTECTIVELY EARTHED can be covered partly or totally by the metal foil.		P
		Where it is intended to measure the TOUCH CURRENT in the SINGLE FAULT CONDITION of interruption of a PROTECTIVE EARTH CONDUCTOR, the		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		metal foil is arranged to contact parts of the ENCLOSURE that are normally PROTECTIVELY EARTHED.		
		Where the surface of the ENCLOSURE contacted by the PATIENT or OPERATOR is larger than 20 cm x 10 cm, the size of the foil is increased corresponding to the area of contact		P
c)		ME EQUIPMENT with a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested using transformer T2.		N/A
8.7.4.7		**Measurement of the PATIENT LEAKAGE CURRENT**		
a)		ME EQUIPMENT with an APPLIED PART is tested according to Figure 15. An ENCLOSURE, other than an APPLIED PART, made of insulating material is placed in any position of NORMAL USE upon a flat metal surface connected to earth with dimensions at least equal to the plan-projection of the ENCLOSURE.		P
b)		ME EQUIPMENT with an F-TYPE APPLIED PART is additionally tested according to Figure 16. SIGNAL INPUT/OUTPUT PARTS are connected to earth, if not already permanently earthed in the ME EQUIPMENT. The value of the voltage to be set at the transformer T2 in Figure 16 is equal to 110 % of the MAXIMUM MAINS VOLTAGE For this measurement, non-PROTECTIVELY EARTHED metal ACCESSIBLE PARTS including PATIENT CONECTIONS of other APPLIED PARTS (if present) are connected to earth.		P
c)		ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested according to Figure 17 The value of the voltage set at the transformer T2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. The specific pin configuration used when applying the external voltage is to be worst case based on testing or circuit analysis		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
d)		ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED or a TYPE BF APPLIED PART and with metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED is additionally tested according to Figure 18. The value of the voltage set at the transformer T2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. This test need not be conducted if it can be demonstrated that there is adequate separation of the parts involved		P
e)		An APPLIED PART consisting of a surface made of insulating material is tested using metal foil as mentioned under 8.7.4.6. Alternatively a 0,9 % saline solution is used in which the APPLIED PART is immersed. Where the surface of the APPLIED PART intended to contact the PATIENT is considerably larger than that of a foil of 20 cm x 10 cm, the size of the foil is increased to correspond to the area of contact. Such metal foil or saline solution is considered as the only PATIENT CONNECTION for the APPLIED PART concerned		N/A
f)		Where the PATIENT CONNECTION is formed by a fluid which contacts the PATIENT, the fluid is replaced by 0,9 % saline solution, an electrode is placed in the saline solution and this electrode is considered as the PATIENT CONNECTION for the APPLIED PART concerned.		N/A
g)		The PATIENT LEAKAGE CURRENT is measured		
-		for TYPE B APPLIED PARTS, from all PATIENT CONNECTIONS connected directly together		P
-		for TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function either connected directly together or loaded as in NORMAL USE.		P
-		For TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn.		N/A
h)		The total PATIENT LEAKAGE CURRENT is measured from and to all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
i)		If the PATIENT CONNECTIONS of the APPLIED PART are loaded in NORMAL USE, the measuring device is connected to each PATIENT CONNECTION in turn.		N/A
8.7.4.8		**Measurement of the PATIENT AUXILIARY CURRENT**		
		ME EQUIPMENT with an APPLIED PART is tested according to Figure 19, using an appropriate measuring supply circuit unless the ME EQUIPMENT has only a single PATIENT CONNECTION.		P
		The PATIENT AUXILIARY CURRENT is measured between any single PATIENT CONNECTION and all other PATIENT CONNECTIONS, either connected directly together or loaded as in NORMAL USE		P
8.7.4.9		**ME EQUIPMENT with multiple PATIENT CONNECTIONS**		
		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:	PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT does not exceed the allowable values.	P
-		Disconnected from the PATIENT; and		N/A
-		Disconnected from the PATIENT and earthed.		N/A
8.8		**Insulation**		
8.8.1		**General**		
		Only insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION, shall be subject to testing.		N/A
8.8.2		**Distance through solid insulation or use of thin sheet material**		
		Solid insulation which forms SUPPLEMENTARY INSULATION OR REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V shall either:		N/A
a)		having a distance through insulation of at least 0.4 mm,		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
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; - three 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 test voltages as specified in table 6.	 (Refer Table F) No flashover or breakdown observed.	P
8.8.4		**Insulation other than wire insulation**		
8.8.4.1		**Mechanical strength and resistance to heat**		
		The resistance to heat shall be retained by all types of insulation, including insulation partition walls during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.		-
8.8.4.2		**Resistance to environmental stress**		
		The insulating characteristics and mechanical strength of any MEANS OF PROTECTION shall be so designed or protected that it is not likely to be impaired by environmental stress including deposition of dirt or by dust resulting from wear of parts within the ME EQUIPMENT to such an extent that creepage distances and air clearances are reduced below the values specified in 8.9 .	In Compliance	P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		Ceramic material not tightly sintered, and the like, and beads alone shall not be used as supplementary insulation or reinforced insulation		N/A
		Insulating material in which heating conductor are embedded may be considered as one means of protection but shall not used as two MEANS OF PROTECTION.		N/A
8.9		**CREEPAGE DISTANCES AND AIR CLERANCES**		
8.9.1		**Values**		
8.9.1.1		CREEPAGE DISTANCES and AIR CLEARANCES of ME EQUIPMENT shall be equal to or greater than the values of	Creepage distances& Clearances found above the required values.	P
		– for insulation between parts of opposite polarity of the MAINS PART on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE, one MEANS OF OPERATOR PROTECTION in accordance with Table 13, Table 14 and Table 16; and	Refer Table G	P
		- for insulation providing at least a MEANS OF PROTECTION, in accordance with Table 12 to Table 16 (inclusive) except as specified in 8.9.1.2 to 8.9.1.15. See also 8.9.2 to 8.9.4.		N/A
8.9.1.2		**CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1**		
		The values of Table 12 to Table 16 (inclusive) do not apply to CREEPAGE DISTANCES and AIR CLEARANCES forming MEANS OF OPERATOR PROTECTION that comply with the requirements of IEC 60950-1		N/A
8.9.1.3		**CREEPAGE DISTANCES across glass, mica, ceramic and similar materials**		N/A
8.9.1.4		**Minimum CREEPAGE DISTANCE**		
		If the minimum CREEPAGE DISTANCE derived from Table 12 to Table 16 (inclusive) is less than the applicable minimum AIR CLEARANCE, that value of minimum AIR CLEARANCE shall be applied as the minimum CREEPAGE DISTANCE.		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.9.1.5		**ME EQUIPMENT RATED for high altitudes**		
		Unless otherwise declared by the MANUFACTURER, ME EQUIPMENT is RATED to operate at an altitude ≤ 2 000 m.		P
8.9.1.6		**Interpolation**		
		If the WORKING VOLTAGE has a value between those given in Table 12 to Table 16 (inclusive).		N/A
		for determining CREEPAGE DISTANCES, linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;		N/A
		for determining AIR CLEARANCES for PEAK WORKING VOLTAGES above 2 800 V peak or d.c. linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;		N/A
		for determining AIR CLEARANCES for PEAK WORKING VOLTAGE up to 2 800 V peak or d.c., the higher of the two values shall be applied.		N/A
8.9.1.7		**Material groups classification**		
		Material groups classified in accordance with Table 9	group IIIb	P
8.9.1.8		**Pollution degree classification**		
		Pollution degree 1 is used to describe a micro-environment that is sealed so as to exclude dust and moisture.		N/A
		Pollution degree 2 is used to describe a micro-environment where only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is to be expected.	Pollution degree 2	P
		Pollution degree 3 is used to describe a micro-environment that is subject to conductive pollution, or to dry non-conductive pollution that could become conductive due to expected condensation		N/A
		Pollution degree 4 is used to describe a micro-environment where continuous conductivity occurs due to conductive dust, rain or other wet conditions.		N/A
8.9.1.9		**Overvoltage category classification**		
		The applicable value of the MAINS	In compliance, tested at	P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		TRANSIENT VOLTAGE shall be determined from the overvoltage category according to IEC 60664-1 and the NOMINAL a.c. MAINS VOLTAGE using Table 10.	transient voltage(Vpeak):2500V against V r.m.s. 300 (Please refer table H)	
8.9.1.10		**AIR CLEARANCE for MAINS PARTS**		
		For MAINS PARTS operating on RATED MAINS VOLTAGES up to 300 V, the required AIR CLEARANCE shall be the value in Table 13 for the r.m.s. or d.c. RATED MAINS VOLTAGE plus the additional AIR CLEARANCE in Table 14 for the PEAK WORKING VOLTAGE.		P
8.9.1.11		**SUPPLY MAINS overvoltage**	Test conducted as per overvoltage category II (Please refer table H)	
8.9.1.12		**SECONDARY CIRCUITS**		
		A SECONDARY CIRCUIT derived from a SUPPLY MAINS will normally be overvoltage category I according to IEC 60664-1 if the MAINS PART is overvoltage category II; (Table 15.)		N/A
		Where the SECONDARY CIRCUIT is earthed or the ME EQUIPMENT is INTERNALLY POWERED, Table 15 applies.		N/A
		Where a SECONDARY CIRCUIT is not earthed and is derived from a SUPPLY MAINS, the circuit shall be subjected to the requirements for primary circuits in Table 13 and Table 14..		N/A
8.9.1.13		**PEAK WORKING VOLTAGES above 1400 V peak or d.c.**		
		– the AIR CLEARANCE is at least 5 mm;		N/A
		– the insulation involved passes a dielectric strength test according to 8.8.3 using:		N/A
		• an a.c. test voltage whose r.m.s. value is equal to 1,06 times the PEAK WORKING VOLTAGE or		N/A
		a d.c. test voltage equal to the peak value of the a.c. test voltage prescribed above;		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		the AIR CLEARANCE path is partly or entirely through air or along the surface of an insulating material of material group I.		N/A
8.9.1.14		**Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION**		
		Minimum CREEPAGE DISTANCES for two MEANS OF OERATOR PROTECTION are obtained by doubling the values shown in Table 16 for one MEANS OF OPERATOR PROTECTION.		N/A
8.9.1.15		**CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS**		
		CREEPAGE DISTANCES and AIR CLEARANCES needed to satisfy 8.5.5.1 for DEFIBRILLATION-PROOF APPLIED PARTS shall not be less than 4 mm.		N/A
8.9.2		Application	No reduction of a distance occur below the specified value by deformation or movement of the parts	P
8.9.3		**Spaces filled by insulating compound**		
8.9.3.1		Where distances between conductive parts are filled with insulating compound, including where insulation is reliably cemented together with insulating compound, so that AIR CLEARANCES and CREEPAGE DISTANCES do not exists, only the requirements for solid insulation apply.		N/A
8.9.3.2		**Insulating compound forming solid insulation between conductive parts**		
		For situations where insulating compound forms solid insulation between conductive parts, a single finished sample is tested.		N/A
8.9.3.3		**Insulating compound forming a cemented joint with other insulating parts**		
		For situations where insulating compound forms a cemented joint with other insulating parts, the reliability of the joint is checked by testing three samples		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.9.3.4		**Thermal cycling**	In Compliance	P
8.9.4		**Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES**		P
8.10		**Components and wiring**		
8.10.1		**Fixing of components**		
		Components of ME EQUIPMENT, the unwanted movement of which could result in an unacceptable RISK, shall be mounted securely to prevent such movement.		P
8.10.2		**Fixing of wiring**		
		Conductors and connectors of ME EQUIPMENT shall be so secured or insulated that accidental detachment shall not result in a HAZARDOUS SITUATION.		P
		Stranded conductor shall not be solder-coated if they are affixed by any clamping means and poor contact could result in a HAZARDOUS SITUATION.		N/A
8.10.3		**Connections between different parts of ME EQUIPMENT**		
		Flexible cords detachable without the use of a TOOL that are used for interconnection of different parts of ME EQUIPMENT shall be provided with means for connection such that compliance of metal ACCESSIBLE PARTS is not compromised when a connection is loosened or broken due to the disengagement of one of the connecting means.	No other part present	N/A
8.10.4		**CORD-connected HAND-HELD parts and cord-connected foot-operated control devices**	ME EQUIPMENT have CORD-connected Hand-Held parts	-
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	Hand-Held control device	P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		a.c. or 60 V d.c. in circuits isolated from the MAINS PART by two MEANS OF PROTECTION. The d.c. limit of 60 V applies to d.c. with not more than 10 % peak to peak ripple. If the ripple exceeds that amount, the 42.4 V peak limit applies.		
8.10.4.2		**Connection cords**		
		Anchorages of cords of ACTIVE ACCESSORIES shall be designed to minimize the risk to PATIENTS and OPERATORS arising from damage to conductors or insulation caused by cable flexure or excessive tension.		P
		After the test, the cord shall not have worked loose nor shall it show any damage.	In compliance , withstands the test of 8.11.3	P
8.10.5		**Mechanical protection of wiring**		
a)		Internal cables and wirings 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.	No moving part present No such part exists	N/A
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.		P
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 five times the outer diameter of the lead concerned.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.10.7		**Insulation of internal wiring**		
a)		If insulating sleeving is needed on internal wiring of ME EQUIPMENT, it shall be adequately secured, Sleeving that can only be removed by breaking or cutting or that is secured at both ends may be used to satisfy this requirement.	In Compliance	P
b)		Inside ME EQUIPMENT the sheath of a flexible cord shall not be used as MEANS OF PROTECTION, if it is subject to mechanical or thermal stresses outside its RATED characteristics.		N/A
c)		Insulated conductors of ME EQUIPMENT that in NORMAL USE are subject to temperatures exceeding 70^0 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		**Isolation from the SUPPLY MAINS**		
a)		ME EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously.		N/A
		Permanently installed ME EQUIPMENT connected to a polyphase SUPPLY mains may be provided with a device that does not interrupt the neutral conductor, provided that local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed the limits specified in 8.4.2 c)		N/A
		For PERMANENTLY INSTALLED ME EQUIPMENT, the means provided to isolate its circuits electrically from the SUPPLY MAINS shall be capable of being locked in the off position if		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		– reconnection would result in a HAZARDOUS SITUATION; or		N/A
		– any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position.		N/A
		The locking mechanism may be in a SUPPLY MAINS switch provided by the RESPONSIBLE ORGANIZATION		N/A
b)		Means for isolation either shall be incorporated in ME EQUIPMENT or, if external, shall be described in the technical description. (see 7.9.3.1)		N/A
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.		N/A
d)		A supply main shall not be incorporated in a POWER SUPPLY CORD or any other external, flexible lead.	In compliance	P
e)		The actuator of a SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with 60447.		N/A
f)		In NON-PERMANENTLY INSTALLED ME EQUIPMENT that has no SUPPLY MAINS switch, a suitable plug device used to isolate ME EQUIPMENT from the SUPPLY MAINS shall be considered as complying with the requirements of 8.11.1 a). An APPLIANCE COUPLER or a flexible or a flexible cord with a MAINS PLUG may be used.		N/A
g)		A fuse or a semiconductor device shall not be used as an isolating means in the sense of this subclause.		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
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.	In compliance	P
i)		Any part with the ENCLOSURE of ME EQUIPMENT with a circuit voltage exceeding 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device that is accessible at all times shall be protected against being touched even after opening of the enclosure by an additional covering		N/A
8.11.2		**MULTIPLE-SOCKET OUTLETS**		
		Multiple SOCKET-OUTLETS that are integral with the 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		**Application**		
		The MAINS PLUG of ME EQUIPMENT shall not be fitted with more than one POWER SUPPLY CORD.		P
8.11.3.2		**Types**		
		Any POWER SUPPLY CORD of ME EQUIPMENT shall not be less robust than ordinary tough rubber-sheathed flexible cord (IEC 60245-1: 2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1: 1993, ANNEX a, designation 53).	In Compliance	P
		A polyvinyl chloride INSULATED POWER SUPPLY CORD shall not be used for ME EQUIPMENT having external metal parts with a temperature exceeding 75^0 C and which can be touched in NORMAL USE by the cord, unless it is RATED for that temperature.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
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.	In Compliance	P
8.11.3.4		**APPLIANCE COUPLERS**		
		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		**Cord anchorage**		
a)		The conductors of a POWER SUPPLY CORD shall be relieved from strain, including twisting, and the insulation of the conductors shall be protected from abrasion at the point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage.		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:		N/A
		- 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, unless it is a flexible bushing that forms part of the cord guard specified in 8.11.3.6 and which shall comply with the requirements for one MEANS OF PROTECTION.		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.		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
d)		Screws if any that have to be operated when replacing the POWER SUPPLY CORD shall not serve to fix any component other than parts of the cord anchorage.		N/A
e)		Conductors of the POWER SUPPLY CORD shall be so arranged that if the cord anchorage fails, the PROTECTIVE EARTH CONDUCTOR is not subject to strain as long as the phase conductors are in contact with their terminals.		N/A
8.11.3.6		**CORD guards**		
		POWER SUPPLY CORDS of other than stationary ME equipment shall be protected against excessive bending at the inlet opening of the equipment or the MAINS CONNECTOR by means of a cord guard of insulating material or by mean of an appropriately shaped opening in the ME EQUIPMENT.		N/A
8.11.4		**MAINS TERMINAL DEVICES**		
8.11.4.1		**General requirements for MAINS TERMINAL DEVICES**		
		PERMANENTLY INSTALLED ME EQUIPMENT have a NON-DETACHABLE POWER SUPPLY CORD that is replaceable by SERVICE PERSONNEL shall be provided with MAINS TERMINAL DEVICES that ensure reliable connection.		N/A
		Reliance shall not be place upon the terminals alone to maintain the conductors in position. Unless barriers are provided such that CREEPAGE DISTANCES and AIR CLEARANCES that serve as a MEANS OF PROTECTION cannot be reduced to less than the values specified in 8.9, if any conductor breaks away.		N/A
		Terminal of components other than terminal blocks may be used as terminals intended for external conductor if they comply with the requirements of this subclause and are properly marked according to 7.3.7.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		Screws and nuts that clamp external conductors shall not serve to fix any other component, except that they may also clamp internal conductors if these are so arranged that they are unlikely to be displaced when fitting the supply conductors.		N/A
8.11.4.2		**Arrangements of MAINS TERMINAL DEVICES**		
a)		For ME EQUIPMENT with rewirable cords where terminals are provided for the connection of external cords or POWER SUPPLY CORDS, these terminals together with any PROTECTIVE EARTH TERMINAL shall be closely grouped, so as to provide a convenient means of connection.		P
b)		For details of PROTECTIVE EARTH CONDUCTOR connections. see 8.6.	See 8.6	-
c)		For marking of MAINS TERMINAL DEVICES See 7.3	See 7.3	-
d)		MAINS TERMINAL DEVICES shall not be accessible without the use of a TOOL	In Compliance	P
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 circuited a MEANS OF PROTECTION is unlikely.		N/A
8.11.4.3		**Fixing of mains terminals**		
		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

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
8.11.4.4		**Connections of mains terminals**		
		Terminals with clamping means for a rewirable flexible cord shall not require special preparation of the conductors in order to effect correct connection, and they shall be so designed or placed 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. It shall be possible to check that the conductors are correctly connected and positioned before the ACCESS COVER is fitted.		P
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 have a functional earth connection according to 8.6.9 and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT, except that		N/A
		- for PERMANENTLY INSTALLED ME EQUIPMENT, the neutral conductor shall not be fused.		N/A
		- if examination shows that two MEANS OF PROTECTION are present between all parts of opposite polarity within the MAINS PART, and between all parts of the MAINS PART and earth, then the fuses or OVER-CURRENT RELASES may be omitted. these insulation requirements shall be continued up to and within any component. The effect of short-circuit		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		fault conditions in other circuits shall be VERIFIED before eliminating fuses or OVER-CURRENT RELEASES.		
		- A PROTECTIVE EARTH CONDUCTOR shall not incorporate a fuse or OVER-CURRENT RELEASE.		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 POWER SUPPLY CORD as specified in 8.11.3.3.		P
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.		P
9.	**201.9**	**Protection against MECHANICAL HAZARDS OF ME EQUIPMENT and ME SYSTEM**		
9.2		**MECHANICAL HAZARDS associated with moving parts**		
9.2.1		**General**		
		ME EQUIPMENT with moving parts shall be designed built and laid so that, when PROPERLY INSTALLED and used as indicated in the ACCOMPANYING DOCUMENT or under reasonably foreseeable misuse, the RISKS associated with those moving parts are reduced to an acceptable level.		N/A
9.2.3		**TRAPPING ZONE**		
9.2.2.1		When feasible, ME EQUIPMENT with a TRAPPING ZONE shall comply with the requirements of one or more of the following:		N/A
		Gaps as specified in 9.2.2.2; or		N/A
		Safe distances as specified in 9.2.2.3; or		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		Guards and other RISK CONTROL 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		**Gaps**		
		A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if the gaps of the TRAPPING ZONE comply with the dimensions specified.		N/A
9.2.2.3		**Safe distances**		
		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:13857:2008 . The distances are measured from the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE or under reasonably foreseeable misuse.		N/A
9.2.2.4		**GUARDS AND other RISK CONTROL MEASURES**		
9.2.2.4.1		**Access to TRAPPING ZONES**		
		A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if GUARDS or other RISK CONTROL measures		N/A
		- 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**		
		FIXED GUARDS shall be securely held in place by systems that cannot be dismantled without the use of a TOOL.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
9.2.2.4.3		**Movable GUARDS**		
		Movable Guards that can be opened without the use of a TOOL;		N/A
		- 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
9.2.2.4.4		**Other RISK CONTROL measures**		
		Protective measures shall be designed and incorporated into the control system so that;		
		- moving parts cannot start to move while they are in reach of persons;		N/A
		Other RISK CONTROL measures (e.g. electro-mechanical) shall be designed and incorporated into the control system so that		N/A
		– once the ME EQUIPMENT has started to move, if the TRAPPING ZONE is reached, system movement shall stop; and		N/A
		– if the RISK CONTROL measure is defeated in a SINGLE FAULT CONDITION, a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device		N/A
9.2.2.5		**Continuous activation**		
		Where it is impractical to make the TRAPPING ZONE inaccessible, continuous activation may be used as a RISK CONTROL measure. A TRAPPING ZONE is not considered to present a MECHANICAL HAZARD if;		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
a)		the 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)		the continuous activation system is defeated in a SINGLE FAULT CONDITION, then a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4), or the ME EQUIPMENT shall otherwise be SINGLE FAULT SAFE (see 4.7		N/A
9.2.2.6		**Speed of movement(s)**		
		The speed of movement(s) that position parts of the ME EQUIPMENT or PATIENT, where contact with the ME EQUIPMENT could result in an unacceptable RISK, shall be limited so that the OPERATOR will have adequate control of the movement.		N/A
		The overtravel of such movement, occurring after operation of a control to stop the movement, shall not result in an unacceptable RISK.		N/A
9.2.3		**Other MECHANICAL HAZARDS associated with moving parts**		
9.2.3.1		**Unintended movement**		
		Controls shall be so positioned, recessed, or protected by other means so that they cannot be accidentally actuated unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise or activation does not result in an unacceptable RISK		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
9.2.3.2		**Overtravel end stops**		
		Overtravel past range limits of ME EQUIPMENT parts shall be prevented. End stops or other stopping means shall be provided to act as the ultimate travel limiting measure.		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.		P
b)		The proximity and response of the OPERATOR to actuate the emergency stopping device can be relied on to prevent HARM.		P
c)		The emergency stopping device actuator shall be readily accessible to the OPERATOR.		P
d)		Emergency stopping device shall not be part of the normal operation of the ME EQUIPMENT.		P
e)		Operation of an emergency switching or stopping means shall neither introduce a further MECHANICAL HAZARD nor interfere with the complete operation necessary to remove the original HAZARD		P
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

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
h)		The emergency stopping device shall have an actuator coloured and red designed to be indicate and easily identifiable from that of other controls		P
i)		The actuator that interrupts/opens mechanical movements shall be marked on, or immediately adjacent to, the face of the actuator with symbol IEC 60417-5638 or the word "STOP"	Emergency stop has been provided on the touch screen display.	N/A
j)		The emergency stopping device, once actuated, shall maintain the ME EQUIPMENT in the overload condition until a deliberate action, different from that used to actuate it, is performed.		P
k)		The emergency stopping device shall be shown to be suitable for its application.		P
9.2.5		**Release of Patient**		
		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 RISK CONTROL measure or emergency stopping. Special attention shall be given to the following:		
		- Uncontrolled or unintended movement of the ME equipment that could result in an unacceptable RISK shall be prevented.		P
		- Situation where the PATIENT is subjected to an unacceptable RISKS, due to the proximity of moving parts, removal or normal exit routes, or other HAZARDS, shall be prevented.		P
		- when, after removal of counterbalanced parts, other parts of the me equipment can move in a hazardous way, measures shall be provided to reduce the risk to an acceptable level		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
9.3		**MECHANICAL Hazard Associated with surface, corners and edges**		
		Rough surface, sharp corners and edges of ME EQUIPMENT that could cause injury or damage shall be avoided or covered.	In Compliance	P
9.4		**Instability hazards**		
9.4.1		**General**		
		ME equipment and its parts, other than FIXED ME EQUIPMENT intended to be placed on a surface such as a floor or a table in NORMAL USE shall not overbalance (tip over) or move unexpectedly	In Compliance	P
9.4.2		**Instability – Overbalance**		
9.4.2.1		**Instability in transport position**		
		ME EQUIPMENT or its parts shall not overbalance when placed in an transport position of NORMAL USE on a plane inclined at an angle of 10° from the horizontal plane.	 Stable at 10° angle	P
9.4.2.2		**Instability excluding transport position**		
		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 5^0 from the horizontal plane.	Stable at 5° angle	P
9.4.2.3		**Instability from horizontal and vertical forces**		
a)		ME EQUIPMENT or its parts having a mass of 25 kg or more other than FIXED ME EQUIPMENT that is intended to be used on the floor shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety sign ISO 7010-P017 (see		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		Table D.2, safety sign 5), or it shall not overbalance due to being pushed, leaned, rested upon etc		
		If marking is provided because the ME EQUIPMENT overbalances, the marking shall be visible during NORMAL USE, but not on surfaces for which pushing is associated with NORMAL USE		N/A
b)		ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, that is intended to be used on the floor or on a table shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety signs ISO 7010-P018 or ISO 7010-P019 as appropriate (see Table D.2, safety signs 6 and 7), or it shall not overbalance due to being sat or stepped upon.		P
		If marking is provided because the ME EQUIPMENT overbalances, the marking shall be visible during potential stepping or sitting misuse.		N/A
9.4.2.4		**Castors and wheels**		
9.4.2.4.1		**General**		
		The means used for transportation of MOBILE ME EQUIPMENT, e.g. castors or wheels, shall not resulting an unacceptable RISK when the MOBILE ME EQUIPMENT is moved or parked in NORMAL USE.		N/A
9.4.2.4.2		**Force for propulsion**		
		The force required for moving MOBILE ME EQUIPMENT along a hard and flat horizontal surface shall not exceed 200 N unless the instructions for use state that more than one person is needed		N/A
9.4.2.4.3		**Movement over a threshold**		
		MOBILE ME EQUIPMENT exceeding 45 kg shall be able to pass over a 10 mm threshold. Passing over a 10 mm threshold shall not result in an overbalancing.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
9.4.3		**Instability from unwanted lateral movement (Including sliding)**		
9.4.3.1		**Instability in transport position**		
a)		Brakes of power-driven MOBILE ME EQUIPMENT shall be designed so that they are normally activated and can only be released by continuous actuation of a control.	Not a MOBILE ME EQUIPMENT	N/A
b)		MOBILE ME EQUIPMENT shall be fitted with means intended to prevent any unwanted movement of the ME EQUIPMENT or its parts in the transport position.		N/A
c)		MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 10° when in its transport position.		N/A
9.4.3.2		**Instability excluding transport position**		
a)		Mobile ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 5° when in any position excluding transport position	Not a MOBILE ME EQUIPMENT	N/A
b)		MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement from lateral forces.		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 (for example handles, lifted safely, unless the method of handling is obvious and no unacceptable RISK can develop when this is done. If the means for lifting are handles, they shall be suitably placed to	Mass of ME EQUIPMENT is less than 20 kg	N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		enable the ME EQUIPMENT or its part to be carried by two or more persons.		
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
9.5		**Expelled parts HAZARDS**		
9.5.1		**Protective means**		
		Where expelled parts could result in an unacceptable RISK, the ME EQUIPMENT shall be provided with a means for protecting against such RISK.		N/A
9.5.2		**Cathode ray tubes**		
		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		**General**		
		ME EQUIPMENT shall be designed so that human exposure to acoustic energy and vibration shall not result in an unacceptable RISK.		P
9.6.2		**Acoustic energy**		
9.6.2.1		**Audible Acoustic energy**		
		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 levels below		N/A
		- 80 dBA for a cumulative exposure of 24 h over a 24 h period; an offset of 3 dBA is to be added to this value when halving the cumulative exposure time over a 24 h period.		N/A
		- 140 dBC (peak) sound pressure level		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		for impulsive or impact acoustic energy.		
9.6.2.2		**Infrasound and ultrasound energy**		
		When applicable, the MANUFACTURER shall address the RISKS associated with infrasound or ultrasound in the RISK MANAGEMENT PROCESS.		P
9.6.3		**Hand-transmitted vibration**		
		Except for vibrations directly required to carry out the INDENTED USE of the ME EQUIPMENT, means shall be provided to protect the PATIENT OPERATOR and other persons if in NORMAL USE for hand transmitted frequency-weighted r.m.s. acceleration generated by the ME EQUIPMENT		N/A
		- 25 m/s^2 for a cumulative time of 8 h during a 24 h period.		N/A
9.7		**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		
9.7.1		**General**		
		The requirements of this subclause apply to vessels and parts of ME EQUIPMENT subject to pressure, the rupture of which could result in an unacceptable RISK.		N/A
		The Parts of a pneumatic or hydraulic system that are used as a support system shall additionally comply wit the requirements in 9.8.		N/A
9.7.2		**Pneumatic and hydraulic parts**		
		Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES shall be so designed that:		N/A
		- no unacceptable RISK results from loss of pressure or loss of vacuum;		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		- no unacceptable RISK results from a fluid jet caused by leakage or a component failure.		N/A
		- Reservoirs and similar vessels (e.g. hydro-pneumatic accumulator) that can lead to an unacceptable RISK are automatically depressurized when the ME EQUIPMENT is isolated from its power supply. If this not possible, means shall be provided for the isolation (e.g. cutting off from the peripheral circuit), or local depressurizing of reservoirs and similar vessels, and pressure, indication.		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 waning label drawing attention to the necessity of depressurizing these elements before any setting or maintenance activity on the ME EQUIPMENT or ACCESSORIES.		N/A
9.7.3		**Maximum Pressure**		
		The maximum pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITON and SINGLE FAULT CONDITION shall be considered to be whichever is the highest of the following:		N/A
a)		The RATED maximum supply pressure from an external source;		N/A
b)		The pressure setting of a pressure-relief device provided as part of the assembly;		N/A
c)		The maximum pressure that can be developed by a source of pressure that is part of the assembly, unless the pressure is limited by a pressure-relief device.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
9.7.4		**Pressure rating of ME EQUIPMENT parts**		
		The maximum pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE for the part, except as allowed for pressure relief devices. In 9.7.7		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		N/A
		- the product of pressure and volume is greater than 200 kPA		N/A
9.7.6		**Pressure-control device**		
		In ME EQUIPMENT for which 9.7.7 requires a pressure-relief device, 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**		
		ME EQUIPMENT shall incorporate pressure-relief device(s) where the MAXIMUM PREMISSIBLE WORKING PRESSURE could otherwise be exceeded.		
a)		It shall be connected as close as reasonably practical to the pressure vessel or parts of the system that is intended to protect.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
b)		It shall be so installed that it is accessible for inspection, maintenance and repair;		N/A
c)		It shall not be capable of being adjusted or rendered inoperative without the use of a TOOL ;		N/A
d)		It shall have its discharge opening so located and directed that the released material is not directed towards any person;		N/A
e)		It shall have its discharge opening so located and directed that operation of the device will not deposit material on parts that could result in an unacceptable RISK.		N/A
f)		It shall be of adequate discharge capacity to ensure that the pressure will not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE of the system to which it is connected by more than 10% in the event of a failure in the control of the supply pressure.		N/A
g)		There shall be no shut-off valve between a pressure-relief device and the parts that it is intended to protect.		N/A
h)		The minimum number of cycles of operation shall be 100000, except for one-time use devices such as bursting disks.		N/A
9.7.8		**RATED maximum supply pressure**	See 7.2.18	N/A
9.8		**MECHANICAL HAZARDS ASSOCIATED with support systems**		
9.8.1		**General**		
		Where ME EQUIPMENT parts are designed to support loads or to provide actuating forces, the following requirements shall be applied if a mechanical fault could constitute an unacceptable RISK.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		- 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 MECHANICAL HAZARDS arising from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions.		N/A
		- All likely failure effects shall be considered in the RISK ANYALYSIS. These include excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability , stress-assisted corrosion cracking wear, material creep, material deterioration and residual stresses resulting from the manufacturing PROCESSES, e.g. machining assembling, welding, heat treatment or surface coating.		N/A
		- The ACCOMPANYING DOCUMENTS shall instructions on attachment of structures to a floor, wall, ceiling, etc making adequate allowances for quality of the materials used to make the connection and shall list the required materials. Additionally there shall be advice on checking the adequacy of the surface of the structure to which the parts will be attached.		N/A
9.8.2		**TENSILE SAFETY FACTOR**		
		Support systems shall maintain structural integrity during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. TENSILE SAFETY FACTORS shall not be less than those shown in table unless an alternative method demonstrates structural integrity throughout the EXPECTED SERVICE LIFE of the ME EQUIPMENT, or the support is a foot rest. The requirements for foot rests are in		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		9.8.3.2 a)		
9.8.3		**Strength of PATIENT or OPERATOR Support or suspension systems**		
9.8.3.1		**General**		
		ME EQUIPMENT parts serving for support or immobilization of PATIENTS shall be designed and manufactured so there is no unacceptable the RISK OF physical injuries or of accidental loosening of fixings.		N/A
		The SAFE WORKING LOAD of ME EQUIPMENT or its parts serving for support or suspension of PATIENTS or OPERATORS shall be the sum of the mass of the PATIENTS or the mass of the OPERATORS plus the mass of ACCESSORIES intended by the MANUFACTURERS to be supported or suspended by the ME EQUIPMENT or ME EQUIPMENT parts.		N/A
		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
		When the maximum allowable value of the mass of the PATIENT is less than 135 kg, that value shall be marked on the ME EQUIPMENT and described in ACCOMPANYING DOCUMENTS.		N/A
9.8.3.2		**Static forces due to loading from persons**		
		In analyzing forces and toques on support assemblies, the part of the SAFE WORKING LOAD representing the mass of the PATIENTS or OPERATORS is distributed on the support/suspension surface in a manner representing the human body.		N/A
		In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD representing the		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		mass of ACCESSORIES shall be deployed as in NORMAL USE or,.		
a)		For a foot rest that is intended to temporarily support a standing PATIENT or OPERATOR, the whole mass of the PATIENT or OPERATOR is distributed over an area of 0.1m^2.		N/A
b)		For an area of support/suspension where a PATIENT or OPERATOR can sit, deflection of a support surface from PATIENT or OPERATOR loading shall not result in an unacceptable RISK.		N/A
9.8.3.3		**Dynamic forces due to loading from persons**		
		Where dynamic forces (due to sitting down, standing up, PATIENT handling PROCESS or the like) can be exerted on ME equipment parts intended to support or suspend a PATIENT or OPERATOR in NORMAL USE, the ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.		N/A
9.8.4		**System with MECHANICAL PROTECTIVE devices**		
9.8.4.1		**General**		
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.		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

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		- 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		**Use after activation of a MECHANICAL PROTECTIVE DEVICE**		
		If ME EQUIPMENT can still be used after failure of the suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE such as secondary cable, it shall become obvious to the OPERATOR that the MECHANICAL PROTECTIVE DEVICE has been activated.		N/A
		The MECHANICAL PROTECTIVE DEVICE shall require the use of a TOOL to be reset or replaced.		N/A
9.8.4.3		**MECHANICAL PROTECTIVE DEVICE intended for single activation**		
		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.		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

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
9.8.5		**Systems without MECHNICAL PROECTIVE DEVICES**		
		A MECHANICAL PROTECTIVE DEVICE is not required if;		
		- the support system parts are not impaired by wear and have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 1 and 2 of Table 21; or		N/A
		- the supports system parts are impaired by wear but have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 3 and 4 of Table 21.		N/A
10.	**201.10**	**Protection against unwanted and excessive radiation hazards.**		
10.1		**X-Radiation**		
10.1.1		**ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation.**		
		For ME EQUIPMENT not intended to produce X-radiation for diagnostic or therapeutic purposes, but which might produce ionizing radiation the AIR KERMA rate shall not exceed 5 µGy/h at a distance of 5 cm from a surface of the ME equipment taking account of the background radiation.		N/A
10.1.2		**ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation**		
		Unintended X-radiation from ME EQUIPMENT designed to produce diagnostic or therapeutic X radiation shall be reduced as far as possible by application of applicable particular and collateral standards, or in the absence of these standards by application of the RISK MANAGEMENT PROCESS.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
10.2		**Alpha, beta, gamma, neutron and other particle radiation**		
		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated WITH alpha, beta, gamma, neutron and other particle radiation.		N/A
10.3		**Microwave radiation**		
		The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz shall not exceed 10 W/m2 at any point 50 mm away from a surface of the ME EQUIPMENT under reference test conditions. This requirement does not apply to parts of the apparatus where microwave radiation is propagated intentionally, for example, at waveguide output ports.		N/A
10.4		**Lasers**		
		For lasers that produce or amplify electromagnetic radiation in the wavelength range from 180 nm to 1 mm, the relevant requirements of IEC 60825-1:2007 shall apply. If laser light barriers or similar products are used within equipment, they shall comply with the requirements of IEC 60825-1:2007.		N/A
10.5		**Other visible electromagnetic radiation**		
		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the risks associated with visible electromagnetic radiation, other than that produced by lasers and light emitting diodes.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
10.6		**Infrared radiation**		
		When applicable, the MANUFACTURE shall address in the RISK MANAGEMENT PROCESS the risks associated with infrared radiation, other than that produced by lasers and light emitting diode.		N/A
10.7		**Ultraviolet Radiation**		
		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the risks associated with ultraviolet radiation, other than that produced by lasers and light emitting diode.		N/A
11.	**201.11**	**Protection against excessive temperatures and other HAZARDS**		
11.1		**Excessive temperatures in ME EQUIPMENT**		
11.1.1		*** Maximum temperature during NORMAL USE**		
		When ME EQUIPMENT is operated in worst-case NORMAL USE including the maximum ambient operating temperature specified in the technical description	(see 7.9.3.1)	-
		- ME EQUIPMENT shall not reach temperatures exceeding the values given in table 22 and table 23	In compliance	P
		- the ME EQUIPMENT shall not cause the surface of the test corner to exceed 90° C; and		P
		- THERMAL CUT-OUTS shall not operate in NORMAL CONDITION.		N/A
11.1.2		**Temperature of APPLIED PARTS**		
11.1.2.1		**APPLIED PARTS intended to supply heat to a PATIENT**		

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		The temperature (hot or cold surfaces) or (Where appropriate) the clinical effects shall be determined and documented in the RISK MANAGEMENT FILE. The temperature and clinical effects shall be disclosed in the disclosed in the instructions for use.		N/A
11.1.2.2		**APPLIED PARTS not intended to supply heat to a PATIENT**		
		The limits of Table 24 shall apply in both NORMAL CONDITION and SINGLE FAULT CONDITION. If the surface temperature of an APPLIED PART exceeds 41 °C:		N/A
–		the maximum temperature shall be disclosed in the instructions for use;		N/A
–		the conditions for safe contact, e.g. duration or condition of the PATIENT, shall be disclosed; and		N/A
–		the clinical effects with respect to characteristics such as body surface, maturity of PATIENTS, medications being taken or surface pressure shall be determined and documented in the RISK MANAGEMENT FILE.		N/A
11.1.3		**Measurements**	In compliance, temperature at the surface of the test corner does not exceeds 90 °C	P
11.1.4		**GUARDS**		
		Guards intended to prevent contact with hot or cold accessible surfaces of ME EQUIPMENT shall be removable only with the aid of a TOOL.		N/A
11.2		**Fire Prevention**		
11.2.1		**Strength and rigidity required to prevent fire in ME EQUIPMENT**		
		Enclosures shall have the strength and rigidity necessary to avoid a fire that could occur as a result of a total or partial collapse caused by reasonably foreseeable misuse.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
11.2.2		**ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVRIONMENTS**		**N/A**
11.2.2.1		**RISK of fire in an OXYGEN RICH ENVIRONMENT**		
		In ME EQUIPMENT and ME SYSTEMS, the RISK of fire in an OXYGEN RICH ENVIRONMENT shall be reduced as far as possible under NORMAL CONDITION or SINGLE FAULT CONDITIONS. An unacceptable RISK of fire is considered to exist in an OXYGEN RICH ENVIRONMENT when a source of ignition is in contact with ignitable material and there is no means that would limit the spread of a fire.		N/A
a)		A source of ignition is considered to exist in an OXYGEN RICH ENVIRONMENT when any of the following conditions exist in NORMAL CONDITION and SINGLE FAULT CONDITION.		
1)		the temperature of the material is raised to its ignition temperature:		N/A
2)		Temperatures could affect solder or solder joints causing loosening, short circulating or other failure that could result in sparking or raising the temperature		N/A
3)		parts affecting safety crack or change their outer shape exposing temperatures exceeding 300^{o} C or sparks due to overheating.		N/A
4)		temperatures of parts or components could exceed 300^{o} C;		N/A
5)		Sparks provide adequate energy for ignition by exceeding the limits..		N/A
b)		The following configurations, alone or in combination as appropriate are considered to provide an acceptable RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT.		

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
1)		Electrical components in an compartment with an OXYGEN RICH ENVIRONMENT shall have power supplies with limited energy levels. Those energy levels shall be less than those which are considered to be sufficient for ignition. (see 11.2.2.1 a)		N/A
2)		Compartments that contain parts or components that can be a source of ignition (as defined in 11.2.2.1 a) only under SINGLE FAULT CONDITION (as identified in 11.2.3) and that can be penetrated by oxygen shall be ventilated such that the oxygen concentration will not exceed 25 %		N/A
3)		A compartment that contains parts or components that can be a source of ignition 9as defined in 11.2.2.1 a) only under SINGLE FAULT CONDITION (as identified in 11.2.3) is separated from another compartment that contains an OXYGEN RICH ENVIRONMENT by sealing all joints and any holes for cables, shafts, or for other purpose. The effect of possible leaks and failures under SINGLE FAULT CONDITION. (as identified in 11.2.3) that could cause ignition shall be evaluated using a RISK ASSESSMENT to determine the appropriate maintenance intervals.		N/A
4)		Electrical components in a compartment containing an OXYGEN RICH ENVIRONMENT that can become a source of ignition (as defined in 11.2.2.1 a) only under SINGLE FAULT CONDITIONS (as identified in 11.2.3) shall be enclosed in such a way that should ignition occur within the ENCLOSURE. The fire would self-extinguish rapidly and no hazardous amount of toxic gases would reach the PATIENT.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
11.2.2.2		**External Exhaust Outlets For Oxygen Rich Environment**		
		External exhaust outlets of an OXYGEN RICH ENVIRONMENT shall not be located so that the RISK of ignition occurs because of any electrical component (which could cause a spark in NORMAL USE or SINGLE FAULT CONDITION as identified in 11.2.3) mounted on the outside of the ME EQUIPMENT or an ME SYSTEM. RISK of ignition is considered to be sufficiently low if oxygen concentration in the immediate surroundings of the electrical component does not exceed 25 % under the least favorable conditions of operation.		N/A
11.2.2.3		**Electrical connections in OXYGEN RICH ENVIRONMENTS**		
		Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE shall not produce sparks because of loosening or breaking unless they are limited to power and energy to the values identified in 11.2.2.1 a) 5)		N/A
		Prevention of loosening or breaking is accomplished by the following or equivalent method.		N/A
		- screw attachments shall be protected against loosening during use by methods such as varnishing, the use of spring washers or application of adequate torques.		N/A
		- Soldered, crimped and pin-and-socket connection of cables that exit the ENCLOSURE shall include additional mechanical fixing.		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		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		constructed in accordance with 11.2.2.1 b)2)		
		- 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 (as defined in 11.2.2.1 a)		N/A
		- failure of insulation (whether solid material or spacing) providing the equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION (As described in 8.8 and 8.9) that could create a source of ignition (as defined in 11.2.2.1a)		N/A
		- Failure of a pneumatic component that results in leakage of oxygen-enriched gas.		N/A
11.3		**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		
		This subclause provides an alternative means of compliance with selected HAZARDOUS SITUATIONS and fault conditions as identified in 13.1.2. In doing so, the following constructional requirements shall be met or specifically analyzed In the RISK MANAGEMENT FILE and if not met, specific justification shall also be given.		N/A
a)		Insulated wire within the fire ENCLOSURE shall have a flammability classification equivalent FV-1 or better, according to the appropriate parts of the IEC 60695 series. Connectors, printed circuit boards and insulating material on which components are mounted shall have a flammability classification FV-2 or better, according to IEC 60695-11-10.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
b)		The fire ENCLOSURE shall meet the following requirements;		
1)		The bottom shall have no openings or, to the extent specified in Figure 39, shall be constructed with baffles as specified in Figure 38, or be made of metal, perforated as specified in Table 25, or be a metal screen with a mesh not exceeding 2mmX2mm centre to centre and a wire diameter of at lest 0.45 mm.		N/A
2)		The sides shall have no openings within the area that is included within the inclined line C in Figure 39.		N/A
3.		The ENCLOSURE, and any baffle or flame barrier, shall be made of metal (EXCEPT magnesium) or of non-metallic materials, except for constructions according to table 25 and constructions with a mesh, having a flammability classification of FV-2 (or better) for TRANSPORTABLE ME EQUIPMENT and FV-1 (or better) for FIXED ME EQUIPMENT or STATIONARY ME EQUIPMENT in accordance with IEC 60695-11-10.		N/A
		The ENCLOSURE, and any baffle or flame barrier, shall have adequate rigidity.		N/A
11.4		**ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics**		
		ME EQUIPMENT, ME SYSTEMS or their parts described in the ACCOMPANYING DOCUMENTS for use with flammable anaesthetics (Category AP) or flammable anaesthetics with oxidants (category APG) shall meet the applicable requirements of Annex G.		N/A
11.5		**ME EQUIPMENT and me systems intended for use in conjunction with flammable agents**		
		The Manufacturer's RISK		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		MANAGEMENT PROCESS shall address the possibility of fire and associated mitigations.		
11.6		**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT.**		
11.6.1		**General**		
		The construction of ME EQUIPMENT and ME SYSTEMS shall ensure a sufficient degree of protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization as well as compatibility with substances used with the ME EQUIPMENT.		N/A
11.6.2		**Overflow in ME EQUIPMENT**		
		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 wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE. If no warning or safety notice is given regarding the maximum fill level, no HAZARDOUS SITUATION or an unacceptable RISK due to overflow shall develop if TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 15^0		N/A
11.6.3		**Spillage on ME EQUIPMENT AND ME SYSTEMS**		
		ME EQUIPMENT and ME SYSTEMS requiring the handling of liquids in normal usE, including ME EQUIPMENT or ME SYSTEMS used in an environment where the PROCESS has determined that spillage on the ME EQUIPMENT is likely to occur, shall be so constructed		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		that spillage does not wet parts that are likely to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.		
11.6.4		**Leakage**		
		See 13.2.6.		N/A
11.6.5	**201.11. 6.5**	**Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS.**		
		Enclosure of ME EQUIPMENT and ME SYSTEMS designed to give a specified degree of protection against harmful ingress of water or particulate matter shall provide this protection in accordance with the classification of IEC 60529.	IP20	P
11.6.6		**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS.**		
		ME EQUIPMENT, ME SYSTEMS and their parts, including APPLIED PARTS and ACCESSORIES, shall be capable of withstanding, without damage or deterioration of safety provisions, the cleaning and disinfection PROCESSES specified in the instructions for use.	In Compliance	P
		The MANUFACTURER shall evaluate the effects of multiple cleaning/disinfections during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, ME SYSTEM, their parts and ACCESSORIES and enclosure that these PROCESSES do not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.		P
11.6.7	**201.11. 6.7**	**Sterilization of ME EQUIPMENT and ME SYSTEMS**		
		ACTIVE ACCESSORIES and all detachable parts thereof, except Active connectors detachable from cords without use of tools, shall comply with the requirements of this particular standard after being tested according to this Subclause of the qeneral standard.		N/A
		ME EQUIPMENT, ME SYSTEMS and		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		their parts of ACCESSORIES intended to be sterilized shall be assessed and documented according to ISO 11135-1, ISO 11137-1 or ISO 17665-1 as appropriate.		
11.6.8		**Compatibility with substances used with the ME EQUIPMENT**		
		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with compatibility with substances used with the ME EQUIPMENT. Such RISKS may be addressed through the application of appropriate ISO or IEC standards	The desired test reports are being maintained by the manufature	P
11.7		**Biocompatibility of ME EQUIPMENT and ME SYSTEMS**		
		ME EQUIPMENT, ME SYSTEM 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 the guidance and principles given in the ISO 10993 series of standards	The successful test reports are maintained with the manufacturer	P
11.8	**201.11.8**	**Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT**		
		ME EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in a the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	In Compliance	P
12	**201.12**	**Accuracy of controls and instruments and protection against hazardous outputs**		
12.1	**201.12.1**	**Accuracy of controls and instruments**		
		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accuracy of controls and instruments.		P
	201.12.1.101	**Output amplitude**		
		A means shall be provided to control the Stimulator output from minimum to	In Compliance	P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		maximum continuously, or in discrete increments of not more than 1mA or 1V per increment. At its minimum setting, the output shall not exceed 2 % of that available at the maximum setting of the control.		
	201.12. 1.102	**PULSE Parameters**		
		The values of pulse durations, pulse repletion frequencies and amplitudes, including any d.c component, whether caused by an offset or by an unsymmetrical waveform, as described in the accompanying Documents or indicated on the ME EQUIPMENT shall not deviate by more than ±20% when measured with a load resistance within in the range specified in the accompanying documents.	In Compliance	P
12.2	**201.12. 2**	**USABILITY of ME Equipment**		
		The MANUFACTURER shall address the Risk(s) of poor USABILITY, including those associated with identification, marking and documents, through a USABILITY ENGINEERING PROCESS complying with IEC 60601-1-6		P
	201.12. 2.101	**Electrodes**		
		The STIMULATOR shall comply with this standard when operated with either open-circuited or short-circuited electrodes.	In Compliance	P
12.3		**ALARM SYSTEMS**		
		If the MANUFACTURER has implemented an ALARM SYSTEM, this ALARM SYSTEM shall comply with IEC 60601-1-8.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
12.4	**201.12.4**	**Protection against hazardous output**		
12.4.1		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with hazardous output arising from the intentional exceeding of safety limits.		P
	201.12.4.101	**Supply voltage fluctuations**		
		Supply voltage fluctuations of ±10% shall not affect the STIMULATOR output amplitude, PULSE duration or pulse repetition frequency by more than ± 10%.	In Compliance	P
	201.12.4.102	**Output interlock**		
		A stimulator that is capable of delivering an output in excess of 10mA or 10V shall not be energizeable unless the output amplitude control(s) is (are) first set to its (their) minimum position.		--
		This requirement shall also apply upon the restoration of the SUPPLY MAINS following a temporary interruption or following replacement of the INTERNAL ELECTRICAL POWER SOURCE.		N/A
		This requirement shall not apply when a stimulator is released from a pause mode, having been operating prior to being paused.		N/A
	201.12.4.103	**Output indicator**		
		In NORMAL CONDITION and SINGLE FAULT condition, ME EQUIPMENT shall indicate when it can deliver an output of more than 10mA or 10V, or can deliver PULSES having an energy exceeding 10 mJ per PULSE, into a load resistance of 1000 Ω . If the indication is by means of a signal lamp, its color shall be yellow.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
	201.12.4.104	**Limitation of output parameters**		
	a)	ME EQUIPMENT intended for therapeutic applications:		-
		With a load resistance of 500 Ω the output current shall not exceed the limits in TABLE 201.101.		-
		If the output has a.c. and d.c. components, then these components shall be measured separately and compared with the allowable limits.		-
		For PULSE DURATIONS of less than 0.1s the PULSE energy with a load resistance of 500 Ω shall not exceed 300mJ per PULSE. For longer PULSE DURATIONS, the above mentioned current limit for d.c. applies.		-
		Additionally, the output voltage shall not exceed a peak value of 500V, when measured under open-circuit condition.		-
		Where the APPLIED PART(s) is (are) energized by more than one patient circuit simultaneously		-
	b)	ME EQUIPMENT intended for diagnostic applications:		-
		For ME EQUIPMENT intended for dentistry and ophthalmology, the d.c. current with a load resistance of 2 000 Ω shall not exceed 10 mA.		-
12.4.2		**Indications relevant to safety**		
		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the need to indicate any hazardous output.		N/A
12.4.3		**Accidental selection of excessive output values**		
		*** OUTPUT REDUCTION MEAN**		
		Where ME EQUIPMENT is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accidental selection of excessive output values.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
12.4.4		**Incorrect output**		
		The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with incorrect output.		N/A
12.4.5		**Diagnostic or therapeutic radiation**		
12.4.5.1		**Limits**		
		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 in the vicinity, from unwanted or excessive radiation emitted by the ME EQUIPMENT.		N/A
12.4.5.2		**Diagnostic X-ray equipment**		
		ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes shall comply with IEC 60601-1-3.		N/A
12.4.5.3		**Radiotherapy equipment**		
12.4.5.4		**Other ME EQUIPMENT producing diagnostic or therapeutic radiation**		
		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than for diagnostic X-rays and radiotherapy		N/A
12.4.6		**Diagnostic or therapeutic acoustic pressure**		
		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with diagnostic or therapeutic acoustic pressure.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
13	**201.13**	**HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**		
13.1		**Specific HAZARDOUS SITUATIONS**		
13.1.1		**General**		
		When applying the SINGLE FAULT CONDITIONS as described in 4.7 and listed in 13.2, one at a time, none of the HAZARDOUS SITUATIONS in 13.1.2 to 13.1.4 (inclusive) shall occur in the ME EQUIPMENT.	No hazardous situation occurred	P
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		N/A
		– deformation of ENCLOSURES to such an extent that compliance with 15.3.1 is impaired;		N/A
		– temperatures of APPLIED PARTS exceeding the allowed values identified in Table 24 when measured as described in 11.1.3;		N/A
		– temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;	Temperature of accessible parts remains within the limits	P
		– exceeding the allowable values for “other components and materials” identified in Table 22 times 1.5 minus 12.5 °C. Limits for windings are found in Table 26, Table 27 and Table 31. In all other cases, the allowable values of Table 22 apply.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
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;	Refer clause 8.7.3	-
		– exceeding the voltage limits for the ACCESSIBLE PARTS including APPLIED PARTS indicated in 8.4.2.		N/A
13.1.4		**Specific MECHANICAL HAZARDS**		
		For specific MECHANICAL HAZARDS, see 9.1 to 9.8 (inclusive).	Refer clause 9	-
13.2		**SINGLE FAULT CONDITIONS**		
13.2.1		During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) shall also be applied in the least favorable combination.		P
13.2.2		**Electrical SINGLE FAULT CONDITION**		
		Requirements and tests relating to this SINGLE FAULT CONDITION are found in 8.1.	Refer clause 8.1	**-**
13.2.3		**Overheating of transformers in ME EQUIPMENT**		
		Requirements and tests relating to this SINGLE FAULT CONDITION are found in 15.5.	Refer clause 15.5	-
13.2.4		**Failure of THERMOSTATS**		
		Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.13 and 15.4.2 for overloading situations.		N/A
13.2.5		**Failure of temperature limiting devices**		
		Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.13 and 15.4.2 for overloading situations.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
13.2.6		**Leakage of fluid**		
		ME EQUIPMENT shall be so constructed that liquid that might escape in a SINGLE FAULT CONDITIONS does not result in an unacceptable RISK.		N/A
		Since only small amounts of liquid will escape when they leak; sealed rechargeable batteries are exempted from this requirement.		N/A
		A RISK MANAGEMENT PROCESS shall be used to determine the appropriate test conditions for the ME EQUIPMENT.		N/A
13.2.7		**Impairment of cooling that could result in a HAZARDOUS SITUATION**		
		ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the failure of COOLING systems to operate as intended.		N/A
13.2.8		**Locking of moving parts**		
		ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE when moving parts become jammed.		N/A
		Moving parts are locked if ME EQUIPMENT:		
		- has moving ACCESSIBLE PARTS including APPLIED PARTS liable to be jammed, or		N/A
		- is liable to be operated while unattended (this include ME EQUIPMENT that is automatically or remotely controlled)or		N/A
		- has one or more motors with a locked torque smaller than the full load torque.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
13.2.9		**Interruption and short circuiting of motor capacitors**		
		ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the short circuit and open circuit of motor capacitors.		N/A
13.2.10		**Additional test criteria for motor operated ME EQUIPMENT**		
		For every test in the SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, taking into account the exemptions stated in 13.1.2, motor-operated ME EQUIPMENT is operated starting from COLD CONDITION, at RATED voltage or at the upper limit of the RATED voltage range for the following periods of time:		
a)		30s for		
		- HAND-HELD ME EQUIPMENT;		N/A
		- ME EQUIPMENT that has to be kept switched on by hand		N/A
		- ME EQUIPMENT that has to be kept under physical by hand;		N/A
b)		5 min for other ME EQUIPMENT intended only for attended use (attended use excludes automated or remotely controlled ME EQUIPMENT that could operate when the OPERATOR is not present);		N/A
c)		For the maximum period of a timer, if such a device terminates the operation, for ME EQUIPMENT not listed under a) or b);		N/A
d)		As long as necessary to establish THERMAL STABILITY for all the remaining ME EQUIPMENT.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
13.2.11		**Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS**		
		Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in 11.2.2.		N/A
13.2.12		**Failure of parts that might result in a MECHANICAL HAZARD**		
		Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in Clause 9 and 15.3.	Refer clause 9 & 15.3	-
13.2.13		**Overload**		
13.2.13.1		**General overload test conditions**		
		After the tests of 13.2.13.2 to 13.2.13.4 (inclusive), ME EQUIPMENT, when cooled down to approximately room temperature, within 3°C of the temperature in the test environment shall remain safe.		N/A
13.2.13.2		**ME EQUIPMENT with heating elements**		
a)		ME EQUIPMENT having heating elements is checked for compliance as follows:		
		1)for thermostatically controlled ME EQUIPMENT having heating elements that is intended for built-in or for unattended operation or that has a capacitor not protected by a fuse or the like connected in parallel with the contacts of the THERMOSTAT		N/A
		2) for ME EQUIPMENT having heating elements RATED for non-CONTINUOUS OPERATION: by the tests of 13.2.13.2 b) and 13.2.13.2 c);		N/A
		3) for other ME EQUIPMENT having heating elements: by the test of 13.2.13.2 b).		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		b) ME EQUIPMENT having heating elements is tested under the conditions specified in 11.1, but without adequate heat discharge, the supply voltage being 90 % or 110 % of the RATED supply voltage, whichever is the least favourable		N/A
		c) Heating parts of ME EQUIPMENT are tested with the ME EQUIPMENT operated in NORMAL CONDITION, at a supply voltage 110 % of the RATED supply voltage and as specified in 11.1. The following test conditions are met.		N/A
		1) Any control that serves to limit the temperature in NORMAL CONDITION, except a THERMAL CUT-OUT, is disabled.		N/A
		2) If the ME EQUIPMENT is provided with more than one control, they are disabled in turn.		N/A
		3) The ME EQUIPMENT is operated at the RATED DUTY CYCLE until THERMAL STABILITY is achieved, irrespective of the RATED operating time.		N/A
13.2.13.3		**ME EQUIPMENT with motors**		
a)		ME EQUIPMENT having motors is checked for compliance as follows:	No motor used	
		1) For the motor part of the ME EQUIPMENT, compliance is checked by the tests of 13.2.8 to 13.2.10 (inclusive), 13.2.13.3 b), 13.2.13.3 c) and 13.2.13.4, as applicable		N/A
		2) For ME EQUIPMENT that also contains heating parts, the tests are performed at the prescribed voltage, with the motor part and the heating part operated simultaneously so as to produce the least favourable condition.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		3) If more than one of the tests is applicable for the same ME EQUIPMENT, these tests are performed consecutively.		N/A
b)		Motors are checked for running overload protection if they are:		
		1) intended to be remotely controlled or automatically controlled (by a single control device without redundant protection), or		N/A
		2) likely to be subjected to CONTINUOUS OPERATION whilst unattended.		N/A
c)		ME EQUIPMENT with three-phase motors is operated with normal load, connected to a three phase (SUPPLY MAINS) with one phase disconnected. Periods of operation are according to 13.2.10.		N/A
13.2.13.4		**ME EQUIPMENT RATED for non-CONTINUOUS OPERATION**		
		ME EQUIPMENT RATED for non-CONTINUOUS OPERATION other than		
		– HAND-HELD ME EQUIPMENT;		N/A
		– ME EQUIPMENT that has to be kept switched on manually;		N/A
		– ME EQUIPMENT that has to be kept under physical load by hand;		N/A
		– ME EQUIPMENT with a timer and a back-up timer system		N/A
		is operated under normal load and at RATED voltage or at the upper limit of the RATED voltage range until the peak temperature does not increase by more than 5 °C in one hour, or until any protective device operates.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
14	**201.14**	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		
14.1		**General**		
		The requirements in 14.2 to 14.12 (inclusive) shall apply to PEMS unless:		
		– none of the PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS) provides functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE; or		N/A
		– the application of RISK MANAGEMENT as described in 4.2 demonstrates that the failure of any PESS does not lead to an unacceptable RISK.		N/A
14.2		**Documentation**		
		The documents required by Clause 14 shall be reviewed, approved, issued and changed in accordance with a formal document control PROCEDURE.		N/A
14.3		**RISK MANAGEMENT plan**		
		The RISK MANAGEMENT plan required by 4.2.2 shall also include a reference to the PEMS VALIDATION plan		N/A
14.4		**PEMS DEVELOPMENT LIFE-CYCLE**		
		A PEMS DEVELOPMENT LIFE-CYCLE shall be documented		N/A
		The PEMS DEVELOPMENT LIFE-CYCLE shall include a set of defined milestones.		N/A
		Each activity shall be defined including its inputs and outputs.		N/A
		Each milestone shall identify the RISK MANAGEMENT activities that must be completed before that milestone		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
14.5		**Problem resolution**		
		A documented system for problem resolution within and between all phases and activities of the PEMS DEVELOPMENT LIFE-CYCLE shall be developed and maintained.		N/A
14.6		**RISK MANAGEMENT PROCESS**		
14.6.1		**Identification of known and foreseeable HAZARDS**		
		When compiling the list of known or foreseeable HAZARDS, the MANUFACTURER shall consider those HAZARDS associated with software and hardware aspects of the PEMS including those associated with the incorporation of the PEMS into an IT-NETWORK components of third-party origin and legacy subsystems.		N/A
14.6.2		The following requirements for PEMS supplement 4.2.2		N/A
14.7		**Requirement specification**		
		For the PEMS and each of its subsystems (e.g. for a PESS) there shall be a documented requirement specification		N/A
		The requirement specification for a system or subsystem shall include and distinguish any ESSENTIAL PERFORMANCE and any RISK CONTROL measures implemented by that system or subsystem.		N/A
14.8		**Architecture**		
		For the PEMS and each of its subsystems, architecture shall be specified that shall satisfy the requirement specification.		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

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
14.10		**VERIFICATION**		
		VERIFICATION is required for all functions that implement BASIC SAFETY, ESSENTIAL PERFORMANCE or RISK CONTROL measures.		N/A
14.11		**PEMS VALIDATION**		
		A PEMS VALIDATION plan shall include the validation of BASIC SAFETY and ESSENTIAL PERFORMANCE,		N/A
		The PEMS VALIDATION shall be performed according to the PEMS VALIDATION plan. The results of PEMS VALIDATION activities shall be documented.		N/A
		No member of a design team shall be responsible for the PEMS VALIDATION of their own design		N/A
14.12		**Modification**		
		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		**PEMS intended to be incorporated into an IT-NETWORK**		
		If the PEMS is intended to be incorporated into an IT-NETWORK that is not validated by the PEMS MANUFACTURER, the MANUFACTURER shall make available instructions for implementing such connection including the following:		N/A
a)		the purpose of the PEMS's connection to an IT-NETWORK;		N/A
b)		the required characteristics of the IT-NETWORK incorporating the PEMS;		N/A
c)		the required configuration of the IT-NETWORK incorporating the PEMS;		N/A
d)		the technical specifications of the network connection of the PEMS including security specifications;		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
e)		the intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK; and		N/A
f)		a list of the HAZARDOUS SITUATIONS resulting from a failure of the IT-NETWORK to provide the characteristics required to meet the purpose of the PEMS connection to the IT NETWORK.		N/A
		In the ACCOMPANYING DOCUMENTS, the MANUFACTURER shall instruct the RESPONSIBLE ORGANIZATION that:		
-		connection of the PEMS to an IT-NETWORK 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 IT-NETWORK could introduce new RISKS and require additional analysis; and		N/A
-		changes to the IT-NETWORK include:		
		• changes in the IT-network configuration;		N/A
		• connection of additional items to the IT-NETWORK;		N/A
		• disconnecting items from the IT-NETWORK;		N/A
		• update of equipment connected to the IT-NETWORK; and		N/A
		• Upgrade of equipment connected to the IT-NETWORK.		N/A
15	**201.15**	**Construction of ME EQUIPMENT**		
15.1		**Arrangements of controls and indicators of ME EQUIPMENT**		
		When applicable, the MANUFACTURER shall address the RISKS associated with the arrangement of controls and indicators of ME EQUIPMENT in the USABILITY ENGINEERING PROCESS.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
15.2		**Serviceability**		
		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.	In Compliance	P
		Parts of ME EQUIPMENT that are likely to be replaced or adjusted shall be so located and secured as to permit inspection, servicing, replacement and adjustment without damage to, or interference with, adjacent parts or wiring.	In Compliance	P
15.3		**Mechanical strength**		
15.3.1		ME EQUIPMENT or its parts shall have adequate mechanical strength and shall not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.	Refer Clause 15.3.2 to 15.3.5	P
15.3.2		**Push test**		
		ENCLOSURES of ME EQUIPMENT shall have sufficient rigidity to protect against unacceptable RISK.	No damage and an unacceptable risk condition occurred after applying the force of 250N for 5s.	P
15.3.3		**Impact test**		
		ENCLOSURES of ME EQUIPMENT shall have sufficient resistance to impact to protect against unacceptable RISK.	No damage and no unacceptable risk condition occurred after freely falling a steel ball of diameter 50mm having mass 500g from the height of 1.3m.	P
15.3.4		**Drop test**		
15.3.4.1		**HAND-HELD ME EQUIPMENT**		
		HAND-HELD ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts shall not result in an unacceptable RISK as a result of a free fall.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
15.3.4.2		**PORTABLE ME EQUIPMENT**		
		PORTABLE ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts shall withstand the stress caused by a free fall from the height indicated in Table 29 onto a hard surface.		P
15.3.5		**Rough handling test**		
		MOBILE ME EQUIPMENT and ME EQUIPMENT parts that are MOBILE shall withstand the stress caused by rough handling and movement and shall not result in an unacceptable RISK.		N/A
15.3.6		**Mould stress relief test**		
		ENCLOSURES of moulded or formed thermoplastic materials shall be so constructed that any shrinkage or distortion of the material due to release of internal stresses caused by the moulding or forming operation does not result in an unacceptable RISK.	In Compliance	P
15.3.7		**Environmental influences**		
		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		N/A
15.4		**ME EQUIPMENT components and general assembly**		
15.4.1		**Construction of connectors**		
		Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors of ME EQUIPMENT shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where an unacceptable RISK would otherwise exist. In particular:		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		a) Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to outlets on the same ME EQUIPMENT intended for other functions, unless it can be proven that no unacceptable RISK can result.		P
		b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE shall not be interchangeable.		N/A
15.4.2		**Temperature and overload control devices**		
15.4.2.1		**Application**		
		a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used in ME EQUIPMENT if their use lead to a HAZARDOUS SITUATION described in 13.1 by such resetting.		N/A
		b) THERMAL CUT-OUTS with a safety function that have to be reset by a soldering operation that can affect the operating value shall not be fitted in ME EQUIPMENT.		N/A
		c) ME EQUIPMENT, where a failure of a THERMOSTAT could lead to a HAZARDOUS SITUATION described in 13.1, an independent non-SELF-RESETTING THERMAL CUT-OUT shall additionally be provided.		N/A
		d) Loss of function of the ME EQUIPMENT caused by operation of a THERMAL CUT-OUT or OVERCURRENT RELEASE shall not result in the loss of ESSENTIAL PERFORMANCE or any of the HAZARDOUS SITUATIONS described in 13.1		N/A
		e) Capacitors or other spark-suppression devices of ME EQUIPMENT shall not be connected between the contacts of THERMAL CUT-OUTS.		N/A
		f) The use of a THERMAL CUT-OUT or OVER-CURRENT RELEASE in the design shall not affect the safety of the ME EQUIPMENT.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		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		**Temperature settings**		
		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		**Housing**	No housing	
		ME EQUIPMENT, housings containing batteries from which gases can escape during charging or discharging shall be ventilated so that there is no unacceptable RISK from the accumulation of gases and possible ignition is prevented.		N/A
		Battery compartments of ME EQUIPMENT shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in a HAZARDOUS SITUATION.		N/A
15.4.3.2		**Connection**		
		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		P
15.4.3.3		**Protection against overcharging**		
		Where overcharging of any battery of ME EQUIPMENT could result in an unacceptable RISK, the design shall prevent overcharging		P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
15.4.3.4		**Lithium batteries**		
		Primary lithium batteries shall comply with the requirements of IEC 60086-4. Secondary lithium batteries shall comply with the requirements of IEC 62133. See also 7.3.3.	24V/1600mAH NIMH battery CE Certified used	P
15.4.3.5		**Excessive current and voltage protection**		
		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		**Indicators**		
		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	No such indicator light	N/A
		Indicator lights shall be provided on ME EQUIPMENT incorporating non-luminous heaters to indicate that the heaters are operational,	No heater present	N/A
		Indicator lights shall be provided on ME EQUIPMENT to indicate that an output exists where an 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		**Pre-set controls**		
		When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with pre-set controls		N/A
15.4.6		**Actuating parts of controls of ME EQUIPMENT**		
15.4.6.1		**Fixing, prevention of maladjustment**		
		a) All actuating parts of ME EQUIPMENT shall be so secured that they cannot be pulled off or work loose during NORMAL USE.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		b) Controls, shall be so secured that the indication of any scale always corresponds with the position of the 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 the use of a TOOL.		N/A
15.4.6.2		**Limitation of movement**		
		Stops of adequate mechanical strength shall be provided on rotating or movable parts of controls of ME EQUIPMENT,		N/A
15.4.7		**Cord-connected HAND-HELD and foot-operated control devices**		
15.4.7.1		**Mechanical strength**		
		a) HAND-HELD control devices of ME EQUIPMENT 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		**Accidental operation of ME EQUIPMENT**		
		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.		P
15.4.7.3		**Entry of liquids**		
		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 used in areas such as emergency rooms or operating theatres where liquids are likely to be present at floor level and that contain electrical circuits shall be classified at least IPX6 according to IEC 60529		N/A
15.4.8		**Internal wiring of ME EQUIPMENT**		
		Aluminium wires of less than 16 mm^2 cross-section shall not be used in ME EQUIPMENT.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
15.4.9		**Oil containers**		
		a) Oil containers in PORTABLE ME EQUIPMENT shall be adequately sealed to prevent loss of oil in any position. The container design shall allow for the expansion of the oil.		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		**Overheating**		
15.5.1.1		**Transformers**		
		Transformers of ME EQUIPMENT shall be protected against overheating in the event of short circuit or overload of any output winding.		N/A
15.5.1.2		**Short-circuit test**		
		The output winding under test is short circuited. The test is continued until the protective device operates or THERMAL STABILITY is achieved. For transformers not tested according to the 5X frequency and 5X voltage test of 15.5.2 a) or the 2X frequency and 2X voltage test of 15.5.2 b), the short circuit is applied directly across the output windings.		N/A
15.5.1.3		**Overload test**		
		Windings with more than one protective device could require multiple overload tests in order to fully evaluate worst-case NORMAL USE loading and fusing.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
15.5.2		**Dielectric strength**		
		This subclause is not applicable to transformers operating at a frequency above 1 kHz, which are tested in accordance with 8.8.3.		N/A
		ME EQUIPMENT transformer windings shall have adequate insulation to prevent internal short circuits that could cause overheating where such overheating could result in a HAZARDOUS SITUATION.		N/A
15.5.3		**Construction of transformers used to provide separation as required by 8.5**		
		Transformers of ME EQUIPMENT that form MEANS OF PROTECTION as required by 8.5 shall comply the following:		
		– Means shall be provided to prevent displacement of end turns beyond the interwinding insulation.		N/A
		– If a protective earthed screen has only one turn, it shall have an insulated overlap of not less than 3 mm. The width of the screen shall be at least equal to the axial winding length of the primary winding.		N/A
		The exit of the wires from the internal windings of toroidal transformers shall be provided with double sleeving complying with the requirements for two MEANS OF PROTECTION and having a total wall thickness of at least 0,3 mm, extending at least 20 mm outside the winding		N/A
		– The insulation between primary and secondary windings shall comply with 8.8.2.		N/A
		– CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.4 with the following exceptions:		N/A
		• Enamelled or lacquered winding wires are considered as contributing 1 mm each to the CREEPAGE DISTANCES specified in 8.9.4 for MEANS OF PATIENT PROTECTION.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		• CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except when:		N/A
		– either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;		N/A
		– the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint		N/A
		• CREEPAGE DISTANCES within moulded transformers are considered not to exist if it can be shown that no gas bubbles are present and the thickness of the insulation between enamelled or lacquered primary and secondary windings is at least 1 mm for reference voltages *U* not exceeding 250 V and increased proportionally for higher reference voltages.		N/A
16	**201.16**	**ME SYSTEMS**		
16.1		**General requirements for the ME SYSTEMS**		
		After installation or subsequent modification, an ME SYSTEM shall not result in unacceptable RISK.		N/A
		An ME SYSTEM shall provide		
		– within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and		N/A
		- Outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards.		N/A
16.2		**ACCOMPANYING DOCUMENTS of an ME SYSTEM**		
		ME SYSTEM, (including a modified ME SYSTEM), shall be accompanied by documents containing all the data necessary for the ME SYSTEM to be used as intended by the MANUFACTURER, and an address to which the RESPONSIBLE ORGANIZATION can refer. The		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME SYSTEM.		
		These documents shall include:		
		a) the ACCOMPANYING DOCUMENTS for each item of ME EQUIPMENT that is provided by the MANUFACTURER		N/A
		b) the ACCOMPANYING DOCUMENTS for each item of non-ME EQUIPMENT that is provided by the MANUFACTURER		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;		N/A
		– instructions for the installation, assembly and modification of the ME SYSTEM to ensure continued compliance with this standard;		N/A
		– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM (see 11.6.6 and 11.6.7);		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;		N/A
		– a warning that an additional MULTIPLE SOCKET-OUTLET or extension cord shall not be connected to the ME SYSTEM;		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;		N/A
		– the maximum permitted load for any MULTIPLE SOCKET-OUTLET(S) used with the ME SYSTEM;		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		– 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;		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;		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;		N/A
		– the permissible environmental conditions of use of the ME SYSTEM including conditions for transport and storage; and		N/A
		– 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		**Power supply**		
		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		N/A
		If an ME SYSTEM:		
		– is intended to receive its power from an isolated power supply (IPS) or an uninterruptible power supply (UPS), and		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		– the ME SYSTEM can draw large transient currents when being switching on or off or when operating,		N/A
		the MANUFACTURER shall restrict such transient currents to the allowed level according to the specification of the IPS or the UPS from which the ME SYSTEM is intended to be supplied.		N/A
		If an IPS or UPS is not specified, the actual transient current level shall be disclosed in the technical description and any installation instructions.		N/A
16.4		**ENCLOSURES**		
		Parts of non-ME EQUIPMENT in the PATIENT ENVIRONMENT that can be contacted by the OPERATOR during routine maintenance, calibration, etc		N/A
16.5		**SEPARATION DEVICES**		
		FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of equipment of an ME SYSTEM or other systems can cause the allowable values of LEAKAGE CURRENT to be exceeded, then safety measures incorporating a SEPARATION DEVICE shall be applied.		N/A
		The WORKING VOLTAGE shall be the highest voltage across the SEPARATION DEVICE during a fault condition, but not less than the MAXIMUM MAINS VOLTAGE.		N/A
16.6		**LEAKAGE CURRENTS**		
16.6.1		**TOUCH CURRENT**		
		In NORMAL CONDITION, the TOUCH CURRENT from or between parts of the ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 100 µA.		N/A
16.6.2		**EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET**		
		The ME SYSTEM or part of the ME SYSTEM is supplied from a MULTIPLE SOCKET-OUTLET, then the current in the PROTECTIVE EARTH CONDUCTOR of the MULTIPLE SOCKET-OUTLET shall not exceed 5 mA.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
16.6.3		**PATIENT LEAKAGE CURRENT**		
		The PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of an ME SYSTEM in NORMAL CONDITION shall not exceed the values specified for ME EQUIPMENT, as given in Table 3 and Table 4		N/A
16.6.4		**Measurements**		
16.6.4.1		**General conditions for ME SYSTEMS**		
		a) The TOUCH CURRENT, the PATIENT LEAKAGE CURRENT the total PATIENT LEAKAGE CURRENT and the total EARTH LEAKAGE CURRENT are measured after the ME SYSTEM has been brought up to operating temperature		N/A
		b) The ME SYSTEM is connected to a supply with a voltage equal to the highest RATED MAINS VOLTAGE. When the characteristics of an ME SYSTEM can only be measured properly after it has been installed at the site of the RESPONSIBLE ORGANIZATION		N/A
16.6.4.2		**Connection of the ME SYSTEM to the measuring supply circuit**		
		a) The ME SYSTEM is tested after being assembled according to its ACCOMPANYING DOCUMENTS		N/A
		b) Measuring arrangement		N/A
16.7		**Protection against MECHANICAL HAZARDS**		
		If a MECHANICAL HAZARD exists, the ME SYSTEM shall comply with the applicable requirements of Clause 9.		
16.8		**Interruption of the power supply to parts of an ME SYSTEM**		
		An ME SYSTEM shall be so designed that an interruption and restoration of the power to the ME SYSTEM as a whole, or any part of the ME SYSTEM, shall not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE. .		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
16.9		**ME SYSTEM connections and wiring**		
16.9.1		**Connection terminals and connectors**		
		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 unless it can be proven that no unacceptable RISK can result. In particular:		N/A
		– Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to other outlets of the same ME SYSTEM that are likely to be located in the PATIENT ENVIRONMENT		N/A
16.9.2		**MAINS PARTS, components and layout**		
16.9.2.1		**MULTIPLE SOCKET-OUTLET**		
		a) A MULTIPLE SOCKET-OUTLET shall:		
		– only allow connection by using a TOOL (see Figure I.1), or		N/A
		– be of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083		N/A
		– be supplied via a separating transformer		N/A
b)		A MULTIPLE SOCKET-OUTLET		
		– shall be marked with safety sign ISO 7010-W001		N/A
		– shall be marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes		N/A
		– shall be marked to indicate which equipment or equipment parts may be safely attached		N/A
		– may be a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT.		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
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,		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		N/A
		– The separating transformer shall comply with this standard. Alternatively the separating transformer may comply with the requirements of IEC 61558-2-1, except that 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

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		– 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 of the kinds identified in IEC/TR 60083		N/A
16.9.2.2		**PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS**		
		For each part of an ME SYSTEM that shares a MAINS CONNECTION, the impedance and current carrying capability of the total protective earth path of an ME SYSTEM when tested as a unit shall comply with 8.6.4. The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ		N/A
		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		**Protection of conductors**		
		Conductors that connect different items of equipment within an ME SYSTEM shall be protected against mechanical damage.		N/A
17	**201.17**	**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		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict
		- 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.		N/A
	202	**Electromagnetic compatibility - Requirements and tests**		N/A

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Table A : List of Critical Components

Sr.	Part Identification	Part Life time	Device operating Duty cycle per Month	Total run of device in 60 month	Remark
1	LCD	10,00,000 actuation	12500 actuation	12500x 60 = 75000 actuation	Part life is more than 5 year
2	Rocker Switch	5,00,000 actuation	500 actuation	500 x 60 = 30000 actuation	Part life is more than 5 year
3	Carbon Electrode	6 months	NA	NA	Accessories to be replace after 6 month , defined in User Manual
4	Lead wires	6 months	NA	NA	Accessories to be replace after 6 month , defined in User Manual

Table B

S. No	Accessories	Qty
1	Electrode cable (5 Pin 4 Core) Length: 1.8 meter The lead wire conform of the 21 CFR 298 lenght	02
2	Carbon Electrode (Size:2") Elastic Belt (36") Elastic Belt (18")	08 02 04
3	Ultrasound Applicator FDA Cleared, 510(K): K063135 (5cm)	01
4	Adaptor with AC cord INPUT: 100-240 VAC, 50/60Hz OUTPUT: 24 VDC (2.5A)	01

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Table C

7.1.3	Marking durability	
Marking tested	**Remarks**	**Verdict**
Rubbed by hand without undur pressure	Marking remain legible	P
Rubbed by Cloth soaked with distilled water for 15sec	Marking remain legible	P
Rubbed by Cloth soaked with 96% of ethanol for 15sec	Marking remain legible	P
Rubbed by Cloth soaked with isopropyl alcohol for 15Sec	Marking remain legible	P
Supplementary information:		

Table D

8.4.3	ME EQUIPMENT Intended to be Connected to a Power Source by Plug									P
Voltage measured between:	Measurements [V]									Remarks
	1	2	3	4	5	6	7	8	9	10	
supply pins (pin 1 & pin 2)	0.88	0.020	0.27	0.31	0.11	0.09	0.098	0.811	0.71	0.91	Less than 60V after 1s of Plug removal

Table E

8.7	Leakage Currents and Patient Auxiliary Currents		
Type of leakage current and test condition (including single faults) operating condition	Measured Value (µA)	Maximum Allowed value (mA)	Remarks
Earth leakage current	-	-	N/A
Earth & Enclosure leakage current (Normal condition)	Under 1 µA	100µA	P
Earth & Enclosure leakage current (single fault condition)	Under 1 µA	500µA	P
Patient leakage current	5.84 µA	10 µA	P
Patient auxiliary current	1.35 µA	10 µA	P
Abbreviations used: mA: mili-ampere, µA: micro-amperes			

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Table F

8.8.3	Electric Strength			P
	For Double Insulation			
Test voltage applied between		**Voltage**	**Duration**	**Breakdown (Yes/No)**
Between live part and metal part of enclosure		1500V	60s	No

Table G

8.9	CREEPAGE DISTANCES and AIR CLEARANCES	P
	Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION	
Creepage Distance	**Required Creepage (mm)**	**Measured Clearance (mm)**
one MEANS OF OPERATOR PROTECTION	4 mm	> 4 mm
AIR Clearance Distance	**Required Clearance (mm)**	**Measured Creepage (mm)**
one MEANS OF OPERATOR PROTECTION	2.5 mm	> 2.5 mm

Table H

8.9.1	Mains Transient Voltage		P
Nominal a.c. supply mains voltage line-to-neutral upto & including Vr.m.s.	**Test voltage**	**Duration**	**Breakdown (Yes/No)**
300*	2500V**	60s	No
*including 230/400 or 277/480 V			
**as per overvoltage category II			

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Specification of tests and Expected Results for TC.05.03.001-ESTIM CC Tests

Waveform #1.1 – IFC Premodulated 2P CC

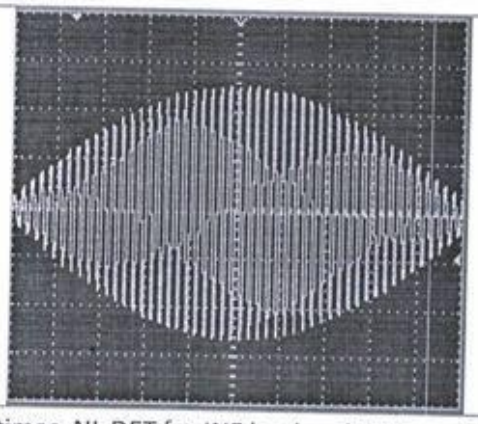
Specification

- IFC Premodulated 2P CC
- Setup: all parameters must be in accordance with DEFAULT setup;
- Measurements must be done for Intensity:
  - TH = 15mA (GUI Setup) = 15mApp;
  - MAX=100mA (GUI Setup) = 100mApp;

Expected Results

Expected results and variation of results are defined in table below. Regular shape of waveform (REG. SHAPE) is defined on figure below.

Waveform



Notes

- Sometimes, NL DET for INF load and TH intensity will not be detected. In that case, NL DET for INF load should be tested on 2 x TH intensity.
- The Vpp must be measured as the Vpp of signal's envelope.
- For measurement of Vpp, the scale on scope must be set on proper value for different values of the intensities.

Intensity [mA]	*Load [E]*	*Waveform*	*ΔI [ma]*	*Vpp [V]*	*Vdcbus [V]*	*SC Det*	*NL Det*
TH 15mA	*0*	"0" DC	< 10 (+/-5)	*not.imp.*	10 (+/-1)	DET	NOT DET
	1K	REG. SHAPE	< 10 (+/-5)	15 (+5/-0)	14 (+/-2)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	24 (+/-2)	NOT DET	DET
MAX 100mA	*0*	"0" DC	15 (+/-10)	*not.imp.*	11 (+/-2)	DET	NOT DET
	1K	REG. SHAPE	65 (+/-10)	100 (+5/-0)	56 (+/-3)	NOT DET	NOT DET
	INF	DEFORM.	45 (+/-10)	*not.imp.*	104 (+/-4)	NOT DET	DET

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Waveform #1.2 – TENS Asymetrical CC

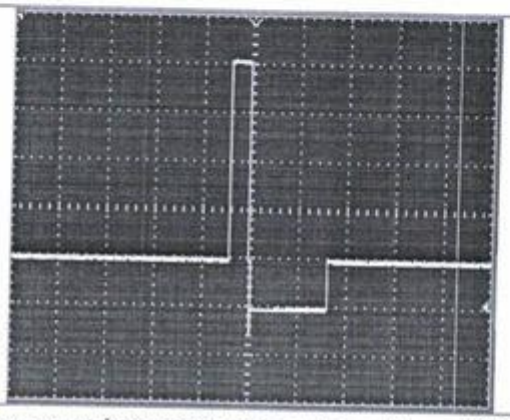
Specification

- TENS Asymetrical CC
- Setup: Pulse Width = 50usec, all other parameters must be in accordance with DEFAULT setup;
- Measurements must be done for Intensity:
  - TH = 23mA (GUI Setup) = 23mA p0;
  - MAX=110mA (GUI Setup) = 110mAp0;

Expected Results

Expected results and variation of results are defined in table below. Regular shape of waveform (REG. SHAPE) is defined on figure below.

Waveform



Notes

- The Vpp must be measured as the voltage difference from positive to negative value of the signal.
- In some case, some small spikes can happened. There should not be included in measurement of Vpp.
- For measurement of Vpp, the scale on scope must be set on proper value for different values of the intensities.

Intensity [mA]	*Load [E]*	*Waveform*	*ΔI [ma]*	*Vpp [V]*	*Vdcbus [V]*	*SC Det*	*NL Det*
TH 23mA	*0*	"0" DC	< 10 (+/-5)	*not.imp.*	10 (+/-1)	DET	NOT DET
	1K	REG. SHAPE	< 10 (+/-5)	29 (+/-4)	41 (+/-2)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	54 (+/-2)	NOT DET	DET
MAX 110mA	*0*	"0" DC	< 10 (+/-5)	*not.imp.*	14 (+/-2)	DET	NOT DET
	1K	REG. SHAPE	30 (+/-15)	138 (+/-10)	140 (+/-5)	NOT DET	NOT DET
	INF	DEFORM.	60 (+/-15)	*not.imp.*	216 (+/-5)	NOT DET	DET

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Waveform #1.3 – Short Pulse Burst 2P CC

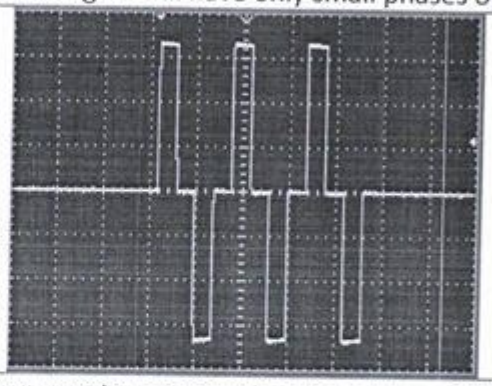
Specification

- Short Pulse Burst 2P CC
- Setup: Pulse Width = 1000usec, Freq = 142 Hz, all other parameters must be in accordance with DEFAULT setup;
- Measurements must be done for Intensity:
  - TH = 23mA (GUI Setup) = 23mA p0;
  - MAX=130mA (GUI Setup) = 130mAp0;

Expected Results

Expected results and variation of results are defined in table below. Regular shape of waveform (REG. SHAPE) is defined on figure below. The pulse width and frequency used in this test generate that the signal will have only small phases of "0" value.

Waveform



Notes

- The Vpp must be measured as the voltage difference from positive to negative value of the signal.
- In some case, some small spikes can happened. There should not be included in measurement of Vpp.
- For measurement of Vpp, the scale on scope must be set on proper value for different values of the intensities.

Intensity [mA]	*Load [E]*	*Waveform*	*ΔI [ma]*	*Vpp [V]*	*Vdcbus [V]*	*SC Det*	*NL Det*
TH 23mA	*0*	"0" DC	< 10 (+/-5)	*not.imp.*	11 (+/-2)	DET	NOT DET
	1K	REG. SHAPE	40 (+/-10)	46 (+/-5)	31 (+/-2)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	48 (+/-2)	NOT DET	DET
MAX 130mA	*0*	"0" DC	110 (+/-15)	*not.imp.*	17 (+/-4)	DET	NOT DET
	1K	REG. SHAPE	880 (+/-80)	260 (+/-10)	136 (+/-10)	NOT DET	NOT DET
	INF	DEFORM.	230 (+/-30)	*not.imp.*	223 (+/-5)	NOT DET	DET

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Specification of tests and Expected Results for TC.05.03.002-ESTIM HV Tests

Waveform #2.1 – High Voltage Pulsed Current 2P

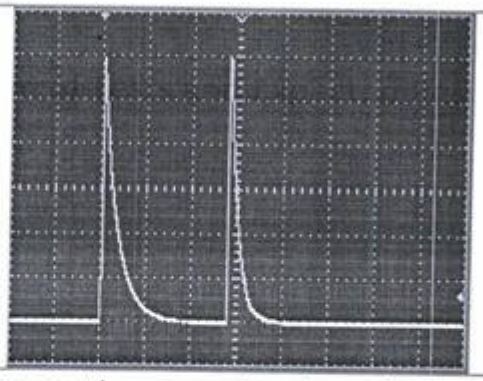
Specification

- High Voltage Pulsed Current
- Setup: Freq = 120 pps, all other parameters must be in accordance with DEFAULT setup;
- Measurements must be done for Intensity:
  - TH = 65V (GUI Setup) = 65Vp0;
  - MAX=500V (GUI Setup) = 500Ap0;

Expected Results

Expected results and variation of results are defined in table below. Regular shape of waveform (REG. SHAPE) is defined on figure below.

Waveform



Notes

- The Vpp must be measured as the peak of one two spikes.
- In some case, some small spikes can happened. There should not be included in measurement of Vpp.
- For measurement of Vpp, the scale on scope must be set on proper value for different values of the intensities. The probe x100 must be used.
- SC DET cannot be detected for any condition.

Intensity [V]	*Load [E]*	*Waveform*	*ΔI [ma]*	*Vpp [V]*	*Vdcbus [V]*	*SC Det*	*NL Det*
TH 65V	*0*	"0" DC	< 10 (+/-5)	*not.imp.*	28 (+/-5)	NOT DET	NOT DET
	1K	REG. SHAPE	< 10 (+/-5)	65 (+/-15)	28 (+/-5)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	28 (+/-5)	NOT DET	DET
MAX 500V	*0*	"0" DC	120 (+/-60)	*not.imp.*	175 (+/-15)	NOT DET	NOT DET
	1K	REG. SHAPE	120 (+/-60)	500 (+/-30)	175 (+/-15)	NOT DET	NOT DET
	INF	DEFORM.	100 (+/-60)	*not.imp.*	175 (+/-15)	NOT DET	DET

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Specification of tests and Expected Results for TC.05.03.003-ESTIM CV Tests

Waveform #3.1 – IFC Premodulated 2P CV

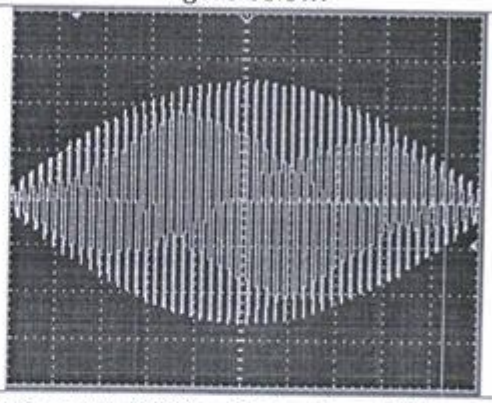
Specification

- IFC Premodulated 2P CV
- Setup: all parameters must be in accordance with DEFAULT setup;
- Measurements must be done for Intensity:
  - TH = 23V (GUI Setup) = 23Vp0;
  - MAX=100V (GUI Setup) = 100Vp0;

Expected Results

Expected results and variation of results are defined in table below. Regular shape of waveform (REG. SHAPE) is defined on figure below.

Waveform



Notes

- Sometimes, NL DET for INF load and TH intensity will not be detected. In that case, NL DET for INF load should be tested on 2 x TH intensity.
- The Vpp must be measured as the Vpp of signal's envelope.
- For measurement of Vpp, the scale on scope must be set on proper value for different values of the intensities.

Intensity [V]	*Load [E]*	*Waveform*	*ΔI [ma]*	*Vpp [V]*	*Vdcbus [V]*	*SC Det*	*NL Det*
TH 23V	*0*	"0" DC	165 (+/-20)	*not.imp.*	23 (+/-5)	DET	NOT DET
	1K	REG. SHAPE	15 (+/-10)	46 (+/-5)	29 (+/-5)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	27 (+/-5)	NOT DET	DET
MAX 100V	*0*	"0" DC	200 (+/-20)	*not.imp.*	23 (+/-5)	DET	NOT DET
	1K	REG. SHAPE	270 (+/-20)	200 (+/-10)	112 (+/-5)	NOT DET	NOT DET
	INF	DEFORM.	20 (+/-10)	*not.imp.*	107 (+/-5)	NOT DET	DET

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Waveform #3.2 – TENS Asymetrical CV

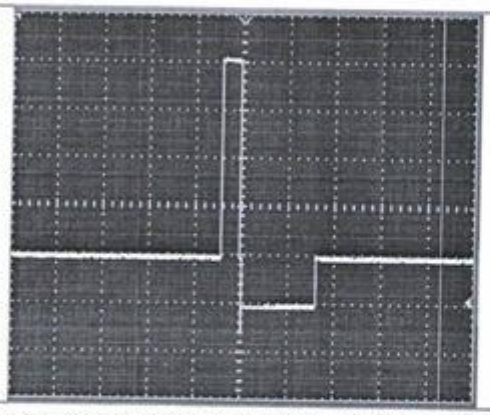
Specification

- TENS Asymetrical CV
- Setup: Pulse Width = 50usec, all other parameters must be in accordance with DEFAULT setup;
- Measurements must be done for Intensity:
  - TH = 23V (GUI Setup) = 23Vp0;
  - MAX=100V (GUI Setup) = 100Vp0;

Expected Results

Expected results and variation of results are defined in table below. Regular shape of waveform (REG. SHAPE) is defined on figure below.

Waveform



Notes

- The Vpp must be measured as the voltage difference from positive to negative value of the signal.
- In some case, some small spikes can happened. There should not be included in measurement of Vpp.
- For measurement of Vpp, the scale on scope must be set on proper value for different values of the intensities.

Intensity [V]	*Load [E]*	*Waveform*	*ΔI [ma]*	*Vpp [V]*	*Vdcbus [V]*	*SC Det*	*NL Det*
TH 23V	*0*	"0" DC	< 10 (+/-5)	*not.imp.*	21 (+/-5)	DET	NOT DET
	1K	REG. SHAPE	< 10 (+/-5)	29 (+/-5)	34 (+/-5)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	34 (+/-5)	NOT DET	DET
MAX 100V	*0*	"0" DC	< 10 (+/-5)	*not.imp.*	20 (+/-5)	DET	NOT DET
	1K	REG. SHAPE	15 (+/-10)	125 (+/-10)	115 (+/-5)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	115 (+/-5)	NOT DET	DET

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Waveform #3.3 – Short Pulse Burst 2P CV

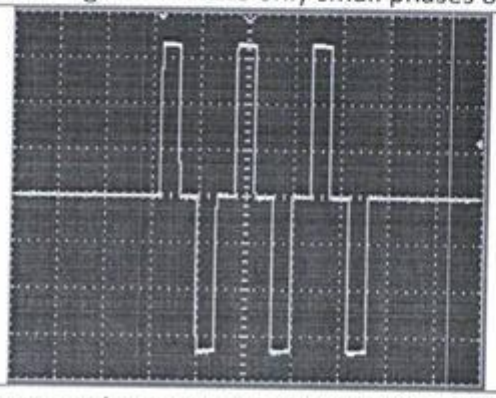
Specification

- Short Pulse Burst 2P CV
- Setup: Pulse Width = 1000usec, Freq = 142 Hz, all other parameters must be in accordance with DEFAULT setup;
- Measurements must be done for Intensity:
  - TH = 23V (GUI Setup) = 23Vp0;
  - MAX=100V (GUI Setup) = 100Vp0;

Expected Results

Expected results and variation of results are defined in table below. Regular shape of waveform (REG. SHAPE) is defined on figure below. The pulse width and frequency used in this test generate that the signal will have only small phases of "0" value.

Waveform



Notes

- The Vpp must be measured as the voltage difference from positive to negative value of the signal.
- In some case, some small spikes can happened. There should not be included in measurement of Vpp.
- For measurement of Vpp, the scale on scope must be set on proper value for different values of the intensities.

Intensity [V]	*Load [E]*	*Waveform*	*ΔI [ma]*	*Vpp [V]*	*Vdcbus [V]*	*SC Det*	*NL Det*
TH 23V	*0*	"0" DC	190 (+/-30)	*not.imp.*	20 (+/-5)	DET	NOT DET
	1K	REG. SHAPE	40 (+/-10)	46 (+/-5)	30 (+/-5)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	30 (+/-5)	NOT DET	DET
MAX 100V	*0*	"0" DC	190 (+/-30)	*not.imp.*	22 (+/-5)	DET	NOT DET
	1K	REG. SHAPE	590 (+/-50)	200 (+/-10)	116 (+/-5)	NOT DET	NOT DET
	INF	DEFORM.	20 (+/-10)	*not.imp.*	112 (+/-5)	NOT DET	DET

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Specification of tests and Expected Results for TC.05.03.004-ESTIM uC Tests

Waveform #4.1 – Microcurrent 2P

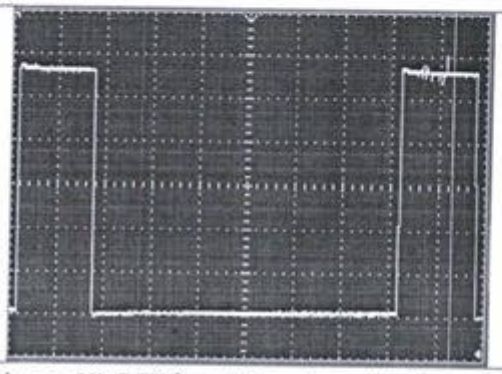
Specification

- Microcurrent 2P
- Setup: Pulse Freq = 10kHz, all other parameters must be in accordance with DEFAULT setup;
- Measurements must be done for Intensity:
  - TH = 160uA (GUI Setup) = 160uAp0;
  - MAX=1000uA (GUI Setup) = 1000uAp0;

Expected Results

Expected results and variation of results are defined in table below. Regular shape of waveform (REG. SHAPE) is defined on figure below.

Waveform



Notes

- Sometimes, NL DET for INF load and TH intensity will not be detected. In that case, NL DET for INF load should be tested on 2 x TH intensity.
- In some case, some small spikes can happened. There should not be included in measurement of Vpp.
- For measurement of Vpp, the scale on scope must be set on proper value for different values of the intensities.
- For measurement of Vpp, the scale on scope must be set on proper value for different values of the intensities. The probe x1 must be used.
- SC cannot be detected for any condition.

Intensity [uA]	*Load [E]*	*Waveform*	*ΔI [ma]*	*Vpp [V]*	*Vdcbus [V]*	*SC Det*	*NL Det*
TH	*0*	"0" DC	< 10 (+/-5)	*not.imp.*	25 (+/-2)	NOT DET	NOT DET
	1K	REG. SHAPE	< 10 (+/-5)	250 (+/-20)	25 (+/-2)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	25 (+/-2)	NOT DET	DET
MAX	*0*	"0" DC	< 10 (+/-5)	*not.imp.*	25 (+/-2)	NOT DET	NOT DET
	1K	REG. SHAPE	< 10 (+/-5)	1000 (+/-50)	25 (+/-2)	NOT DET	NOT DET
	INF	DEFORM.	< 10 (+/-5)	*not.imp.*	25 (+/-2)	NOT DET	DET

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Worst case power Consumptions

Common (LCD, DB, IB1, UIB, idle currents..)	
Specification	• n/a
Expected Results	• Max Power consumption 11W
Notes	-
Battery charger	
Specification	• n/a
Expected Results	• Max Power consumption 12W
Notes	-
USG	
Specification	• Continuous mode
Expected Results	• Max Power Consumption at 1MHz 30W • Max Power Consumption at 3MHz 40W • Max Power Consumption during Head Warming 8W
Notes	Type 2

E-stim Waveforms

Waveform #1	IFC Traditional (4P) CC
Specification	• Setup: Frequency 5000kHz, SCAN OFF (other parameters are default);
Expected Results	Max Power consumption 5W
Notes	Type 1
Waveform #2	Tens Symetrical Biphasic
Specification	• Setup: Frequency 200Hz, P.W. 1000uS
Expected Results	• Max Power consumption 17W CC • Max Power consumption 14W CV
Notes	Type 2
Waveform #3	Tens Asymetric Biphasic
Specification	• Setup: Frequency 181Hz, P.W. 1000uS
Expected Results	• Max Power consumption 13W CC • Max Power consumption 12W CV
Notes	Type 2
Waveform #4	Russian 2P

60601-1	60601-2-52	Requirements	Result/Remarks	Verdict

Waveform #4	Russian 2P
Specification	• Setup: Frequency 100Hz, P.W. 5000uS
Expected Results	• Max Power consumption 3W CC • Max Power consumption 9W CV
Notes	Type 2
Waveform #5	Russian standard 4P
Specification	• n/a
Expected Results	• Max Power consumption 5W CC • Max Power consumption 18W CV
Notes	Type 1
Waveform #6	High Voltage
Specification	• n/a
Expected Results	• Max Power consumption 2W
Notes	Type 1
Waveform #7	Tens Alternative Rectangular
Specification	• Setup: Frequency 250Hz, P.W. 1000uS
Expected Results	• Max Power consumption 13W CC • Max Power consumption 12W CV
Notes	Type 2
Waveform #8	Tens Monophasic Rentangular
Specification	• Setup: Frequency 250Hz, P.W. 1000uS
Expected Results	• Max Power consumption 9W CC • Max Power consumption 8W CV
Notes	Type 2
Waveform #9	Short Pulse
Specification	• Setup: Frequency 200Hz, P.W. 1000uS
Expected Results	• Max Power consumption 15W CC • Max Power consumption 12W CV
Notes	Type 2
Waveform #10	Short Pulse Burst
Specification	• Setup: Frequency 142Hz, P.W. 1000uS
Expected Results	• Max Power consumption 22W CC • Max Power consumption 22W CV
Notes	Type 2