



MEDICAL DIRECTIVE—SAFETY TEST REPORT

For

Hair Removal System

Model: BM204, BM205, BM14, BM12S, BM101, BM212, BM18, BM18-1, BM18-2, BM051, BM03, BM052, BM053, BM054, BM055, BM056, BM057, BM058, BM059, BM060, BM061, BM062, BM063, BM064, BM065, BM066, BM067, BM068, BM069, BM070, IPLS1, IPLS2, IPLS3, IPLS4, IPLS5, IPLS6, IPLS7, IPLS8, IPLS9, IPLS10, IPLS11, IPLS12, IPLS13, IPLS14, IPLS15, DL108, DL109, DL110, DL111, DL112, DL113, DL114, DL115, DL116, DL117, DL118, DL119, DL120, DL121, DL122, DL123, DL124, DL125, DL126, DL127, DL128, DL129, DL130

Brand Name: NEWANGIE

Report No.: ENC2502191GZ62L1

Date of Issue: Feb. 24, 2025

Prepared For

Hebei Newangie Technology Co., Ltd.

Room 402, Building A-5, Guoxietang Industrial Park, No.509 Taihang South Street, Hi-Tech Zone, Shijiazhuang City, 050035 Hebei Province, P.R.China

Prepared By

East Notice Certification Service Co., Ltd.

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**TEST REPORT****EN 60601-1****Medical electrical equipment --****Part 1: General requirements for basic safety and essential performance**

Report reference No. : ENC2502191GZ62L1

Tested by : Sam Liu

Review by (+ Signature). : Yemig

Approved by (+ signature) : Ray Zhou

Date of issue : Feb. 24, 2025

Contents : Total 54 pages

**Testing laboratory**

Name : East Notice Certification Service Co., Ltd.

Address : 1/F, Haohui Commercial Building, Zhuji Street, Dongpu Town,
Tianhe District, Guangzhou City, China

Testing location : Same as above

Application

Name..... : Hebei Newangie Technology Co., Ltd.

Address : Room 402, Building A-5, Guoxietang Industrial Park, No.509
Taihang South Street, Hi-Tech Zone, Shijiazhuang City, 050035
Hebei Province, P.R.China**Manufacturer**

Name..... : Hebei Newangie Technology Co., Ltd.

Address..... : Room 402, Building A-5, Guoxietang Industrial Park, No.509
Taihang South Street, Hi-Tech Zone, Shijiazhuang City, 050035
Hebei Province, P.R.China**Test specification**

Standard : EN 60601-1:2006+A13:2024, EN 60825-1:2014+A11:2021

Test procedure : CE- SAFETY Test

Procedure deviation : N/A

Non-standard test method : N/A

Test Report Form/blank test report

Test Report Form No. : ENC60601-1-A24

Test Report Form Originator : ENC

Test item

Description : Hair Removal System

Brand name : NEWANGIE

Model and/or type reference : BM18 (Additional models: see next page)

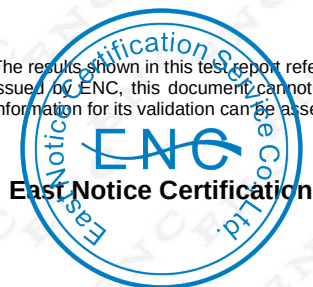
Rating(s) : 100-240V~, 50/60Hz, 3000W

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Test case verdicts Test case does not apply to the test object.....: N(/A) Test item does meet the requirement: P(ass) Test item does not meet the requirement.....: F(ail)
Testing Date of receipt of test item: Feb. 14, 2025 Date(s) of performance of test: Feb. 14, 2025 – Feb. 24, 2025
General remarks "(see remark #)" refers to a remark appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report a comma is used as the decimal separator. When determining the test result, measurement uncertainty has been considered. Note: This report shall not be altered, increase and deleted. The results relate only to the items tested. This report shall not be published as advertisement without the approval of ENC. This report shall not be copied partly without the written approval of ENC. Should any objections to the test reports occurred, should submit it to the Company within ten days since the issuing of the report, Fail to accept.
Special description: 1. All tests are basic on model BM18. 2. Additional models: BM204, BM205, BM14, BM12S, BM101, BM212, BM18-1, BM18-2, BM051, BM03, BM052, BM053, BM054, BM055, BM056, BM057, BM058, BM059, BM060, BM061, BM062, BM063, BM064, BM065, BM066, BM067, BM068, BM069, BM070, IPLS1, IPLS2, IPLS3, IPLS4, IPLS5, IPLS6, IPLS7, IPLS8, IPLS9, IPLS10, IPLS11, IPLS12, IPLS13, IPLS14, IPLS15, DL108, DL109, DL110, DL111, DL112, DL113, DL114, DL115, DL116, DL117, DL118, DL119, DL120, DL121, DL122, DL123, DL124, DL125, DL126, DL127, DL128, DL129, DL130. 3. All models have same electrical structure as BM18, except for the different appearance and power. 4. Specified maximum ambient temperature is 40°C.
Summary of testing All tests were found satisfactory in accordance with EN 60601-1:2006+A13:2024. The product was classified as Class 4 Laser product according to EN 60825-1:2014+A11:2021.

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Marking on the appliance:

Hair Removal System	
Model: BM18	
Input: 100-240V~, 50/60Hz, 3000VA	
SN	
Hebei Newangie Technology Co., Ltd.	
Room 402, Building A-5, Guoxietang Industrial Park, No.509	
Taihang South Street, Hi-Tech Zone, Shijiazhuang City, 050035	
Hebei Province, P.R.China	
 XXXX	     MADE IN CHINA

Remark:

The height of mark shall be at least 10mm.

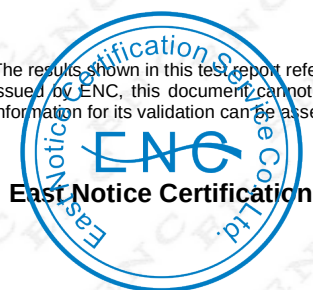
The additional markings which do not give rise to misunderstanding maybe added.

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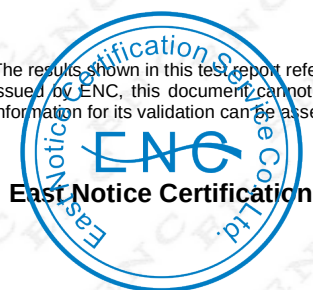
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
4	GENERAL REQUIREMENTS		--
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		P
4.2	RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS		P
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007)	See Appended RM Results Table 4.2.2.	P
4.2.3	Evaluating RISK		P
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		P
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN		P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		P
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		P
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the EN 60601-1 series.		P
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	No essential performance	N
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		N
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		N
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE		N
	- RISK CONTROL measures implemented		N
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		N
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE	5 years contained in RMF	P

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means are comparable to the RESIDUAL RISKS resulting from requirements of this standard	No alternative means provided	N
	Alternative means based scientific data or clinical opinion or comparative studies		N
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10	See Appended RM Results Table 4.6	P
	Assessment identified the APPLIED PART TYPE requirements	BF	P
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2 .	See Appended RM Results Table 4.7	P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically		P
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation		P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified		P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	See Appended RM Results Table 4.8	P
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following		P
	a) Applicable safety requirements of a relevant IEC or ISO standard	See appended table 8.10	P
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard	See appended table 8.10	P
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK	No such components	N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE		N
4.10	Power supply		P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:		P
4.11	Power input		P
	Power input Measurement	(see appended table 4.11)	P

5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		--
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2	Type tests carried	P
5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected		P
5.3	a) Tests conducted within the environmental conditions specified in technical description	Temperature: 15~30 °C Humidity: ≤80% 86kPa~106kPa	P
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests	Testing lab environment under controlled	P
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained		P
5.4	a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use		P
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favourable for the relevant test per instructions for use		P
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits in technical description		P
	d) Potable water used for cooling	The equipment will can't into work when the water low the request of the cooling water	P

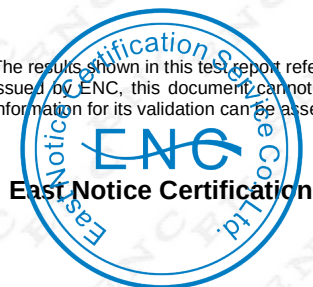
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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
5.5	a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V)		P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)	50/60Hz	P
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current	Only one rated voltage	N
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered		N
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions	No such accessories	N
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	Not connected a separate power	N
5.6	When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample		P
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3	Before the test of 8.7.4 and 8.8.3, the humidity preconditioning is performance	P
5.8	Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent influencing results of any subsequent test		P
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P

6	CLASSIFICATION		--
6.1	General		--
	For purposes of this standard, equipment shall be classified as follows.		P
6.2	Type of protection against electric shock		P
	Class I equipment	Class I equipment	P

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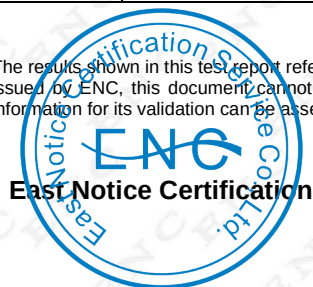
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Class II equipment		N
	Internally powered equipment		N
	Applied parts shall be classified as type B applied parts, type BF applied parts or type CF applied parts (see 7.2.10 and 8.3). Applied parts may be classified as defibrillation-proof applied parts (see 8.5.5).	BF	P
6.3	Protection against harmful ingress of water or particulate matter (see 6.1.1)	IPX0	P
6.4	Methods of sterilization or disinfection		P
6.5	Suitability for use in an oxygen rich environment		--
	Category AP equipment		N
	Category APG equipment		N
6.6	Mode of operation:		--
	-continuous operation		P
	-short-time operation, specified operation; period		N
	-intermittent operation, specified operation; rest period		N
	-continuous operation with short-time, stated permissible loading time		P
	-continuous operation with intermittent, stated permissible loading/rest time		N

7	IDENTIFICATION, MARKING AND DOCUMENTS		--
7.1	General		P
7.1.1	Usability of the identification, marking and documents		P
7.1.2	Legibility of markings	Legibility.	P
7.1.3	Durability of markings	Durability.	P
7.2	Marking on the outside of equipment or equipment parts		P
7.2.1	Minimum requirements for marking on equipment and on interchangeable parts		P
7.2.2	Identification	See marking plate	P
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		N
	SAFETY SIGN 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		P

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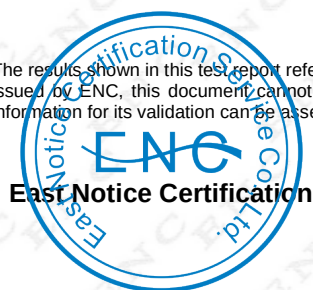
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
7.2.4	Accessories shall be marked with the name or trade-mark of their manufacturer or supplier, and with a model or type reference.	Model: BM18	P
7.2.5	Equipment intended to receive power from other equipment		P
7.2.6	Connection to the supply mains shall be marked with the following information:		--
	– the rated supply voltage(s)	100-240V	P
	– nature of supply	~	P
	– the rated supply frequency	50/60Hz	P
	– For class II equipment, symbol IEC 60417-5172		N
7.2.7	Electrical input power from the supply mains	3000W	P
7.2.8	Output connectors		--
7.2.8.1	Mains power output		N
7.2.8.2	Other power sources		N
7.2.9	IP classification	IPX0	N
7.2.10	Applied parts		P
7.2.11	Mode of operation	Continuous operation	N
7.2.12	Fuses		P
7.2.13	Physiological effects (safety signs and warning statements)		P
7.2.14	High voltage terminal devices		P
7.2.15	Cooling conditions	Water and fan cooling system	P
7.2.16	Mechanical stability		P
7.2.17	Protective packaging		N
7.2.18	External pressure source	Normal	N
7.2.19	Functional earth terminals		N
7.2.20	Removable protective means		N
7.3	Marking on the inside of equipment or equipment parts		--
7.3.1	Heating elements or lampholders		N
7.3.2	High voltage parts		P
7.3.3	Batteries	No battery.	N
7.3.4	Fuses, thermal cut-outs and over-current releases		P

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
7.3.5	Protective earth terminals		P
7.3.6	Functional earth terminals		N
7.3.7	Supply terminals		N
7.3.8	Temperature of supply terminals		N
7.4	Marking of controls and instruments		--
7.4.1	Power switches		--
	– marked with symbols IEC 60417-5007 (DB:2002-10) and IEC 60417-5008	—, O	P
	– indicated by an adjacent indicator light; or		P
	– indicated by other unambiguous means.		N
7.4.2	Control devices		P
7.4.3	Units of measure		N
7.5	Safety signs		--
	a) Constructing a safety sign according to ISO 3864-1:2002,		P
	b) Using the general warning sign ISO 7010:2003-W001		P
	c) Using the general prohibition sign ISO 7010:2003-P001		P
	d) Using the general mandatory action sign ISO 7010:2003-M001		P
7.6	Symbols		--
	Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)		P
7.7	Colors of the insulation of conductors		--
	a) Protective earth conductor has green/yellow insulation	Green/yellow	P
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations		P
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow		P
	d) Color of neutral conductor		N
	e) Colors of phase conductor(s)	Single phases	N
	- Compliance with IEC 227 and IEC 245	Live parts was colored with brown	P

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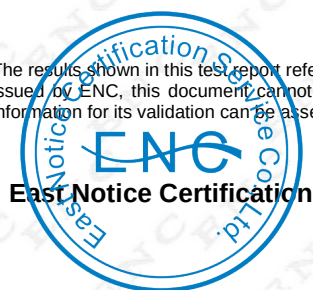


EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors		N
7.8	Indicator lights and push -buttons		P
	a)Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action		P
	-Yellow used to indicate caution or attention required		N
	b)Color red used only for push-buttons by which a function is in case of emergency		P
7.9	Accompanying documents		P
7.9.1	Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Integrally contained all that required document.	P
	Classifications specified in Clause 5 included in both the instructions for use and the technical description	Technical description include in instruction	N
	Markings specified in Sub-clause 7.1 included in the accompanying documents if they have not been permanently affixed to equipment		N
	Warnings statements and the explanation of warning symbols provided in the accompanying documents		N
7.9.2	Instructions for use		--
7.9.2.1	General		P
1)	- the use of the ME EQUIPMENT as intended by the MANUFACTURER,		P
2)	- the frequently used functions, and		P
3)	- any known contradiction(s) to the use of the ME EQUIPMENT		P
(2)	The instructions for use shall include all applicable classification off safety signs and symbols (marked on the ME EQUIPMENT).		P
(3)	The instructions for use shall be in a language that is acceptable to the intended OPERATOR.		P
7.9.2.2	Warning and safety notices		P
(1)	The instructions for use shall include all warning and safety notices.		P
1)	FOR CLASS I ME EQUIPMENT, the instructions for use shall include a warning statement to the effect:" WARNING: To avoid the risk of electric shock, this equipment must only b e connected to a supply mains with protective earth."		N

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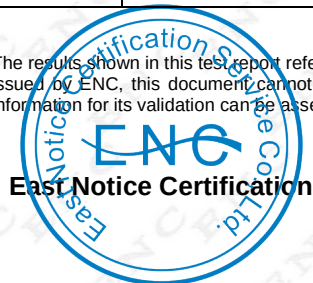
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
2)	The instructions for use shall provide the OPERATOR or RESPONSIBLE ORGANIZATION with warnings regarding any significant RISKS of reciprocal interference posed by the presence of the ME EQUIPMENT during specific investigations or treatments.		P
3)	The instructions for use shall include information regarding potential electromagnetic or other interference between the ME EQUIPMENT AND other devices together with advice on ways to avoid or minimize such interference.		P
4)	If the ME EQUIPMENT is provided with an integral MULTIPLE SOCKET- OUTLET, the instructions for use shall provide a warning statement that connecting electrical equipment to the MOS effectively leads to creating an ME SYSTEM and the result can be a reduced level of safety. For the requirements that are applicable to an ME SYSTEM, the RESPONSIBLE ORGANIZATION shall be referred to this standard.		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
7.9.2.4	Electrical power source		--
	For mains-operated ME EQUIPMENT with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement of such an additional power source.		N
	If leakage from a battery would result in an unacceptable RISK, the instructions for use shall include a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.		N
	If an INTERNAL ELECTRICAL POWER SOURCE is replaceable, the instructions for use shall state its specification.		N
	If loss of the power source would result in an unacceptable RISK, the instructions for use shall contain a warning that the ME EQUIPMENT must be connected to an appropriate power source.		N

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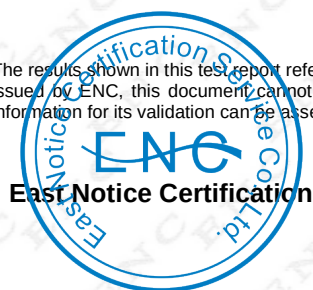
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
7.9.2.5	ME EQUIPMENT description		--
	The instructions for use shall include:		P
	– a brief description of the ME EQUIPMENT;		P
	– how the ME EQUIPMENT functions; and		P
	– the significant physical and performance characteristics of the ME EQUIPMENT.		P
	If applicable, this description shall include the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE (see 9.2.2.3).		N
	The instructions for use shall include information on the materials or ingredients to which the PATIENT or OPERATOR is exposed if such exposure can constitute an unacceptable RISK (see 11.7).		N
	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
	The instructions for use shall indicate any APPLIED PART.		P
7.9.2.6	* Installation		--
	If installation of the ME EQUIPMENT or its parts is required, the instructions for use shall contain:		N
	– a reference to where the installation instructions are to be found (e.g. the technical description), or		N
	– contact information for persons designated by the MANUFACTURER as qualified to perform the installation.		N
7.9.2.7	* Isolation from the SUPPLY MAINS		--
	If an APPLIANCE COUPLER or separable plug is used as the isolation means to satisfy 8.11.1 a), the instructions for use shall contain an instruction not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.		N
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.		N

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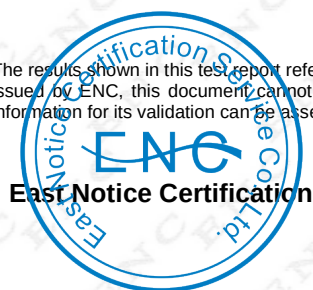
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	The instructions for use shall detail any treatment or handling needed before the ME EQUIPMENT, its parts, or ACCESSORIES can be used.		N
7.9.2.9	Operating instructions		--
	The instructions for use shall contain all information necessary to operate the ME EQUIPMENT in accordance with its specification. This shall include explanation of the functions of controls, displays and signals, the sequence of operation, and connection and disconnection of detachable parts and ACCESSORIES, and replacement of material that is consumed during operation.		P
	The meanings of figures, symbols, warning statements, abbreviations and indicator lights on ME EQUIPMENT shall be explained in the instructions for use.		P
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.		N
	The list shall include an explanation of messages including important causes, and possible action(s) by the OPERATOR, if any, that are necessary to resolve the situation indicated by the message.		N
7.9.2.11	Shutdown PROCEDURE		--
	The instructions for use shall contain the necessary information for the OPERATOR to safely terminate the operation of the ME EQUIPMENT.		N
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:		P
	– details about cleaning and disinfection or sterilization methods that may be used; and		P
	– list the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT parts or ACCESSORIES can tolerate.		N
7.9.2.13	Maintenance		--

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	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.		N
	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.		N
	Additionally, the instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by SERVICE PERSONNEL, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance.		N
	For ME EQUIPMENT containing rechargeable batteries that are intended to be maintained by anyone other than SERVICE PERSONNEL, the instructions for use shall contain instructions to ensure adequate maintenance.		N
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
	If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall sufficiently specify such other equipment to ensure compliance with the requirements of this standard (e.g. part number, RATED voltage, maximum or minimum power, protection class, intermittent or continuous service).		N
7.9.2.15	Environmental protection		--
	The instructions for use shall:		N
	– identify any RISKS associated with the disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE; and		N
	– provide advice on minimizing these RISKS.		N
7.9.2.16	Reference to the technical description		--

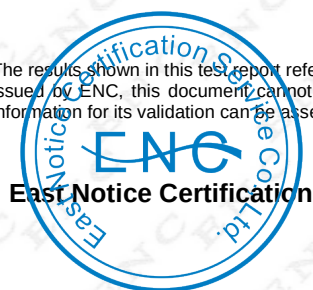
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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	The instructions for use shall contain the information specified in 7.9.3 or a reference to where the material specified in 7.9.3 is to be found (e.g. in a service manual).		N
7.9.3	Technical description		--
	a)All characteristics essential for safe operation	Technical description included in insulation	P
	b)Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment		N
	-Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		N
	c)Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided		N
	d)Environmental conditions for transport or storage specified in accompanying documents and marked on packaging		P

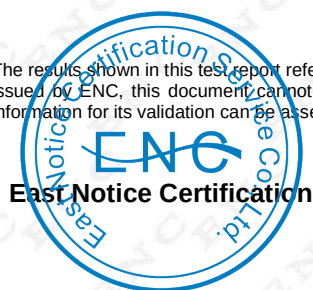
8	PROTECTION AGAINST ELECTRICAL HAZARDS FROM EQUIPMENT		--
8.1	Fundamental rule of protection against electric shock		P
	The limits specified in 8.4 shall not be exceeded for accessible parts and applied parts in normal condition or single fault condition.	See Clause 8.4	P
8.2	Requirements related to power sources	~	P
8.2.1	Connection to a separated power source	No separated power source.	N
8.2.2	Connection to an external d.c. power source	Connection to an external a.c. power source.	N
8.3	Requirements related to classification		P
	Class I and Class II equipment in addition to basic insulation provided with an additional protection	Class I equipment.	P
	Equipment supplied from external d.c. source of reverse polarity results in no safety hazard		N
	Internally powered equipment complies with requirements for Class I Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected		N

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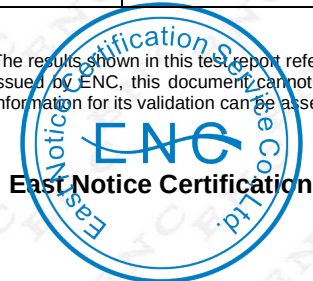
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Applied parts intended for direct cardiac application are of type CF		N
8.4	Limitation of voltage , current or energy		P
8.4.1	Patient connections intended to deliver current		N
8.4.2	Accessible parts including applied parts		P
8.4.3	Equipment intended to be connected to a power source by a plug		P
8.4.4	Internal capacitive circuits	(See appended table 8.4.4a and 8.4.4b)	P
8.5	Separation of parts		N
	Separation method of the applied part from live parts:		--
	1) Basic insulation: applied part earthed.	No such parts.	N
	2)by protectively earthed intermediate circuit limiting leakage current to applied part in event of insulation failure	No protectively earthed circuit	N
	3)by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure		N
	4)by double or reinforced insulation		P
	5)by protective impedances limiting current to applied part		N
	-Additional leakage current test single fault conditions	(see appended table 8.5)	N
	There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed		N
	Supplementary insulation between hand-held flexible shafts and motor shafts(Class I)		N
	Separation method of accessible parts other than applied parts from live parts:		--
	1)basic insulation: accessible part earthed		N
	2)by protectively earthed conductive part(e.g.screen)		N
	3)by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure		N
	4)by double or reinforced insulation		P
	5)by protective impedances limiting current to accessible part		N

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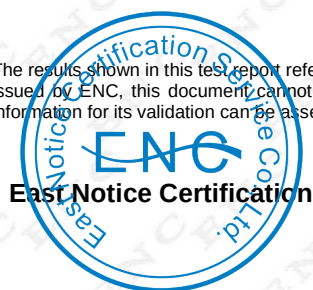
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	-Additional leakage current test in single fault conditions	(see appended table 8.5)	N
	Arrangements used to isolate defibrillation-proof applied parts so designed that:		--
	-no hazardous electrical energies appear during a discharge of a cardiac defibrillator	(see appended table 8.5a)	N
	-after exposure to the defibrillation voltage, the equipment continues to perform its intended function	(see appended table 8.5b)	N
8.6	protective earthing, functional earthing and potential		--
	Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	Class I equipment.	P
	Protective earth terminals suitable for connection to the protective earth conductor		P
	Potential equalization conductor		--
	-Readily accessible		N
	-Accidental disconnection prevented in normal use		N
	-Conductor detachable without the use of a tool		N
	-Accidental disconnection prevented in normal use		N
	-Connection means marked with Symbol9, Table DI		N
	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1\Omega$		N
	-For equipment with an appliance inlet, impedance between protective earth terminal and accessible metal part $\leq 0.1\Omega$	(see appended table 8.6)	P
	For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.2\Omega$		N
	If the impedance of protective earth connections Other than in Cl. 18f) exceed 0.1Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition		N
	Functional earth terminal not used to provide protective earthing		N
	Class II equipment with isolated internal screens		--
	-insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation		N
	-functional earth terminal clearly marked		N

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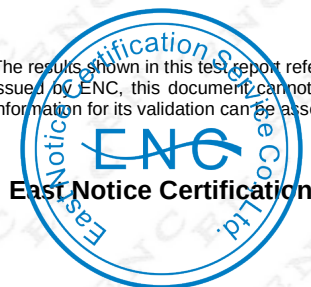
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	-explanation of functional earth terminal provided in the accompanying documents		N
	protective earthing-terminals and connections		N
	Clamping means of the protective earth terminal		N
	Not be able to loosen without the aid of a tool		N
	Screws for internal earth connections are covered or protective against loosening from outside		N
	Earth pin of the appliance inlet regarded as the protective earth terminal		N
	The protective earth connections are covered or protected against loosening from outside		N
	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting		N
8.7	continuous leakage currents and patient auxiliary currents		--
	Leakage currents	(see appended table 8.7)	P
	-earth leakage current		P
	-enclosure leakage current		P
	-patient leakage current		P
	-patient auxiliary current		N
8.8	Dielectric strength		--
	Overall compliance with Clause 20	(see appended table 8.8)	P
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are $\geq$ to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15	Refer to insulation diagram table	P
8.9.1.2	Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested		P
8.9.1.2	Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested		P

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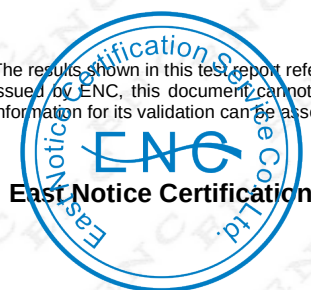
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
8.9.1.3	Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics	No such components used	N
8.9.1.4	When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE		P
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m		P
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m)	2000m	P
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used to determine multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor		N
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE		N
8.9.1.6	When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		P
	– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm)	See Insulation Diagram/Table	P
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm)	See Insulation Diagram/Table	P
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied	No PEAK WORKING VOLTAGE up to 2800 V peak or d.c.	N
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group)	See Insulation Diagram/Table.	P
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112	Material group considered group IIIb	N
	Material of unknown group considered IIIb		P
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N

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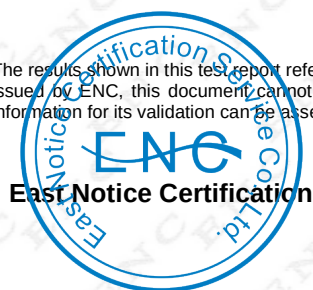
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	– Pollution degree 2: Micro-environment with nonconductive pollution, except occasional conductivity caused by condensation		P
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation		N
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions		N
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION		N
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree	Pollution degree 2	P
8.9.1.9	Overvoltage category classification; value of MAINS TRANSIENT VOLTAGE determined from overvoltage category per IEC60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10		P
	V MT Peak (V)	2500	P
	V MN r.m.s (V)	240	P
8.9.1.10	AIR CLEARANCE for MAINS PARTS (operating on RATED MAINS VOLTAGES up to 300 V) were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE	Operating on rated mains voltages is 100-240V	P
8.9.1.11	SUPPLY MAINS overvoltage category II applied according to IEC 60664-1	Overvoltage category II	P
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used		N
	When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for Cl. 8.9 used		N
8.9.1.12	A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)	The secondary circuit was considered to be overvoltage category I.	P
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		N

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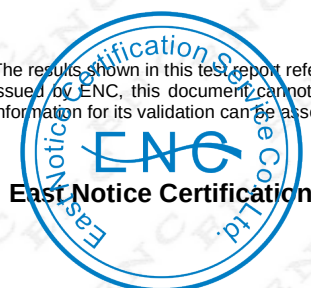
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		P
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I		N
	– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and		N
	– circuits in INTERNALLY POWERED ME EQUIPMENT		N
8.9.1.13	For PEAK WORKING VOLTAGES above 1400 V peak or d.c. Table 15 not applied since all the following conditions were met	No PEAK WORKING VOLTAGES above 1400 V peak or d.c.	N
	– CLEARANCE was at least 5 mm		N
	– insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or		N
	– a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and		N
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I		N
	Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material		N
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION		P
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1		N
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied		N

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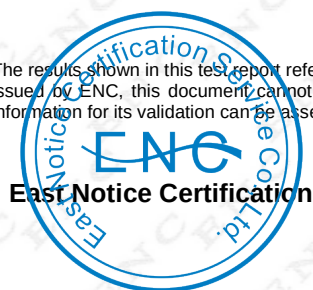
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		N
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by molding, or there is no reduction of a distance below specified value by deformation or movement of parts		N
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		N
8.9.3	Spaces filled by insulating compound		N
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound were such that CLEARANCES and CREEPAGE DISTANCES don't exist	No such insulation components used	N
	Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted		N
	8.9.3.2 For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6		N
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N
	A winding of solvent-based enameled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage		N
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times		N
8.10	Components and wiring		P
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely as indicated in RISK MANAGEMENT FILE	See Appended RM Results Table 8.10.1	P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION		P
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION as indicated in RISK MANAGEMENT FILE		P
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION		P
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS due to poor contact		P
8.10.3	Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as shown by measurement or using test finger		P
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION		N
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		N
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		N
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION		N
8.10.5	Mechanical protection of wiring		P
	a) Internal cables and wiring 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.		P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION as shown by manual tests and RISK MANAGEMENT FILE		P
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE	No guiding rollers used	N
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed		P
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		N
	c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation	No more than 70 °C	N
8.11	Mains parts, components and layout		P
8.11.1	Isolation from supply mains		P
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	Connect the power with a three pins plug	P
	b) Means for isolation incorporated in equipment or, if external, specified in the accompanying documents		N
	c) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328		P
	f) Mains switches not incorporated in a power supply cord	No such switch.	P
	h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a		N

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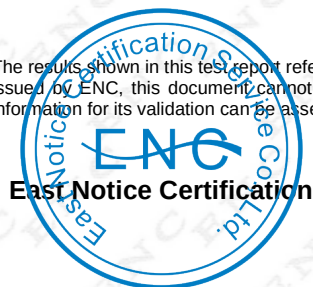


EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	m)Fuses and semiconductor devices not used as isolating devices		P
8.11.2	Mains connectors and appliance inlets		--
	e)Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug		P
	g)Unless functional earth needs to be provided ,Class I appliance inlet is not used in Class II equipment		N
8.11.3	Power supply cords		--
	a)Not more than one connection to a particular supply mains		P
	If alternatives supply allowed, no safety hazards when more than one connection is made simultaneously		N
	The mains plug has only one power supply cord		P
	Non-permanently connected equipment provided with power supply cord or appliance inlet		P
	b)Power supply cords sufficiently robust to comply with the requirements of IEC227,designation 53 and IEC245,designation 53	H05VV-F	P
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C		P
	c)Nominal cross-sectional area of conductors of power supply cords not less than in Table XV	3*1.0mm ²	P
	d)Stranded conductors not soldered if fixed by any clamping means		N
	Connection of power supply cords		P
8.11.3.5	Cord anchorage		--
	Equipment provided with power supply cords has cord anchorage such that the conductors are relieved from strain, including twisting		N
	Tying the cord into a knot or tying the ends with string not used		N
	Cord an anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation		N
	Cord anchorages made of metal provided with an insulating lining		N
	Clamping screws do not bear directly on the cord insulation		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Screws associated with cable replacement are not used to secure other components		N
	Conductors of the power supply cord arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminal		N
	Power supply cord protected against excessive bending		N
	Adequate space inside equipment to allow the supply cable conductors to be introduced and connected		P
8.11.4	Mains terminal devices and wiring of mains part		--
	Mains connected equipment other than those with a detachable supply cord provided with mains terminals, where connections are made with screws ,nuts or equally effective methods		N
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced		P
	Screws and nuts which clamp external conductors not serve to fix any other component.		N
	b)Terminal closely grouped with any protective earth terminal		N
	Mains terminal devices located or shielded that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact.		N
	c)Internal wiring not subject to stress when the means for clamping the conductors are tightened or loosened		N
	d)Cord terminals nor require special preparation of the conductor		N
8.11.5	Mains fuses and over current releases		P
	Fuses or over-current releases provided accordingly for Class I and Class II		P
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operation current		P
	Protective earth conductor not fused		N
	Neutral conductor not fuses for permanently installed equipment		N
8.11.6	Wiring of the mains part		--

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	a)Individual conductor in the mains part with insulation not at least electrically equipment to that of the individual conductors of flexible supply cords complying with IEC227or 245,treated as bare conductor		N
	b)Cross-section area of conductors up to protective device not less than the minimum required for the power supply cord		P
	Cross-sectional area of other wiring and the sizes of ranks on printed wiring circuits sufficient to prevent any fire hazard		N
	Mains supply transformers	Compliance	P
	construction and layout		P
	Internal wiring		--
	a)Cables and wiring protected against contact with a moving part	Fan as a moving part	P
	Wiring having basic insulation only protected by additional fixed sleeving		N
	Components are not likely to be damaged in the normal assembly or replacement of covers		P
	b)Movable leads are not bent around a radius of less than five times the outer diameter of the lead		P
	c)Insulating sleeving adequate		P
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC245 and dielectric test	None	P
	Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material		N
	d)Aluminum wires of less than 16m ² cross section not used	No any aluminum wire	N
	f)Connecting cords between equipment parts considered as belonging to the equipment		P
	Insulation		--
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	Ball-pressure test for enclosure at a temperature of 125°C	P
	c)Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts		N
	Parts of rubber resistant to ageing	No such part.	N

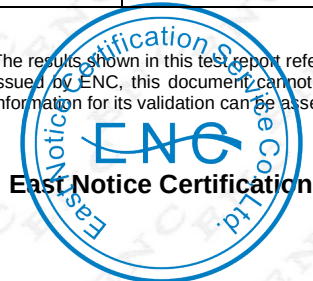
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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
9	MECHANICAL STRENGTH		--
9.1	Mechanical hazards of equipment		P
	Sufficient rigidity of an enclosure tested by: force of 45 N	(see appended table 9)	P
	Sufficient strength of an enclosure tested by: impact hammer	(see appended table 9)	P
	On portable equipment carrying handles or grips withstand the requirements of the loading test	No such equipment.	N
	No damage to parts of patient support and/or immobilization system after the loading test	No such part.	N
	Hand held equipment to equipment parts are safe after drop test	(see appended table 9)	P
	Portable and mobile equipment is able to withstand rough handling		N
9.2	moving parts		--
	Moving parts of a transportable equipment are provided with guards which form an integral parts of the equipment		N
	Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equipment protection is separately provided during installation		N
	Cords(ropes),chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices		N
	Guides or other safeguards are removable only with a tool		N
	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator		N
	Parts of equipment subject to mechanical wear are accessible for inspection		N
	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard		N
	The means for emergency switch is readily identifiable and accessible and does not introduce a further safety hazard		N
	Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Means for stopping of movements operate as a result of one single action		N
9.3	Hazard associated with surfaces, corners and edges		P
	Rough surfaces ,sharp corners and edges which may cause injury or damage avoided or covered	Edges and corners are well rounded and smooth	P
9.4	Instability hazards		P
	Equipment does not overbalance during normal Use when tilted through an angle of 10°		P
	Equipment overbalance when tilted through an angel of 10°		N
	-does not overbalances when tilted through an angle of 5° any position excluding transport		N
	-carry a warning notice stating that transport should only be undertaken in a certain position		N
	-in the position specified for transport does not overbalance when tilted to an angle of 10°		N
	Equipment or its parts with a mass of more than 20 kg is provided with:		N
	-suitable handing devices(grips etc.),or	Not such equipment.	N
	-instructions for lifting and handing during assembly		N
	b)On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons		N
9.5	Expelled parts		N
	Protective means are provided where expelled parts of the equipment could be a hazard	No expelled parts	N
	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion		N
9.8.3	Support systems		N
	Support system with safety device	No support system	N
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects ,or on parts having safety factors not complying with Sub-clause28.4		N
	Safety device has safety factors complying with Sub-clause28.4		N
	Clear indication to the operator that the safety device has been activated after failure of suspension means		N

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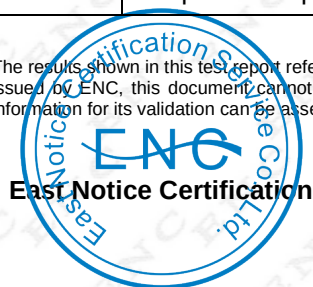


EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Suspension systems of metal		N
	1)Total load does not exceed the safe working load		N
	2)Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired		N
	3)Safety factors not less than 8 where impairment is expected		N
	4)Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5%		N
	5)Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement		N

10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION	--
10.1	X-Radiation	N
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation	N
10.3	The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m ² at any point 50 mm away from a surface of the ME EQUIPMENT under reference test conditions	N
10.4	Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.	N
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE	N
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE	N
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE	N

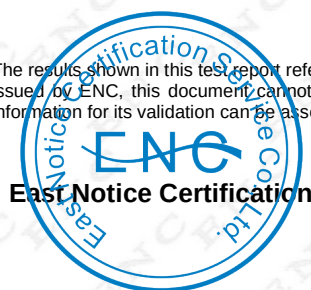
11	EXCESSIVE TEMPERATURES	--
11.1.1	Equipment does not attain temperatures exceeding the Values given in Table Xa over the range of ambient temperatures per Clause10.2.1	(see appended table 11) P

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Equipment does not attain temperatures exceeding the Values given in Table Xb at 25 ambient		P
	Applied parts not intended to supply heat have surface temperatures not exceeding 41°C		N
	Guards to prevent contact with hot surfaces surface temperatures not exceeding 41°C Guards to prevent contact with hot surfaces	No Guards.	N
11.2	Fire prevention		P
	Strength and rigidity necessary to avoid a fire hazard	Refer to table 10	P
11.6	overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection		P
	Equipment contain a liquid reservoir		--
	-the equipment is electrically safe after 15% overfill steadily over a period of 1 min		P
	-transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favourable direction(s)(if necessary with refilling)		P
	Electrical properties of the equipment do not change in connection of spillage test(200 ml of water)		P
	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard		P
	Equipment sufficiently protected against the effects of humidity		P
	Enclosure designed to give a protection against harmful ingress of water classified according to IEC Publication 529		N
	Equipment capable of withstanding cleaning sterilization or disinfection without deterioration of safety provisions	(see appended table 11.6)	N
11.7	Biocompatibility		N
	Parts of equipment and accessories intended to come into contact with biological tissues, cell or body fluids are evaluated in accordance with ISO 10993-1		N
11.8	Interruption of the power supply		P
	Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard	No thermal cut-outs and over-current releases.	N

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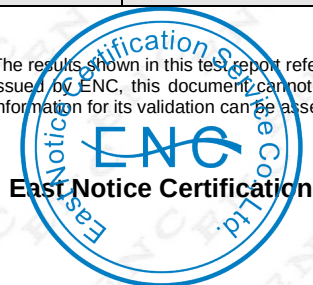


EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function		P
	Means are provided for removal of mechanical constraints on patient in case of a supply mains failure	No mechanical constraints on patient.	N

12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		--
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review	See Appended RM Results Table 12.1	N
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS complying with EN 60601-1-6	Evaluated by the manufacture	N
12.3	MANUFACTURER implemented an ALARM SYSTEM that complies with EN 60601-1-8		N
12.4	Protection against hazardous output		P
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE		N
12.4.2	When applicable, need for indication of parameters associated with hazardous output addressed in RISK MANAGEMENT PROCESS	See Appended RM Results Table 12.4.2	P
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit designed to provide low and high-intensity outputs for different treatments addressed in RISK MANAGEMENT PROCESS, confirmed in RISK MANAGEMENT FILE	See Appended RM Results Table 12.4.3	P
12.4.4	When applicable, RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE	See Appended RM Results Table 12.4.4	P
12.4.5	Diagnostic or therapeutic radiation		P
12.4.6	When applicable, RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE		N

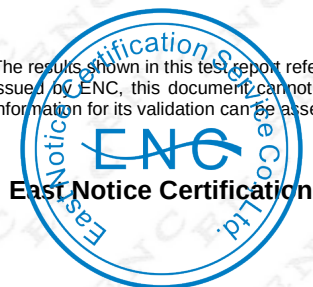
13	HAZARDOUS SITUATIONS AND FAULT CONDITIONS		--
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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
13.1	Specific HAZARDOUS SITUATIONS	(see appended table 13)	P
13.1.1	None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2	See 13.1.2-13.1.4	P
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		P
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3		P
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3		P
	– Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded		P
	Limits for windings in Tables 26, 27, and 31 not exceeded		P
	Table 22 not exceeded in all other cases		P
	Temperatures measured according to 11.1.3		P
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:		P
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION		N
	- or secondary circuits mounted on materials with a minimum flame rating of FV1, and		N
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and		N
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and		N
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide		N

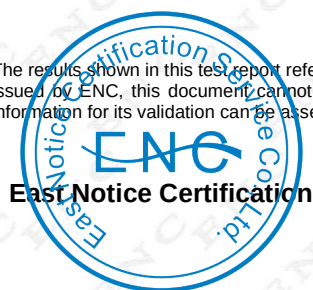
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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS		N
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation		P
	After tests of this Clause, settings of THERMAL CUTOUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		P
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed .		P
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed		P
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS	Complied	P
13. 2	SINGLE FAULT CONDITIONS		P
13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination	See appended Table 13	P
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12	See appended Table 13	P
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to within 3 °C of the temperature in the test environment	Ball-pressure test for nonmetallic enclosure has been carried out at 75°C	P
13.2.13.2	ME EQUIPMENT with heating elements		N
13.2.13.3	ME EQUIPMENT with motors		N
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N

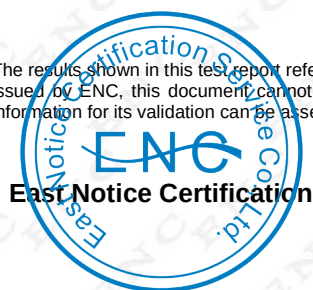
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		P
14.1	General	These requirements of clause applied to this device.	P
	-The PESS provides no basic safety or essential performance	See the software files provided by the manufacturer	P
	Essential performance - the application of ISO 14971 demonstrates that the failure of the PESS does not lead to an unacceptable		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
14.2	The documents required by Clause 14 shall be reviewed, approved, issued and changed in accordance with a formal document control		N
14.3	The risk management plan required by 3.5 of ISO 14971 shall also include a reference to the PEMS validation plan (see 14.11).	See Software test plan	P
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		P
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained where appropriate	See the software files provided by the manufacturer.	P
14.6	Risk management process		P
14.6.1	The manufacturer shall consider those hazards associated with software and hardware aspects of the PEMS including those associated with network/data coupling, components of third-party origin and legacy subsystems.		P
14.6.2	PEMS supplement Subclause 6.1 of ISO 14971.		P
14.7	For the pems and each of its subsystems (e.g. for a PESS) there shall be a documented requirement specification.		P
14.8	the architecture specification shall make use of:		P
	a) Components with high-integrity characteristics;		P
	b) fail-safe functions;		P
	c) redundancy;		P
	d) diversity;		N
	e) partitioning of functionality;		P
	f) defensive design;		P
	g) allocation of risk control measures to subsystems and components of the pems.		P
	h) failure modes of components and their effects;		P
	i) common cause failures;		P
	j) systematic failures;		P
	k) test interval duration and diagnostic coverage;		P
	l) maintainability;		P
	m) protection from reasonably foreseeable misuse;		P

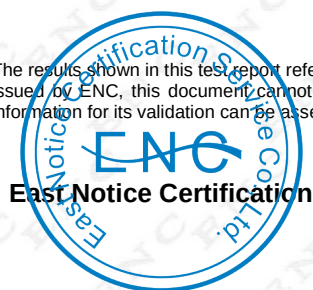
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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	n) the network/data coupling specification, if applicable.		N
14.9	The design shall be decomposed into subsystems, each having both a design and test specification.		P
14.10	Verification is required for all functions that implement basic safety, essential or risk control measures.		P
	- at which milestone(s) verification is to be performed for each function;		P
	- the selection and documentation of verification Strategies, activities, techniques, and the appropriate level of independence of the personnel performing the verification;		N
	- the selection and utilization of verification tools;		N
	- coverage criteria for verification.		N
14.11	a pems validation include the validation of basic safety and essential, and shall require checks for unintended functioning of the pems.		P
14.12	A new design or the continued validity of any previous design documentation shall be assessed under a documented modification/change procedure.		P
14.13	Connection of pems by network/data coupling to other equipment		N
	a) specify the characteristics of the network/data coupling necessary for the pems to achieve its intended use;		N
	b) list the hazardous situations resulting from a failure of the network/data coupling to provide the specified characteristics;		N
	c) instruct the responsible organization		N

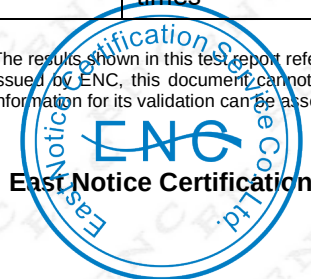
15	CONSTRUCTION OF ME EQUIPMENT		--
15.4.1	List of critical components		P
	Ratings of components not in conflict with the conditions of use in equipment	Components are used according to their ratings	P
	Components, movements of which could result in a safety hazard mounted securely	Well secured.	P
	Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard		P

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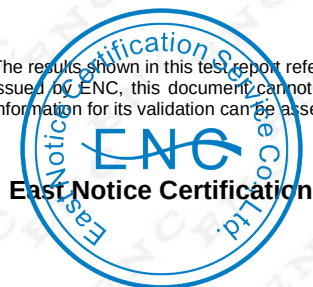
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Connectors provide separation required by Sub-clause 17g		N
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	No patient circuit leads.	N
	Medical gas connections not interchangeable		N
	Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken		P
	Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages.		N
	Connections of capacitors		--
	Not connected between live parts and non-protectively earthed accessible parts		N
	If connected between mains parts and non-protectively earthed metal parts comply with: IEC publication 384-14		N
	Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts		N
	Capacitors or other spark-suppression devices are not connected between contacts of thermal cutouts	No thermal cut-outs.	N
	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment		P
15.4.2	Temperature and overload control devices		--
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment		P
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits		P
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard		N
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard		N
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times		P
	Non-self resetting over-current releases operated 10 times		N

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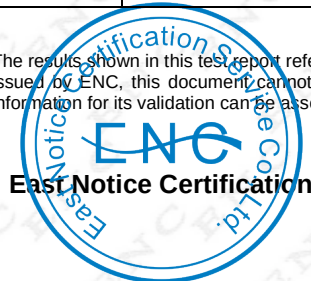
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	Thermostats with varying temperature settings clearly indicated		N
	Operating temperature of thermal cut-outs indicated		N
15.4.3	Batteries		N
	a) Battery compartments;	No such component	N
	-adequately ventilated		N
	-accidentally short-circuiting is prevented		N
	b) Incorrect polarity of connection prevented		N
15.4.3.5	Excessive current and voltage protection		--
	Internal electrical power source provided with device for protection against fire hazard		P
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuse holder		P
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.		N
15.4.4	Indicators-unless indication provided by other means(from the normal operation position),indicator lights are used		P
	-to indicate that equipment is energized		P
	-to indicate the operation of non-luminous heaters if a safety hazard could result		N
	-to indicate when output exists if a safety hazard could result		N
	-charging mode indicator provided		N
15.4.6	Actuating parts of controls	Controlled by soft.	N
	Actuating parts are adequately secured to prevent them working loose during normal use		N
	Controls are secured to prevent the movement relative to scale marking(safety related only)		N
	Detachable indicating devices are prevented from incorrect connection without the use of tool		N
	Stops are provided on rotating controls:		--
	-to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard		N
	-to prevent an unexpected change to writing		N

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
15.4.7	Cord-connected hand-held and foot-operated control devices		--
	a)Contain voltages not exceeding 25V a.c. or 60 V d.c. and isolated from the mains part by Cl.17g		N
	b)Hand-held control devices designed to support the weight of an adult human being		N
	-Foot-operated control devices comply with the support the weight of an adult human being	(see appended table 15.4.7)	N
	c)Devices not change their setting when inadvertently placed		N
	d)Foot-operated control devices are at least IPX1		N
	-For surgical use, electrical switch parts are IPX8		N
	e)Adequate strain relief at the cord entry provided	(see appended table 11.3.5a and 11.3.5b)	N
15.4.9	Oil containers		--
	Oil containers adequately sealed	Not contain oil.	N
	Containers allow for the expansion of the oil		N
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N
15.5	Mains supply transformers of the equipment and transformers providing separation in accordance with 8.5		--
15.5.1	Overheating		P
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative		P
	Short-circuit of secondary windings not caused excessive temperature		P
	Overload of secondary windings not caused excessive temperature	(see appended table 15.5B)	N
	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	(see appended table 15.5)	N
	Construction		N
	a)Separation of primary and secondary windings		N
	-separate bobbins or formers		N
	-one bobbin with insulating partition		N

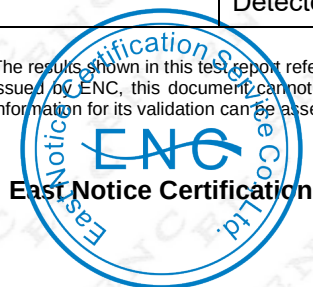
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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
	-one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13mm		N
	-concentrically wound on one bobbin with windings separated by double insulation		N
	c) Means provided to prevent displacement of end turns		N
	d) Insulated overlap of not less than 3mm if a protective earthed screen has only one turn		N
	e) Insulated between the primary and secondary in transformers with double insulation		N
	-1 insulation layer with thickness of at least 1mm		N
	-at least 2 insulation layer with a total thickness of at least 0.3mm		N
	-three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation	see appended table 15.5	N
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3mm extending at least 20 mm outside the winding		N
15.6	Creepage distances and air clearances		--
	a) Values: compliance with at least the values of Table XVI	(see table for insulation diagram)	P
	Creepage distances for slot insulation of motors at least 50% of the specified values		N
	b) Minimum Creepage distances and air clearances in the mains parts of opposite polarity not required if short-circuiting does not produce a safety hazard		N
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and parts	No such part.	N

EN 60825-1		
Test conditions		Value
Temperature		23°C
Relative Humidity		56%
Input Voltage of Power Supply		230 VAC
Test conditions	Measurement Position	100 mm
	Detector's aperture	7 mm

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EN 60601-1				
Clause	Requirement - Test		Result	Verdict
Condition	Model	Laser wave length	Accessible Emission Limit	Class
3	BM18	808nm	0,95 W	4
Conclusion: The AEL Class 4 laser radiation ($P > 0,5W$).				

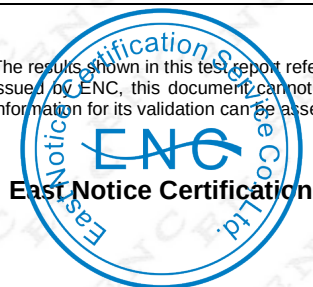
4.11	TABLE: Power input				P
Operation condition	Voltage(V)	Frequency (Hz)	Current (A)	Power(W)	Remark
running	100	60	--	1494,8	P
	240	50	--	2939,7	P
Supplementary information: The rating is 3000W; the maximum measured power is less than 110% of the rating.					

5.9.2	TABLE: Determination of ACCESSIBLE parts		P
Location		Determination method (NOTE1)	Comments
Outer surface of enclosure		Visual; rigid test finger; jointed test finger; test hook.	Can be touched
Supplementary information: NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.			

7.2	TABLE: marking durability		P
Marking tested		Remark	
Rubber for 15s with a doth rage soaked with distilled water		clearly legible, not become curled at edges	
Rubber for 15s with a doth rage soaked with mentholated spirit		Ditto	
Rubber for 15s with a doth rage soaked with isopropyl alcohol		Ditto	
Supplementary information: --			

8.4.4a	TABLE: residual voltage in attachment plug										P
Voltage measured between	Measurements[V]										Remark
	1	2	3	4	5	6	7	8	9	10	
Supply pins (pin1&pin2)	5	7	9	8	7	5	7	6	8	7	P
Line pin1 and enclosure	7	9	9	7	5	7	9	9	7	8	P
Line pin2 and enclosure	9	7	9	7	5	9	7	9	7	7	P
Pin 1 and earth pin	5	9	7	7	6	5	8	7	7	5	P
Pin 2 and earth pin	0	0	0	0	0	0	0	0	0	0	P
Maximum allowable stored charge when measured voltage exceeded 60 v (μ c) : 45											

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict

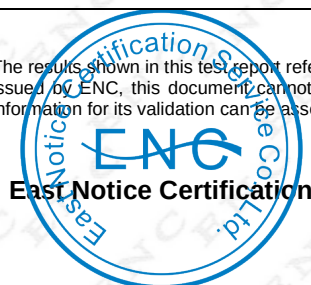
8.4.4b	TABLE: residual voltage or energy in capacitors				N
Capacitor and its location	Residual voltage(v)	Time after disconnection (s)	Capacitor value (μF)	Residual energy (mJ)	Remarks
--	--	--	--	--	--
--	--	--	--	--	--
Supplementary information: --					

8.5a	TABLE: defibrillation-proof applied parts				N
Test Condition: Fig.50 or 51	Accessible part of measurements	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2(mV)	Remarks
--	--	--	--	--	--
--	--	--	--	--	--
Supplementary information: --					

8.5b	TABLE: defibrillation-proof recovery time				N
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents(s)	Measured recovery time(s)	Remarks	
--	--	--	--	--	
--	--	--	--	--	
Supplementary information: --					

8.6	TABLE: protective earthing				P
Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)	
PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part	--	--	--	--	
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part	25A/5s	1,0	31	100	
ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part	--	--	--	--	

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EN 60601-1				
Clause	Requirement - Test	Result		Verdict
	ME equipment with a detachable power supply cord which is supplied or specified by the manufacture, impedance between the protective earth pin in the mains plug and a protectively earthed part, or test with 3m long cord	25A/5s	3,5	120 200
Supplementary information: PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 m ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 mΩ ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 m				

8.7	TABLE: leakage current				P
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (uA)	Remarks	
Fig. 13 - Earth Leakage (ER)	--	--	--	Maximum allowed values: 5 mA NC; 10 mA SFC	
ER, B, NC, S1 = 1, S5 = N	264	50	274	-	
ER, B, NC, S1 = 1, S5 = R	264	50	282		
ER, B, SFC, S1 = 0, S5 = R	264	50	435		
ER, B, SFC, S1 = 0, S5 = N	264	50	441		
ER, A, NC, S1 = 1, S5 = N	264	50	280		
ER, A, NC, S1 = 1, S5 = R	264	50	285		
ER, A, SFC, S1 = 0, S5 = R	264	50	446		
ER, A, SFC, S1 = 0, S5 = N	264	50	456		
Fig. 14 - Touch Current (TC)	--	--	--	Maximum allowed values: 100uA NC; 500 uASFC	
TC, B, NC, S1 = 1, S5 = N, S7 = 1	264	50	4		
TC, B, NC, S1 = 1, S5 = R, S7 = 1	264	50	4		
TC, B, SFC, S1 = 0, S5 = N, S7 = 1	264	50	4		
TC, B, SFC, S1 = 0, S5 = R, S7 = 1	264	50	4		
TC, B, SFC, S1 = 1, S5 = N, S7 = 0	264	50	6		
TC, B, SFC, S1 = 1, S5 = R, S7 = 0	264	50	6		
TC, A, NC, S1 = 1, S5 = N, S7 = 1	264	50	4		
TC, A, NC, S1 = 1, S5 = R, S7 = 1	264	50	4		
TC, A, SFC, S1 = 0, S5 = N, S7 = 1	264	50	4		

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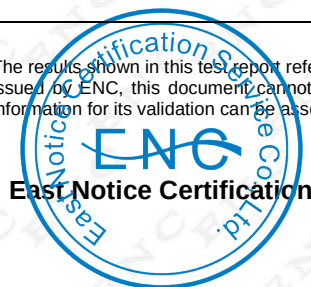


EN 60601-1				
Clause	Requirement - Test		Result	Verdict
TC, A, SFC, S1=0, S5=R, S7=1	264	50	4	
TC, A, SFC, S1 = 1, S5 = N, S7 = 0	264	50	6	
TC, A, SFC, S1 = 1, S5 = R, S7 = 0	264	50	6	
Fig. 15 - Patient Leakage Current (P)	--	--	--	Maximum allowed values: Type B or BF AP: 10 μ A NC; 50 μ A SFC (d.c. current); 100 μ A NC; 500 μ A SFC (a.c.) Type CF AP: 10 μ A NC; 50 μ A SFC (d.c. or a.c. current)
NC, B	264	50	6	
NC, A	264	50	6	
ER - earth leakage current EN - Enclosure leakage current P - Patient leakage current PM - Patient leakage current with mains on the applied parts PA - Patient auxiliary current Fig.15 -refers to Fig.15 in EN601-1 MD -Measuring device A -After humidity conditioning B - Before humidity conditioning 1 -Switch closed or set normal polarity 0 -Switch open or set to reversed polarity NC -Normal condition SFC -Single fault condition				

8.8	TABLE: dielectric strength				P
Insulation under test (area from insulation diagram)	Insulation type(OP-operational/BI-basic/SI -supplementary/DI-double/RI-reinforced)	Reference Voltage(V)	Reference Voltage(V)	Remarks	
L/N to accessible parts	BI	250	1500	P	
Live parts to parts of the enclosure	BI	250	1500	P	
Enclosure to Conductive parts isolated from live parts by basic insulation forming part of double insulation	SI	250	2500	P	
Applied part to live part	RI	250	4000	P	
Supplementary information:--					

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts			P
	Allowed impression diameter (mm)	$\leq 2\text{mm}$		--
	Force (N)	20		--
Part/material		Test temperature ($^{\circ}\text{C}$)	Impression diameter (mm)	

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
Enclosure/External insulating parts		75	0,88
Enclosure		--	--
Insulating material supporting un-insulated Mains Parts		--	--
Switch		125	1,05
Bobbin		125	0,99
Supplementary information:--			

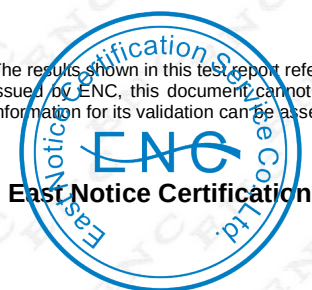
8.9.2	TABLE: Short circuiting of each single one of the creepage distances and air clearances for insulation in the mains part between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4			N
Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE ¹	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks	
Supplementary information: Note 1: AC - air clearance CD - creepage distance				

8.11.3a	TABLE: cord anchorages				N
Cord under test	Mass of equipment	Pull	Torque	Remarks	Verdict
--	--	--	--	--	--
Supplementary information:--					

8.11.3b	TABLE: cord bending			N
Cord under test		Test mass	Measured curvature	Remarks
--		--	--	--
Supplementary information:--				

9	TABLE: mechanical strength		P
Part under test	Test(impact, drop, force, handle, rough handling, mobile)	Remarks	
Enclosure	Impact energy 0.5J,three times	No damage	
Enclosure	Inward force 45N	No damage	
Supplementary information:--			

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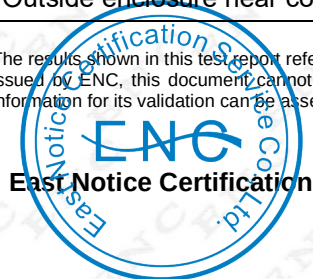


EN 60601-1			
Clause	Requirement - Test	Result	Verdict
9.4	TABLE: stability		
Clause	Part under test	Test condition	Remarks
9.4.2.1	The whole equipment	10 degree	Not overbalance, no hazards
9.4.2.2	The whole equipment	10 degree	Not overbalance, no hazards
9.4.2.3	--	--	--
9.4.2.4.2	The whole equipment	200N at a speed of 0.4m/s±0.1m/s	Not overbalance, no hazards
9.4.2.4.3	Castors and wheels – Movement over a threshold		Not overbalance, no hazards
9.4.3.1	The whole equipment	10 ° incline, unlocked, normal load	The distance less than 50mm
9.4.4	--	--	--
Supplementary information:--			

10	TABLE: X- radiation			N
Part under test		Test condition	Measured radiation(m R)	Remarks
--		--	--	--
Supplementary information:--				

11.1.1	TABLE: normal temperature		P
Test ambient (°C)		See below	
Test supply voltage/frequency (V/Hz) ⁴		264/50Hz	
Monitored point:		Max allowable temperature ¹ from Table 22, 23 or 24 or RM file for AP ⁵ (°C)	Max measured temperature ² , (°C) Test
AC inlet		70	33,5
Plug		70	32,7
Power cord		70	34,1
Power switch		55	33,4
Button switch		55	33,1
Leakage switch		55	33,2
Internal wire		80	46,4
Outside enclosure of power supply		130	68,7
LCD display		60	34,7
PCB		130	51,1
Fan		Ref.	48,4
Pump		105	56,8
Outside enclosure near control circuit		60	34,7

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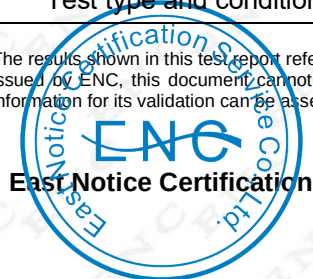
EN 60601-1			
Clause	Requirement - Test	Result	Verdict
Handle		40	35,6
Ambient		--	25,0
Supplementary information: ¹ Maximum allowable temperature on surfaces of test corner is 90 °C ² Max temperature determined in accordance with 11.1.3e) ³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C. ⁴ Supply voltage: - ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage; - Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE. - Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage. ⁵ APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.			

11	TABLE: Maximum temperature during normal use (Table 23 or 24)		P
Clause of ISO 14971	Document Ref. in RMF	Result - Remarks	Verdict
4.2	BM18-RR	Intended use and Identification of characteristics related to safety	P
4.3	BM18-RR	Identification of hazards	P
4.4	BM18-RR	Estimation of the risks	P
5	BM18-RR	Risk evaluation	P
6.2	BM18-RR	Risk control	P
6.3	BM18-RR	Implementation of risk control measure	P
6.4	BM18-RR	Residual risk evaluation	P
6.5	BM18-RR	Risk/benefit analysis	P

11.6a	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		P
Test type and condition		Test type and condition	Remarks
Humidity 93%, 25°C, 48h		Sample	No damage
Dearing alcohol		Main body, accessorize	No damage
Sterilization alcohol		--	--
Supplementary information:--			

11.6b	TABLE: hydrostatic pressure and pressure-relief device cycling test		N
Test type and condition	Part under test	Test pressure	Remarks

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EN 60601-1			
Clause	Requirement - Test	Result	Verdict
--	--	--	--
Supplementary information:--			

13	TABLE: abnormal operation	P
Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2 Electrical SINGLE FAULT CONDITIONS per Clause 8.1:	--	--
Water temperature sensor s-c	Laser output stop immediately, water temperature alarm start up, no hazards	No
Water temperature sensor o-c	Laser output stop immediately, water temperature alarm start up, no hazards	No
Temperature sensor inside the handpiece s-c	Laser output stop immediately, temperature inside the handpiece alarm start up, no hazards	No
Temperature sensor inside the handpiece o-c	Laser output stop immediately, temperature inside the handpiece alarm start up, no hazards	No
U4 pin 2-3 s-c	Laser output stop immediately, no hazards	No
U4 pin 1-8 s-c	Unit alarm start up about 5ms. No Laser output.	No
U4 pin 1-4 s-c	Unit alarm start up about 5ms. No Laser output.	No
U22 pin 2-3 s-c	Unit alarm start up about 5ms. No Laser output.	No
13.2.3 Overheating of transformers per Clause 15.5:	--	--
13.2.4 Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	--	--
13.2.5 Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	--	--
13.2.6 Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	--	--
13.2.7 Impairment of cooling that could result in a HAZARD using test method of	--	--

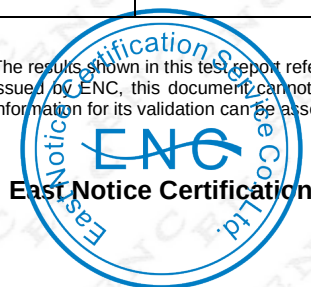
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Clause	Requirement - Test	Result	Verdict
11.1:			
Single ventilation fans locked consecutively		--	--
Lock fan (back of enclosure)	There is no obvious change and the highest temperature is 78,2°C		No
Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		--	--
Opening block	T1 winding: 76,7°C		No
Simulated blocking of filters		--	--
Flow of a cooling agent interrupted		--	--
13.2.8 Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below		--	--
13.2.9 Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited 1 – Also see 13.10		--	--
13.2.10 Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 & 13.2.9:		--	--
13.2.11 Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:		--	--
13.2.12 Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):		--	--
Supplementary information:			
¹ Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.			

15.3	TABLE: Mechanical Strength tests		P
Clause	Name of Test	Test conditions	Observed results/Remarks
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No damage, no breakdown
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No damage, no breakdown
15.3.4.1	Drop Test (hand-held)	Free fall height (m) = 1	No damage, no breakdown (Handheld part tested)
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	No damage, no breakdown
15.3.5	Rough handling test	Travel speed (m/s) = 0.4m/s±0.1 m/s	No damage, no breakdown
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 70	No any shrinkage and distortion, no hazards

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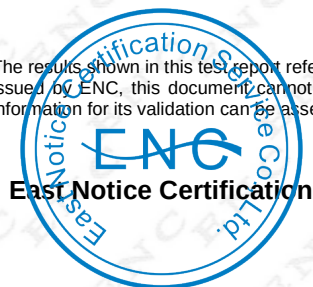


EN 60601-1			
Clause	Requirement - Test	Result	Verdict

Supplementary information:--

15.4.1	TABLE: list of critical components parts			P
Object/part No.	Manufacturer/trade mark	Type/model	Technical data	Mark(s) of conformity ¹⁾
Plug	King Cord Co., Ltd.	KC-015	250Vac, 10A	VDE 40015272
Power cord	King Cord Co., Ltd.	H05VV-F	3x1.0mm ²	VDE 40042910
Connector	Ningbo Ousheng Electric Appliance Co., Ltd.	ST3	250V~ 16A	VDE 40022825
Appliance inlet	Pronic Electronics (Shenzhen) Co., Ltd.	PST-101	250V~ 16A	VDE 40014579
Fuse	Littelfuse	0218010	250V~, 10A	VDE
Power supply	MEAN WELL ENTERPRISES CO LTD	LRS-600-24	Input: AC 100- 120V; 3.0A or AC 200-240V; 1.7A; 50/60Hz; Output: 24Vd.c.25A	UL E183223
Alt.	MEAN WELL ENTERPRISES CO LTD	LRS-150-12	Input: AC 100- 120V; 3.0A or AC 200-240V; 1.7A; 50/60Hz; Output: 12Vd.c.12.5A	UL E183223
X capacitor	Sunil Electronics Ind. Co., Ltd.	463D	Rated 0.33uF, 275V, X2	Intertek (SE/06107-2E)
Y capacitor	Murata Mfg. Co., Ltd.	KY	Rated 3300uF, 250V, Y2	VDE (40006273)
AC contactor	Ningbo Ousheng Electric Appliance Co., Ltd.	ST3	250V~ 10A	VDE
Relays	DELIXI	F4-11	16A, 690V	VDE
Leakage switch	Schneider	C32	50Hz,400V~	CQC
Button switch	ONPOW push button manufacture Co., Ltd.	LAS1-A Y090-10-Y	10A, 250Va.c.	VDE 40050498
Laser	Hebei Newangie Technology Co., Ltd.	BM18	808nm; Max 120J/cm ²	Test with appliance
Screen	DWIN	DMG80600S10 4-02WT	V0, 105°C	UL

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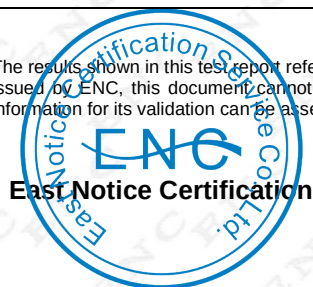


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Clause	Requirement - Test		Result	Verdict
Fan	MINEBEAMITSUMI INC.	3110KL-04W-B 59	12Vd.c, 0.23A	VDE
Varistor	HUIZHOU SONGLONGXIN DIAN;	10D471K	300V~, 85°C	VDE 40040037
Tube	SHENZHEN WAHCHANGWEI INDUSTRIAL CO LTD	SRS-70	VW-1 600V 200°C	UL E233803
Alt.	Interchangeable	Interchangeable	VW-1 600V 200°C	UL
Internal wire	Zhongshan City Mingliang Wire Co Ltd	1015	Min. 18AWG, 600V, 105°C	UL E476592
Alt.	Foshan Shunde Pantai Special Wire Rod Electronics Co Ltd	1015	Min. 26AWG, 300V, 80°C	UL E346532
Pump	Jabsco	31600-0092	12V10A	VDE
Particulate filter	NBW	F20	≤20um	VDE
PCB	HAN SAEM DIGITEC Co., Ltd.	HS-D3	Flame class: V-0	UL E213707
Plastic enclosure	CHI MEI CORPORATION	PA-763	V-1, 60°C, Min. 2.0mm	UL E56070
¹⁾ an asterisk indicates a mark which assures the agreed level of surveillance				

15.4.7	TABLE: foot operated control devices-loading		N
Part under test	Observed results	Remarks	
--	--	--	
Supplementary information:--			

15.5A	TABLE: short circuit						P
Winding under test	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (Min)	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)
T1 pin 1-3	B	Fuse F1	No	30	175	--	25,1
T2 pin 11,12-13	B	No 30 175	No	30	175	--	25,1
Supplementary information:--							

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Clause	Requirement - Test	Result	Verdict

15.5B	TABLE: overload				P
Winding under test	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Remarks
T1 pin 1-3	B	Internal circuit	175	T1 coil:76,4 T1 core:75,6	25,0
T2 pin 11,12-13	B	Internal circuit	175	T2 coil:75,8 T2 core:74,2	25,0
Supplementary information:--					

15.5	TABLE: transformer dielectric strength				N
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks	
--	--	--	--	--	
Supplementary information:--					

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**APPENDIX A
PHOTO(S) OF PRODUCT**



----- End of Report -----

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