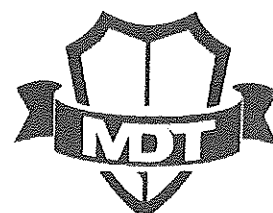




2010000720S



检测
CNAS L0637



1988

TEST REPORT

Test Report No: RZ12030010

Test object: Syringe Pump

Manufacturer: Sino Medical-Device Technology Co., Ltd.

Applicant: Sino Medical-Device Technology Co., Ltd.

Test Type: Registration ()

Registered Supplement ()

Others (✓) Certification Test



Guangzhou Medical Instruments Quality Surveillance and
Inspection Center of State Food and Drug Administration



Notice

1. This test report is not valid without stamps of the test organization.
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4. This test report is not valid without the signature of the ratifier.
5. This test report is not valid with any alteration.
6. If any objection occurs, it should be submitted in written way to the test organization in 15 days from the day that this test report had been received.
7. This test report is responsible for the test samples only.

Address: No. 2, Zhu Si Gang Si Ma Lu, Yue Xiu District, Guangzhou

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Fax: 020-87674919

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Initial Page of Test Report

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| | | | | |
|-----------------------------|--|----------------|----------------------------|-----------------------|
| Name of Samples | Syringe Pump | | Samples' Serial № | RZ12030010 |
| | Send-off (✓) | Spot check () | | |
| Trademark |  | | Model / Type | SN-50T66R |
| Client | Sino Medical-Device Technology Co., Ltd. | | Test Type | Certification Test |
| Client's Address | 6th Floor, Building15, Majialong Industry Zone, Nanshan District, Shenzhen, P.R.China | | Products' № / Lot № | / |
| Manufacturer | Sino Medical-Device Technology Co., Ltd. | | Sampling Bill № | / |
| Corporation being inspected | Sino Medical-Device Technology Co., Ltd. | | Producing date | / |
| Sampled by | / | | Samples' Quantity | 1 set |
| Sampled Place | / | | Cardinal Number of Samples | / |
| Sampled Date | / | | Test Place | Self-laboratory |
| Samples' Accepting Date | 2012.04.25 | | Test Date | 2012.04.25~2012.08.13 |
| Test Items | The whole items(with the exception of electromagnetic compatibility) | | | |
| Test According to | IEC 60601-1:1988 + A1:1991 + A2:1995 | | | |
| Test Conclusion | <p>All the test items of this product are in accordance with the requirements of IEC 60601 1:1988 + A1:1991 + A2:1995.</p> <p>Conclusion: Pass.</p> <div style="text-align: right;">  (Stamps of Test Organization) Issued Date: 2012.04.25 YY MM DD 监督检验中心 检验专用章 </div> | | | |
| Remarks | <p>1. / means blank.</p> <p>2.By information and sample inspecting, the models SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR and SN-50T66R are in accord in principle, structure of circuit, they differ only in appearance and some auxiliary functions. So the model SN-50T66R can cover the models SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR.</p> | | | |

Approved by: 王少明

Reviewed by: 胡昌明

Tested by: 陈洁 邱满林

Headship: 王少明

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GENERAL INFORMATION

Test item particulars (see also clause 5):

Classification of installation and use : Portable

Supply connection : Detachable power supply cord
Internally powered

Accessories and detachables parts included in the evaluation : User Manual

Options included : User Manual

Possible test case verdicts:

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

- test object does meet the requirement.....:P

- test object does not meet the requirement:F

Abbreviations used in the report:

- normal condition:N.C.

- single fault condition:S.F.C.

- operational insulation:OP

- basic insulation:BI

- basic insulation between parts of opposite polarity :BOP

- supplementary insulation:SI

- double insulation:DI

- reinforced insulation.....:RI

General remarks:

"(see Attachment #)" refers to additional information appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

The tests results presented in this report relate only to the object tested.

This report shall not be reproduced except in full without the written approval of the testing laboratory.

List of test equipment must be kept on file and available for review.

Summary of contents provided on the last page of this report.

General product information and considerations:

Syringe pump is a drug-injection equipment, which is intended for applications requiring accurate administration dosage, stable flow rate, low dose rate or long-time constant dose rate. The syringe pump is widely used in injection treatment of diseases, such as for children, patients with heart disease, chemotherapy of cancer, treatment in ICU, patients with diabetes, and so on.

Clauses 36(EMC) was not part of the Manufacturers order and this testing.

Clause 52.1 with appliance of IEC60601-1-4 was excluded from testing.

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| IEC 601+ Am. 1 & 2 | | | |
|--------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|----------|---|---|-----|
| 3 | GENERAL REQUIREMENTS | | |
| 3.1 | Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.) | No safety hazards presented during evaluation | P |
| 3.4 | An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained | | N/A |

| | | | |
|----------|---|--------------------|-----|
| 5 | CLASSIFICATION | | |
| 5.1 | Type of protection against electric shock | | P |
| | Class I equipment | Class I | P |
| | Class II equipment | | N/A |
| | Internally powered equipment | | P |
| 5.2 | Degree of protection against electric shock | | P |
| | Type B applied part | | N/A |
| | Type BF applied part | | N/A |
| | Type CF applied part | CF | P |
| | Not classified - no applied parts | | N/A |
| 5.3 | Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1) | IPX4 | P |
| 5.4 | Methods of sterilization or disinfection | | N/A |
| 5.5 | Equipment not suitable for use in the presence of flammable mixtures | | P |
| | Category AP equipment | Not such equipment | N/A |
| | Category APG equipment | Not such equipment | N/A |

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|--------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|-----|--|--|-----|
| 5.6 | Mode of operation: | | P |
| | -continuous operation | | P |
| | -short-time operation, specified operation; period | | N/A |
| | -intermittent operation, specified operation; rest period | | N/A |
| | -continuous operation with short-time, stated permissible loading time | | N/A |
| | -continuous operation with intermittent, stated permissible loading/rest time | | N/A |

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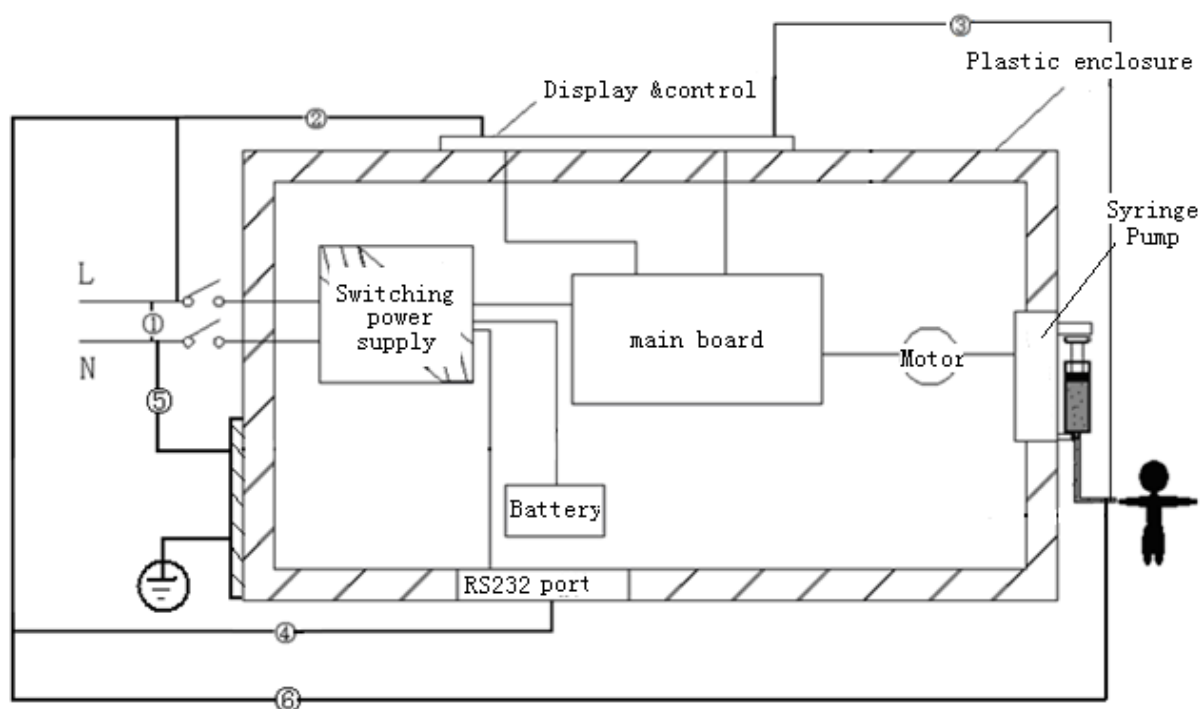
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INSULATION DIAGRAM



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| Table: to insulation diagram | | | | | | | P |
|------------------------------|---|--------------------------|------------------------------|-------------------------------|------------------------------|-------------------------------|------------------|
| Area | Insulation type: operational / basic / supplementary / double / reinforced | Reference voltage (V) | Required creepage (mm) | Required clearance (mm) | Measured creepage (mm) | Measured clearance (mm) | Remarks |
| ① | BI | a.c.240V | 3 | 1.6 | >3 | >1.6 | A-f |
| ② | DI/RI | a.c.240V | 8 | 5 | >8 | >5 | A-a ₂ |
| ③ | BI | a.c.250V | 4 | 2.5 | >4 | >2.5 | B-d |
| ④ | DI/RI | a.c.240V | 8 | 5 | >8 | >5 | A-e |
| ⑤ | BI | a.c.240V | 4 | 2.5 | >4 | >2.5 | A-a ₁ |
| ⑥ | DI/RI | a.c.240V | 8 | 5 | >8 | >5 | B-a |

INSULATION DIAGRAM CONVENTIONS

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with the requirements of clauses 17, 20 and 57.

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|--------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|----------|---|---|-----|
| 6 | IDENTIFICATION, MARKING AND DOCUMENTS | | |
| 6.1 | Marking on the outside of equipment or equipment parts | | P |
| | c) Markings of the specific power supply affixed | | N/A |
| | d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents | | N/A |
| | e) Name and/or trademark of the manufacturer or supplier..... : | Sino Medical-Device Technology Co., Ltd. | P |
| | f) Model or type reference | SN-50T66R | P |
| | g) Rated supply voltages or voltage range(s) | AC 100V~240V | P |
| | Number of phases | single | P |
| | Type of current | AC | P |
| | h) Rated frequency or rated frequency range(s) (Hz) | 50/60Hz | P |
| | j) Rated power input (VA, W or A) | 35VA | P |
| | k) Power output of auxiliary mains socket-outlets | | N/A |
| | Class II symbol | | N/A |
| | Symbol for degree of protection against ingress of water provided | IPX4 | P |
| | Symbol for protection against electric shock |  | P |
| | If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets | | N/A |
| | Symbol for protection of defibrillation-proof applied parts | | N/A |
| | Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable | | N/A |
| | m) Mode of operation (if no marking, suitable for continuous operation) | Continuous operation | P |
| | n) Types and rating of external accessible fuses : | | N/A |


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|---------------------|---|---|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | p) Ratings of external output | | N/A |
| | q) Symbol for physiological effect(s): | | N/A |
| | - attention, consult accompanying documents | | N/A |
| | - non-ionizing radiation, or symbols as adopted by ISO or IEC 417 | | N/A |
| | r) Anesthetic-proof symbol: AP or APG | | N/A |
| | s) Dangerous voltage symbol | | N/A |
| | t) Special cooling requirements | | N/A |
| | u) Limited mechanical stability | | N/A |
| | v) Protective packing requirement(s) | | P |
| | - Marking(s) for unpacking safety hazard(s) | | P |
| | - Equipment or accessories supplied sterile, marked as sterile | | N/A |
| | y) Potential equalization terminal | | N/A |
| | - Functional earth terminal | | N/A |
| | z) Removable protective means | | N/A |
| | Durability of marking test | See appended table 6.1 | P |
| 6.2 | Marking on the inside of equipment or equipment parts | | P |
| | a) Nominal voltage of permanently installed equipment | Not permanently installed equipment | N/A |
| | b) Maximum power loading for heating elements or holders for heating lamps | | N/A |
| | c) Dangerous voltage symbol | | N/A |
| | d) Type of battery and mode of insertion | AA2300mAh | P |
| | - Marking referring to accompanying documents used for battery not intended to be changed by the operator | | P |
| | e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram | T2.0AL250V | P |
| | f) Protective earth terminal |  | P |
| | g) Functional earth terminal | | N/A |

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|--------------------|---|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | h) Supply neutral conductor in permanently installed equipment (N) | | N/A |
| | j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed | | P |
| | - Markings comply with IEC 445 | | P |
| | k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment) | | N/A |
| | l) Statement for suitable wiring materials at temperatures over 75 °C | | N/A |
| | n) Capacitors and/or circuit parts marked as required in Sub-clause 15c | | N/A |
| 6.3 | Marking of controls and instruments | | P |
| | a) Mains switch clearly identified | No mains switch | N/A |
| | - ON and OFF positions marked according to Symbols 15 and 16 of table D1 or indicated by an adjacent indicator light | | N/A |
| | b) Indication of different positions of control devices and switches | | P |
| | c) Indication of the direction in which the magnitude of the function changes, or an indicating device | | N/A |
| | f) The functions of operator controls and indicators are identified | | P |
| | g) Numeric indications of parameters are in SI units except for units listed in Am. 2 | | P |
| 6.4 | Symbols | | P |
| | Used symbols comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable) | | P |
| 6.5 | Colors of the insulation of conductors | | P |
| | a) Protective earth conductor has green/yellow insulation | | P |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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 | green/yellow | P |
| | d) Color of neutral conductor..... : | blue | P |
| | e) Colors of phase conductor(s) : | | N/A |
| | - Compliance with IEC 227 and IEC 245 | Compliance with IEC 227 | P |
| | f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors | No such parts | N/A |
| 6.6 | Medical gas cylinders and connections | | N/A |
| | a) In accordance with ISO ISO/R 32 | No Medical gas cylinders | N/A |
| | b) Identification of connection point | | N/A |
| 6.7 | 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 | | P |
| | b) Color red used only for push-buttons by which a function is interrupted in case of emergency | | N/A |

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|--------------------|---|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 6.8 | ACCOMPANYING DOCUMENTS | | P |
| 6.8.1 | Equipment accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer | | P |
| | Classifications specified in Clause 5 included in both the instructions for use and the technical description | | P |
| | Markings specified in Sub-clause 6.1 included in the accompanying documents if they have not been permanently affixed to equipment | | P |
| | Warning statements and the explanation of warning symbols provided in the accompanying documents | | P |
| 6.8.2 | Instructions for use | | P |
| | a) General information provided in instructions for use | | P |
| | - state the function and intended application of the equipment | | P |
| | - include an explanation of: the function of controls, displays and signals | | P |
| | - the sequence of operation | | P |
| | - the connection and disconnection of detachable parts and accessories | | P |
| | - the replacement of material which is consumed during operation | | P |
| | - information regarding potential electromagnetic or other interference and advice regarding avoidance | | P |
| | - include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety | | P |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | - instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance | | P |
| | General information provided in instructions: | | P |
| | - information for the safe performance or routine maintenance | | P |
| | - parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied | | P |
| | - explanation of figures, symbols, warning statements and abbreviations on the equipment | | P |
| | c) Signal output or signal input parts intended only for connection to specified equipment described | | P |
| | d) Details about acceptable cleaning, disinfection or sterilization methods included | | N/A |
| | e) Warning statement for mains operated equipment with additional power source | | P |
| | f) A warning to remove primary batteries if equipment is not likely to be used for some time | | N/A |
| | g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries | | P |
| | h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1 | | N/A |
| | j) Identification of any risks associated with the disposal of waste products, residues, etc. | | P |
| | - Advice in minimizing these risks | | P |
| 6.8.3 | Technical description | | P |
| | a) All characteristics essential for safe operation provided | | P |
| | b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | - Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use | | P |
| | c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided | | P |
| | d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging | | P |

| | | | |
|----------|--------------------------|----------------------|---|
| 7 | POWER INPUT | | |
| | Power Input Measurements | See appended table 7 | P |

| | | | |
|-----------|--|--|-----|
| 10 | ENVIRONMENTAL CONDITIONS | | |
| 10.1 | Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer | Environmental conditions are specified in Instruction Manual | P |
| 10.2.2a | Rated voltage not exceeding 250 V for hand-held equipment | Not hand-held equipment | N/A |
| | Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4kVA | AC100V~240V | P |
| | Rated voltage not exceeding 500 V for all other equipment | | N/A |
| | Rated input frequency not more than 1kHz | 50/60Hz | P |
| 10.2.2b | Internal replaceable electrical power source specified | | P |

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| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|-----------|--|---------|-----|
| 14 | REQUIREMENTS RELATED TO CLASSIFICATION | | |
| 14.4a | Class I and Class II equipment in addition to basic insulation provided with an additional protection | Class I | P |
| 14.4b | Equipment supplied from external dc source of reverse polarity results in no safety hazard | | N/A |
| 14.5b | Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected | | P |
| 14.6c | Applied parts intended for direct cardiac application are of type CF | | N/A |

| | | | |
|-----------|---|--|-----|
| 15 | LIMITATION OF VOLTAGE AND/OR ENERGY | | |
| 15b | Voltage measured one sec after disconnection of the mains plug does not exceed 60V | (see appended table 15b) 12V | P |
| 15c | For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceed 2 mJ | (see appended table 15c) No such accessible parts | N/A |
| | Marking provided for manual discharging | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|-----------|---|--|-----|
| 16 | ENCLOSURES AND PROTECTIVE COVERS | | |
| 16a | Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test) | | P |
| | Insertion or removal of lamps - protection against contact with live parts provided | | N/A |
| 16b | Opening in a top cover positioned that accessibility of live parts by a test rod is prevented | | N/A |
| 16c | Conductive parts accessible after the removal of handles, knobs, levers | | N/A |
| | - have a resistance of not more than 0.2 Ω | | N/A |
| | - separated from live parts by one of the means described in Sub-clause 17g | | N/A |
| 16d | Parts with voltage exceeding 25V a.c. or 60V d.c. which cannot be disconnected by external mains switch or plug protected against contact | | N/A |
| 16e | Removable enclosures protecting against contact with live parts | | P |
| | - Removal possible only with the aid of a tool | | P |
| | - Use of automatic device making parts not live when the enclosure is opened or removed | | N/A |
| | - Exception 16e applied to the following parts .. : | | N/A |
| 16f | Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts | | N/A |

| | | | |
|-----------|--|--|-----|
| 17 | SEPARATION | | |
| 17a | Separation method of the applied part from live parts: | | P |
| | 1) basic insulation: applied part earthed | | N/A |
| | 2) by protectively earthed conductive part (e.g. screen) | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | 3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure | | N/A |
| | 4) by double or reinforced insulation | | P |
| | 5) by protective impedances limiting current to applied part | | N/A |
| | - Additional leakage current test in single fault conditions | (see appended table 19) | P |
| 17c | There is no conductive connection between applied parts and accessible conductive parts which are not protectively earthed | | P |
| 17d | Supplementary insulation between hand-held flexible shafts and motor shafts (Class I) | | N/A |
| 17g | Separation method of accessible parts other than applied parts from live parts: | | P |
| | 1) basic insulation: accessible part earthed | | P |
| | 2) by protectively earthed conductive part (e.g. screen) | | N/A |
| | 3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure | | N/A |
| | 4) by double or reinforced insulation | Plastic enclosure | P |
| | 5) by protective impedances limiting current to accessible part | | N/A |
| | - Additional leakage current test in single fault conditions | (see appended table 19) | P |
| 17h | Arrangements used to isolate defibrillation-proof applied parts so designed that: | | N/A |
| | - no hazardous electrical energies appear during a discharge of a cardiac defibrillator | No such parts | N/A |
| | - after exposure to the defibrillation voltage, the equipment continues to perform its intended function | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| 18 | PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION | | |
| 18a | Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal | | P |
| 18b | Protective earth terminals suitable for connection to the protective earth conductor | | P |
| 18e | Potential equalization conductor | | N/A |
| | - Readily accessible | | N/A |
| | - Accidental disconnection prevented in normal use | | N/A |
| | - Conductor detachable without the use of a tool | | N/A |
| | - Power supply cord does not incorporate a potential equalization conductor | | N/A |
| | - Connection means marked with Symbol 9, Table DI | | N/A |
| 18f | For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $\leq 0.1 \Omega$ | (see appended table 18) | N/A |
| | - For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $\leq 0.1 \Omega$ | (see appended table 18) | N/A |
| | - For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part $\leq 0.2 \Omega$ | (see appended table 18) | N/A |
| 18g | If the impedance of protective earth connections other than in Cl. 18 f) exceeds 0.1Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition | (see appended table 18) | N/A |
| 18k | Functional earth terminal not used to provide protective earthing | | N/A |
| 18l | Class II equipment with isolated internal screens | | N/A |

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| | - insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation | | N/A |
| | - functional earth terminal clearly marked | | N/A |
| | - explanation of functional earth terminal provided in the accompanying documents | | N/A |

| | | | |
|-----------|---|------------------------------|-----|
| 19 | CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS | | |
| 19.1b | Leakage currents | (see appended table 19) | P |
| | - earth leakage current | | P |
| | - enclosure leakage current | | P |
| | - patient leakage current | | P |
| | - patient auxiliary current | No patient auxiliary current | N/A |

| | | | |
|-----------|-----------------------------------|-------------------------|---|
| 20 | DIELECTRIC STRENGTH | | |
| | Overall compliance with Clause 20 | (see appended table 20) | P |

| | | | |
|-----------|--|-------------------------|-----|
| 21 | MECHANICAL STRENGTH | | |
| 21a | Sufficient rigidity of an enclosure tested by: force of 45 N | (see appended table 21) | P |
| 21b | Sufficient strength of an enclosure tested by: impact hammer | (see appended table 21) | P |
| 21c | On portable equipment carrying handles or grips withstand the requirements of the loading test | | P |
| 21.3 | No damage to parts of patient support and/or immobilization system after the loading test | | N/A |
| 21.5 | Hand held equipment or equipment parts are safe after drop test | (see appended table 21) | N/A |
| 21.6 | Portable and mobile equipment is able to withstand rough handling | (see appended table 21) | P |

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| | | | |
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| 22 | MOVING PARTS | | |
| 22.2a | Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment | | N/A |
| 22.2b | Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation | | N/A |
| 22.3 | Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices | | N/A |
| | Guides or other safeguards are removable only with a tool | | N/A |
| 22.4 | Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation by the operator | | N/A |
| 22.6 | Parts of equipment subject to mechanical wear are accessible for inspection | | N/A |
| 22.7 | Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard | | N/A |
| | The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard | | N/A |
| | Devices for emergency stopping able to break the full load current of the relevant circuit, taking into account possible stalled motor currents | | N/A |
| | Means for stopping of movements operate as a result of one single action | | N/A |

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| | | | |
|-----------|---|--|---|
| 23 | SURFACES, CORNERS AND EDGES | | |
| | Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered | | P |

| | | | |
|-----------|--|----------------------|-----|
| 24 | STABILITY IN NORMAL USE (see appended table 24) | | |
| 24.1 | Equipment does not overbalance during normal use when tilted through an angle of 10° | | P |
| 24.3 | Equipment overbalances when tilted through an angle of 10° | | N/A |
| | - does not overbalance when tilted through an angle of 5° in any position excluding transport | | N/A |
| | - carry a warning notice stating that transport should only be undertaken in a certain position | | N/A |
| | - in the position specified for transport does not overbalance when tilted to an angle of 10° | | N/A |
| 24.6a | Equipment or its parts with a mass of more than 20 kg is provided with: | | N/A |
| | - suitable handling devices (grips etc.), or | mass less than 20 kg | N/A |
| | - instructions for lifting and handling during assembly | | N/A |
| 24.6b | b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons | | N/A |

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| | | | |
|-----------|--|-------------------|-----|
| 25 | EXPULSED PARTS | | |
| 25.1 | Protective means are provided where expelled parts of the equipment could be a hazard | No expelled parts | N/A |
| 25.2 | Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion | | N/A |

| | | | |
|-----------|---|---------------|-----|
| 28 | SUSPENDED MASSES | | |
| 28.3 | Suspension system with safety device | | N/A |
| | 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-clause 28.4 | No such parts | N/A |
| | Safety device has safety factors complying with Sub-clause 28.4.2 | | N/A |
| | Clear indication to the operator that the safety device has been activated after failure of suspension means | | N/A |
| 28.4 | Suspension systems of metal without safety devices | | N/A |
| | 1) Total load does not exceed the safe working load | | N/A |
| | 2) Safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired | | N/A |
| | 3) Safety factors not less than 8 where impairment is expected | | N/A |
| | 4) Safety factors multiplied by 1.5 for metal having an elongation at break of less than 5% | | N/A |
| | 5) Sheaves, sprockets, band wheels and guides so constructed that the safety factors maintained till replacement | | N/A |

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| | | | |
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| 29 | X-RADIATION | | |
| 29.2 | EQUIPMENT not intended to produce X-radiation produces an exposure ≤ 130 nC/kg (0.5 mR) | (see appended table 29) | N/A |

| | | | |
|-----------|--------------------------------------|------------------------------|---|
| 36 | ELECTROMAGNETIC COMPATIBILITY | | |
| | Equipment complies with IEC 601-1-2 | Not evaluated in this report | / |

| | | | |
|-----------|---|-------------------------|-----|
| 37 | COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT | | |
| | Requirements for category AP and APG equipment (Cl. 37 - 41) | Not AP or APG equipment | N/A |

| | | | |
|-----------|--|-------------------------|-----|
| 42 | EXCESSIVE TEMPERATURES | | |
| 42.1 | Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures per Clause 10.2.1 | (see appended table 42) | P |
| 42.2 | Equipment does not attain temperatures exceeding the values given in Table Xb at 25°C ambient | | P |
| 42.3 | Applied parts not intended to supply heat have surface temperatures not exceeding 41°C | <41°C | P |
| 42.5 | Guards to prevent contact with hot surfaces removable only with a tool | | N/A |

| | | | |
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| 43 | FIRE PREVENTION | | |
| | Strength and rigidity necessary to avoid a fire hazard | | P |

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| | | | |
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| 44 | OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION AND DISINFECTION | | |
| 44.2 | Equipment contain a liquid reservoir: | | N/A |
| | - the equipment is electrically safe after 15% overfill steadily over a period of 1 min | (see appended table 44) No liquid reservoirs | N/A |
| | - transportable equipment is electrically safe after additionally having been tilted through an angle of 15° in the least favorable direction(s) (if necessary with refilling) | (see appended table 44) | N/A |
| 44.3 | Electrical properties of the equipment do not change in connection of spillage test (200 ml of water) | (see appended table 44) | P |
| 44.4 | Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard | (see appended table 44) | P |
| 44.5 | Equipment sufficiently protected against the effects of humidity | (see appended table 44) | P |
| 44.6 | Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529 | (see appended table 44) IPX4 | P |
| 44.7 | Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions | (see appended table 44) | P |

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| 45 | PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE | | |
| 45.2 | Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure | (see appended table 45) No Pressure vessels or parts | N/A |
| 45.3 | Maximum pressure does not exceed the maximum permissible working pressure for individual parts | | N/A |
| 45.7 | Unless excessive pressure can not occur, pressure-relief device provided | | N/A |
| 45.7a | Pressure-relief device connected as close as possible to the pressure vessel | | N/A |
| 45.7b | Readily accessible for inspection | | N/A |
| 45.7c | Not capable of being adjusted or rendered inoperative without a tool | | N/A |
| 45.7d | Discharge opening located that the released material is not directed towards person | | N/A |
| 45.7e | Discharge opening located that operation will not deposit material which may cause a safety hazard | | N/A |
| 45.7f | Adequate discharge capacity to ensure pressure does not exceed the maximum permissible working pressure | | N/A |
| 45.7g | No shut-off valve between a pressure-relief device and the parts intended to be protected | | N/A |
| 45.7h | Minimum number of cycles of operation: 100.000 | (see appended table 45) | N/A |

| | | | |
|-----------|---|--|-----|
| 48 | BIOCOMPATIBILITY | | |
| | Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1 | | N/A |

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| 49 | INTERRUPTION OF THE POWER SUPPLY | | |
| 49.1 | Thermal cut-outs and over-current releases with automatic resetting not used if they may cause a safety hazard | | N/A |
| 49.2 | Interruption and restoration of power supply does not result in a safety hazard other than interruption of intended function | No safety hazard | P |
| 49.3 | Means are provided for removal of mechanical constraints on patient in case of a supply mains failure | | N/A |

| | | | |
|-----------|--|--|-----|
| 51 | PROTECTION AGAINST HAZARDOUS OUTPUT | | |
| 51.4 | Equipment furnishing both low-intensity and high-intensity outputs provided with means minimizing possibility of a high intensity output being selected accidentally | | N/A |

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| | | | |
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| 52 | ABNORMAL OPERATION AND FAULT CONDITIONS | | |
| 52.1 | Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13) | (see appended table 52) | P |
| | The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4 | Not evaluated in this report | / |
| 52.5.2 | Failure of thermostats presents no safety hazards | | N/A |
| 52.5.3 | Short-circuiting of either part of double insulation presents no safety hazard | (see appended table 52) | P |
| 52.5.5 | Impairment of cooling: temperatures not exceeding 1.7 times the values of Clause 42 minus 17.5°C | (see appended table 52) No cooling provide | N/A |
| 52.5.6 | Locking of moving parts presents no safety hazard | (see appended table 52) | P |
| 52.5.7 | Interruption and short-circuiting of motor capacitors presents no safety hazard | | N/A |
| 52.5.8 | Duration of motors locked rotor test in compliance with Cl. 52.5.8 | | N/A |
| 52.5.9 | Failure of one component at a time presents no safety hazard | (see appended table 52) | P |
| 52.5.10 | Overload of heating elements presents no safety hazard | | N/A |
| | f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection | | N/A |
| | h) Equipment with three-phase motors can safely operate with one phase disconnected | | N/A |

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| 56 | COMPONENTS AND GENERAL ASSEMBLY | | |
| | List of critical components | (see appended table 56) | P |
| 56.1b | Ratings of components not in conflict with the conditions of use in equipment | | P |
| | Ratings of mains components are identified | | P |
| 56.1d | Components, movements of which could result in a safety hazard mounted securely | | P |
| 56.1f | Conductors and connectors secured and/or insulated to prevent accidental detachment resulting in a safety hazard | | P |
| 56.3a | Connectors provide separation required by Sub-clause 17g | 17g)4) | P |
| | Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment | No such connection | N/A |
| | Medical gas connections not interchangeable | No gas connections | N/A |
| 56.3b | Accessible metal parts can not become live when detachable interconnection cord between different parts of equipment is loosened or broken | | N/A |
| 56.3c | 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/A |
| 56.4 | Connections of capacitors | | N/A |
| | Not connected between live parts and non-protectively earthed accessible parts | No such capacitors | N/A |
| | If connected between mains part and protectively earthed metal parts comply with: IEC Publication 384-14 | | N/A |
| | Enclosure of capacitors connected to mains part and providing only basic insulation, is not secured to non-protectively earthed metal parts | | N/A |

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| | Capacitors or other spark-suppression devices are not connected between contacts of thermal cut-outs | | N/A |
| 56.5 | Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment | | P |
| 56.6 | Temperature and overload control devices | | N/A |
| | a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment | | N/A |
| | Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits | | N/A |
| | Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard | | N/A |
| | Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard | | N/A |
| | Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times | | N/A |
| | Non-self resetting over-current releases operated 10 times | | N/A |
| 56.6b | Thermostats with varying temperature settings clearly indicated | | N/A |
| | Operating temperature of thermal cut-outs indicated | | N/A |
| 56.7 | Batteries | | P |
| | a) Battery compartments: | | P |
| | - adequately ventilated | | N/A |
| | - accidentally short-circuiting is prevented | | P |
| | b) Incorrect polarity of connection prevented | | P |
| 56.8 | Indicators - unless indication provided by other means (from the normal operation position), indicator lights are used (color see 6.7): | | P |
| | - to indicate that equipment is energized | | P |

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| | - to indicate the operation of non-luminous heaters if a safety hazard could result | | N/A |
| | - to indicate when output exists if a safety hazard could result | | N/A |
| | - charging mode indicator provided | | P |
| 56.10 | Actuating parts of controls | (see appended table 56.10) | N/A |
| 56.10b | Actuating parts are adequately secured to prevent them from working loose during normal use | | N/A |
| | Controls are secured to prevent the movement relative to scale marking (safety related only) | | N/A |
| | Detachable indicating devices are prevented from incorrect connection without the use of tool | | N/A |
| 56.10c | Stops are provided on rotating controls: | | N/A |
| | - to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard | | N/A |
| | - to prevent damage to wiring | | N/A |
| 56.11 | Cord-connected hand-held and foot-operated control devices | | N/A |
| | a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17g | No such devices | N/A |
| | b) Hand-held control devices comply with the requirement and test of Sub-clause 21.5 | | N/A |
| | - Foot-operated control devices designed to support the weight of an adult human being | (see appended table 56.11b) | N/A |
| | c) Devices not change their setting when inadvertently placed | | N/A |
| | d) Foot-operated control devices are at least IPX 1 | (see appended table 44) | N/A |
| | - For surgical use, electrical switching parts are IPX 8 | | N/A |
| | e) Adequate strain relief at the cord entry provided | (see appended table 57.4) | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| 57 | MAINS PARTS, COMPONENTS AND LAYOUT | | |
| 57.1 | Isolation from supply mains | | P |
| | a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously | Mains plug | P |
| | Means for isolation incorporated in equipment or, if external, specified in the accompanying documents | in equipment | P |
| | d) Switches used to comply with Sub-clause 57.1a comply with the creepage distances and air clearances as specified in IEC Publication 328 | No switches | N/A |
| | f) Mains switches not incorporated in a power supply cord | | N/A |
| | h) Appliance couplers and flexible cords with mains plugs provide compliance with Sub-clause 57.1a | Mains plug | P |
| | m) Fuses and semiconductor devices not used as isolating devices | | P |
| 57.2 | Mains connectors and appliance inlets | | N/A |
| | e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug | No Auxiliary mains socket-outlets | N/A |
| | g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment | | N/A |
| 57.3 | Power supply cords | | P |
| | a) Not more than one connection to a particular supply mains | Only one | P |
| | If alternative supply allowed, no safety hazards when more than one connection is made simultaneously | | N/A |
| | The mains plug has only one power supply cord | | P |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | Non-permanently connected equipment provided with power supply cord or appliance inlet | Power supply cord | P |
| | b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53 | IEC 227 | P |
| | Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75°C | <75°C | N/A |
| | c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV | | P |
| | d) Stranded conductors not soldered if fixed by any clamping means | | N/A |
| 57.4 | Connection of power supply cords | | N/A |
| 57.4a | Cord anchorages | | N/A |
| | Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting | Power supply cord is detachable | N/A |
| | Tying the cord into a knot or tying the ends with string not used | | N/A |
| | Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation | | N/A |
| | Cord anchorages made of metal provided with an insulating lining | | N/A |
| | Clamping screws do not bear directly on the cord insulation | | N/A |
| | Screws associated with cable replacement are not used to secure other components | | N/A |
| | 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 terminals | | N/A |
| 57.4b | Power supply cord protected against excessive bending | | N/A |

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| 57.4c | Adequate space inside equipment to allow the supply cable conductors to be introduced and connected | (see appended table 57.4b) | N/A |
| 57.5 | Mains terminal devices and wiring of mains part | | N/A |
| | 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/A |
| | If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced | | N/A |
| | Screws and nuts which clamp external conductors not serve to fix any other component | | N/A |
| | b) Terminals closely grouped with any protective earth terminal | | N/A |
| | Mains terminal devices accessible only with use of a tool | | N/A |
| | 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/A |
| | c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened | | N/A |
| | d) Cord terminals not require special preparation of the conductor | | N/A |
| 57.6 | Mains fuses and overcurrent 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 operating current | | P |
| | Protective earth conductor not fused | | P |
| | Neutral conductor not fused for permanently installed equipment | Not permanently installed equipment | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| 57.8 | Wiring of the mains part | | P |
| | a) Individual conductor in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC Publications 227 or 245, treated as bare conductor | | N/A |
| | b) Cross-sectional 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 tracks on printed wiring circuits sufficient to prevent any fire hazard | | P |
| 57.9 | Mains supply transformers | | N/A |
| 57.9.1 | Overheating | No Mains supply transformers | N/A |
| | External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative | | N/A |
| 57.9.1a | Short-circuit of secondary windings not caused excessive temperature | (see appended table 57.9.1a) | N/A |
| 57.9.1b | Overload of secondary windings not caused excessive temperature | (see appended table 57.9.1b) | N/A |
| 57.9.2 | The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests | (see appended table 57.9.2) | N/A |
| 57.9.4 | Construction | | N/A |
| | a) Separation of primary and secondary windings | | N/A |
| | - separate bobbins or formers | | N/A |
| | - one bobbin with insulating partition | | N/A |
| | - one bobbin with concentric windings and having copper screen with a thickness of not less than 0.13 mm | | N/A |
| | - concentrically wound on one bobbin with windings separated by double insulation | | N/A |

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|--------------------|---|------------------------------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | c) Means provided to prevent displacement of end turns | | N/A |
| | d) Insulated overlap of not less than 3 mm if a protective earthed screen has only one turn | | N/A |
| | e) Insulation between the primary and secondary in transformers with double insulation | | N/A |
| | - 1 insulation layer having a thickness of at least 1 mm | | N/A |
| | - at least 2 insulation layers with a total thickness of at least 0.3 mm | | N/A |
| | - three layers provided that each combination of two layers can withstand the dielectric strength test for reinforced insulation | | N/A |
| | g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having total thickness at least 0.3 mm extending at least 20 mm outside the winding | | N/A |
| 57.10 | Creepage distances and air clearances | | P |
| | 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/A |
| | b) Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard | (see appended table 52) | P |
| | c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts | | N/A |

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| | | | |
|-----------|--|--|---|
| 58 | PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS | | |
| 58.1 | Clamping means of the protective earth terminal | | P |
| | Not be able to loosen without the aid of a tool | | P |
| | Screws for internal earth connections are covered or protected against loosening from outside | | P |
| 58.7 | Earth pin of the appliance inlet regarded as the protective earth terminal | | P |
| 58.8 | The protective earth terminal not used for the mechanical connection or the fixing of any component not related to earthing | | P |
| 58.9 | 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 | | P |

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|--------------------|--|---|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 59 | CONSTRUCTION AND LAYOUT | | |
| 59.1 | Internal wiring | | P |
| | a) Cables and wiring protected against contact with a moving part | | P |
| | Wiring having basic insulation only protected by additional fixed sleeving | | N/A |
| | Components are not likely to be damaged in the normal assembly or replacement of covers | | N/A |
| | b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead | | N/A |
| | c) Insulating sleeving adequately secured | | N/A |
| | If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric test | (see appended table 20) | N/A |
| | Conductors subjected to temperatures exceeding 70°C have an insulation of heat-resistant material | | N/A |
| | d) Aluminum wires of less than 16 mm ² cross-section not used | | N/A |
| | f) Connecting cords between equipment parts considered as belonging to the equipment | | N/A |
| 59.2 | Insulation | | P |
| | b) Mechanical strength and resistance to heat and fires retained by all types of insulation | Ball-pressure test: enclosure 75°C 1.0mm | P |
| | c) Insulation not likely to be impaired by deposition of dirt or by dust resulting from wear of parts | | P |
| | Parts of rubber resistant to ageing | No rubber parts | N/A |
| 59.3 | Excessive current and voltage protection | | N/A |
| | Internal electrical power source provided with device for protection against fire hazard | | N/A |

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|--------------------|---|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder | | N/A |
| | Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s. | | N/A |
| 59.4 | Oil containers | | N/A |
| | Oil containers adequately sealed | Not used | N/A |
| | Container allow for the expansion of the oil | | N/A |
| | Oil containers in mobile equipment sealed to prevent the loss of oil during transport | | N/A |
| | Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level | | N/A |

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[illegible]

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|--------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 15c | TABLE: residual voltage or energy in capacitors | | | | N/A |
|----------------------------|---|------------------------------|------------------------|----------------------|---------|
| Capacitor and its location | Residual voltage (V) | Time after disconnection (s) | Capacitance value (µF) | Residual energy (mJ) | Remarks |
| | | | | | |

| 17h1 | TABLE: defibrillation-proof applied parts | | | | N/A |
|------------------------------|---|---------------------------------|------------------------|--|---------|
| Test condition: Fig.50 or 51 | Accessible part of measurement: | Applied part with test voltage: | Test voltage polarity: | Measured voltage between Y1 and Y2(mV) | Remarks |
| | | | | | |

| | | | | | |
|--------------------------------|---|--|---------------------------|---------|-----|
| 17h2 | TABLE: defibrillation-proof recovery time | | | | N/A |
| Applied part with test voltage | Test voltage polarity | Recovery time from accompanying documents(s) | Measured recovery time(s) | Remarks | |
| | | | | | |
| | | | | | |

| | | | | | |
|-----------------------|----------------------------|----------------------|-------------------|---------|-----|
| 18 | TABLE: protective earthing | | | | N/A |
| Test location | Test current(A) | Measured voltage (V) | Resistance (ohms) | Remarks | |
| No accessible PE part | | | | | |

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|--------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 19 | TABLE: leakage current(mA) | | | | P |
|---|----------------------------|--------------------------|-----------------------------|---------------------------------|---------|
| Type of leakage current and test condition (including single faults) | | Supply voltage (V) | Supply frequency (Hz) | Measured max. value(μ A) | Remarks |
| ER,NC, Fig 16, MD.B | | 264 | 60 | 11 | |
| ER,SFC, Fig 16, MD.B | | 264 | 60 | 21 | |
| EN ,NC, Fig.18, MD1, B | | 264 | 60 | 5 | |
| EN ,SFC, Fig.18, MD1, B | | 264 | 60 | 7 | |
| P,NC, Fig.20, MD, B | | 264 | 60 | a.c. <1 | |
| | | | | d.c.<1 | |
| P,SFC, Fig.20, MD, B | | 264 | 60 | a.c.<1 | |
| | | | | d.c. <1 | |
| PM, SFC, Fig.21, MD, B | | 264 | 60 | <1 | |
| ER,NC, Fig 16, MD.A | | 264 | 60 | 12 | |
| ER,SFC, Fig 16, MD.A | | 264 | 60 | 22 | |
| EN ,NC, Fig.18, MD1,A | | 264 | 60 | 6 | |
| EN ,SFC, Fig.18, MD1, A | | 264 | 60 | 8 | |
| P,NC, Fig.20, MD, A | | 264 | 60 | a.c.<1 | |
| | | | | d.c.<1 | |
| P,SFC, Fig.20, MD, A | | 264 | 60 | a.c <1 | |
| | | | | d.c. <1 | |
| PM, SFC, Fig.21, MD, A | | 264 | 60 | <1 | |

(Record at least maximum measured value for each test required by Clause 19 and the specific conditions of the test circuit and equipment).

Abbreviations used:

| | |
|--|---|
| ER - Earth leakage current | A - After humidity conditioning |
| EN - Enclosure leakage current | B - Before humidity conditioning |
| P - Patient leakage current | 1 - Switch closed or set to normal polarity |
| PM - Patient leakage current with mains on the applied parts | 0 - Switch open or set to reversed polarity |
| PA - Patient auxiliary current | NC - Normal condition |
| Fig. 15 - refers to Fig. 15 in IEC601-1 | SFC - Single fault condition |
| MD - Measuring device | |

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| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | | | |
|--|---|------------------------|------------------|----------|---|
| 20 | TABLE:dielectric strength | | | | P |
| Insulation under test (area from insulation diagram) | Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced) | Referenc e voltage (V) | Test voltage (V) | Remarks | |
| ① | BI A-f | a.c.240V | a.c.1500V | Not test | |
| ② | DI/RI A-a ₂ | a.c.240V | a.c.4000V | P | |
| ③ | BI B-d | a.c.250V | a.c.1500V | P | |
| ④ | DI/RI A-e | a.c.240V | a.c.4000V | P | |
| ⑤ | BI A-a ₁ | a.c.240V | a.c.1500V | P | |
| ⑥ | DI/RI B-a | a.c.240V | a.c.4000V | P | |
| No flashover or breakdown(Before and after humidity treatment) | | | | | |

| 21 | TABLE: mechanical strength | | P |
|---------------------|--|-----------|---|
| Part under test | Test (impact, drop, force, handle, rough handling, mobile) | Remarks | |
| Enclosure / display | 45N, impact 0.5J | No damage | |
| The whole device | rough handling : 5cm drop | No damage | |

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| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|------------------|-------------------|--------------------------------|-----------------|
| 24 | TABLE: -stability | | P |
| Part under test | | Test condition | Remarks |
| The whole device | | tilted through an angle of 10° | Not overbalance |

| | | | | |
|-----------------|--------------------|----------------|-------------------------|---------|
| 29 | TABLE: x-radiation | | | N/A |
| Part under test | | Test condition | Measured radiation (mR) | Remarks |
| | | | | |

| | | | | | |
|--|---------------------------|----------------------------------|-------------|---------|---|
| 42 | TABLE: normal temperature | | | | P |
| Supply voltage: 264V/60Hz | | Test Condition: normal condition | | | |
| Ambient temperature : 25.0℃ | | | | | |
| Measuring location | Measured temperature [°C] | Adjust for 40 [°C] | Allowed[°C] | Remarks | |
| Display | 36.2 | 51.2 | 85 | P | |
| Enclosure | 40.3 | 55.3 | 85 | P | |
| button | 38.3 | 53.3 | 85 | P | |
| Battery | 41.7 | 56.7 | 105 | P | |
| motor | 43.2 | 58.2 | 125 | P | |
| Capacitor Y | 56.8 | 71.8 | 90 | P | |
| COR - indicates measurements taken using change-of-resistance method | | | | | |

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|---------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|---|---|------------------|------------------|
| 44 | TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection | | P |
| Test type and condition | | Part under test | Remarks |
| Spillage Leakage Humidity preconditioning Ingress of liquids Cleaning | | The whole device | No safety hazard |

| | | | |
|-------------------------|---|-----------------|---------------|
| 45 | TABLE: hydrostatic pressure and pressure-relief device cycling test | | N/A |
| Test type and condition | | Part under test | Test pressure |
| | | | Remarks |
| | | | |

| | | | |
|---|---------------------------|------------------|---------|
| 52 | TABLE: abnormal operation | | P |
| Test type, condition and clause reference | | Observed results | Remarks |
| Locking of moving parts | | No safety hazard | P |
| Open the PE | | No safety hazard | P |
| Short circuit battery | | No safety hazard | P |
| Failure of component | | No safety hazard | P |

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|--------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | | | | |
|--|--|-------------|----------------|----------------|-------------------------------------|---|
| 56.1 | TABLE: lists of critical component parts | | | | | P |
| Object/part No | Manufacturer/ trademark | Type/model | Technical data | Standard | Mark(s) of conformity ¹⁾ | |
| Power cord | Cixiwanneng electron Co.,Ltd | XW 10A-250V | 10A 250VAC | / | / | |
| Switching power supply | Shenzhen Long.X.C Power supply C0.,LTD | ACMS25-15V | 25W | / | / | |
| brushless DC motor | NIDEC CORPORATION | 22H893G010 | / | / | / | |
| Nickel Metal Hyoride Battery | Great Power Battery Co., Ltd | AA2300 | 12v 2300mAh | UL-MH207 33 | / | |
| 1) an asterisk indicates a mark which assures the agreed level of surveillance | | | | | | |

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|--------------------|--------------------|-----------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|-----------------|-------------------------------------|---------|-----|
| 56.10 | TABLE: actuating parts and controls | | N/A |
| Part under test | Torque applied | Remarks | |
| | | | |

| | | | |
|-----------------|---|---------|-----|
| 56.11b | TABLE: foot operated control device-loading | | N/A |
| Part under test | Observed results | Remarks | |
| | | | |

| | | | | | |
|-----------------|-----------------------|------|--------|---------|---------|
| 57.4a | TABLE: cord anchorage | | | | N/A |
| Cord under test | Mass of equipment | Pull | Torque | Remarks | verdict |
| | | | | | |

| | | | | |
|-----------------|---------------------|--------------------|--|---------|
| 57.4b | TABLE: cord bending | | | N/A |
| Cord under test | Test mass | Measured curvature | | Remarks |
| | | | | |

| | | | | | |
|--------------------|----------------------------------|---------------------------|-----------|---------|---------|
| 57.9.1a | TABLE: transformer short circuit | | | | N/A |
| Winding under test | protection | Measured temperatures(°C) | | | Remarks |
| | | Primary | Secondary | Ambient | |
| | | | | | |

| | | | | | | | |
|--------------------|-----------------|---------------------------|-----------|---------|---------------|--------------------------------------|---------|
| 57.9.1b | TABLE: overload | | | | | | N/A |
| Winding under test | protection | Measured temperatures(°C) | | | Test duration | Test duration or thermal cutout temp | Remarks |
| | | Primary | Secondary | Ambient | | | |
| | | | | | | | |

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| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | | | |
|------------------------|--|--------------|----------------|---------|-----|
| 57.9.2 | TABLE: transformer dielectric strength | | | | N/A |
| Transformer under test | Test voltage applied to | Test voltage | Test frequency | Remarks | |
| | | | | | |

| | | | | |
|--------|-------------------------|------------------------------|--|---------|
| | TABLE: additional tests | | | N/A |
| Clause | Test type and condition | Remarks and observed results | | Verdict |
| | | | | |

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| Clause | Requirement + Test | Result - Remark | Verdict |

Test Equipment

A84-08-03 vernier caliper
A95-21-01 Testing card for air clearance and creepage distance
G2003-19-01 Ball-pressure test apparatus
M2003-17-02 Safety analyzer
M2006-19-04 Withstanding voltage tester
M2003-24-01 Digital multimeter
N92-02-01 Electronical stopwatch
S2005-05-16 hygrothermograph
T2000-12-01 Alternating temperature and humidity testing cabinet
L2005-11-01 Power analyzer
M2006-25-05 AC Power Source
S2005-04-03 Air pressurer
G2006-06-03 Impact-test apparatus
M2005-23-02 Data Acquisition Unit
M2006-21-02 Digital capacitance meter
M2006-09-04 Protective earth resistance tester
M2006-06-04 oscilloscope
X2004-00-01 High voltage probe
H90-01-02 Precision Sound Level Meter
GZ2006-21-01 Stability test-bed
A03-12-01 Steel tape
T2003-17-01 Rain simulator

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Photos and Explanations



Figure 1 The whole view

**SINO MEDICAL-DEVICE TECHNOLOGY CO., LTD.**
www.sinomdt.com

Product Name: Syringe Pump

Voltage: AC 100V~240V 50/60Hz 200mA


Product Model: SN-50T66R


DC 12V 500mA


Safety Class: Class I

IPX4


Rated Power: 35VA







Sino Medical-Device Technology Co., Ltd.
Add: 6th Floor, Building 15, Majialong Industry Zone,
Nanshan District, Shenzhen, P.R.China



EC

REP

Name: Shanghai International Holding Corp. GmbH(Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany


 0123

Figure 2 The label

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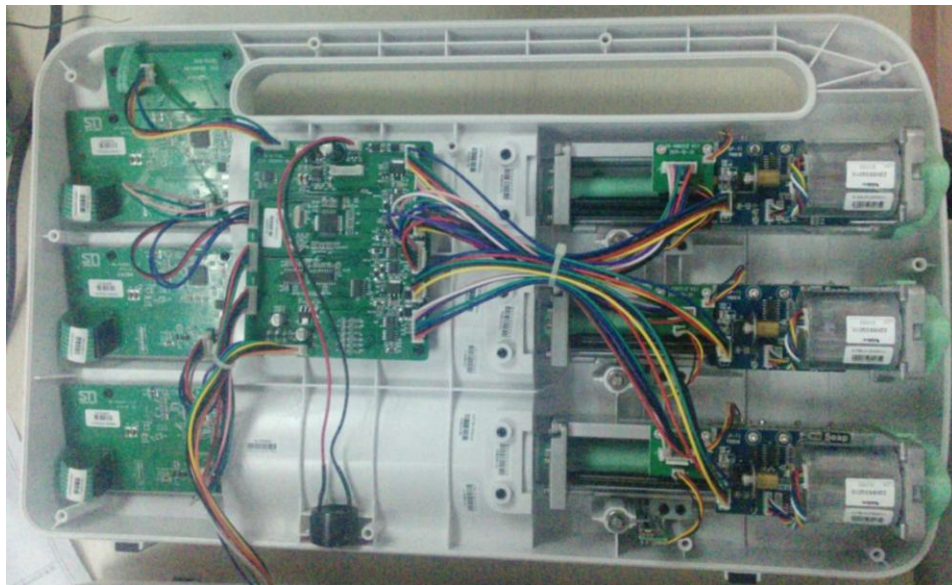


Figure 3 Internal Construction(1)

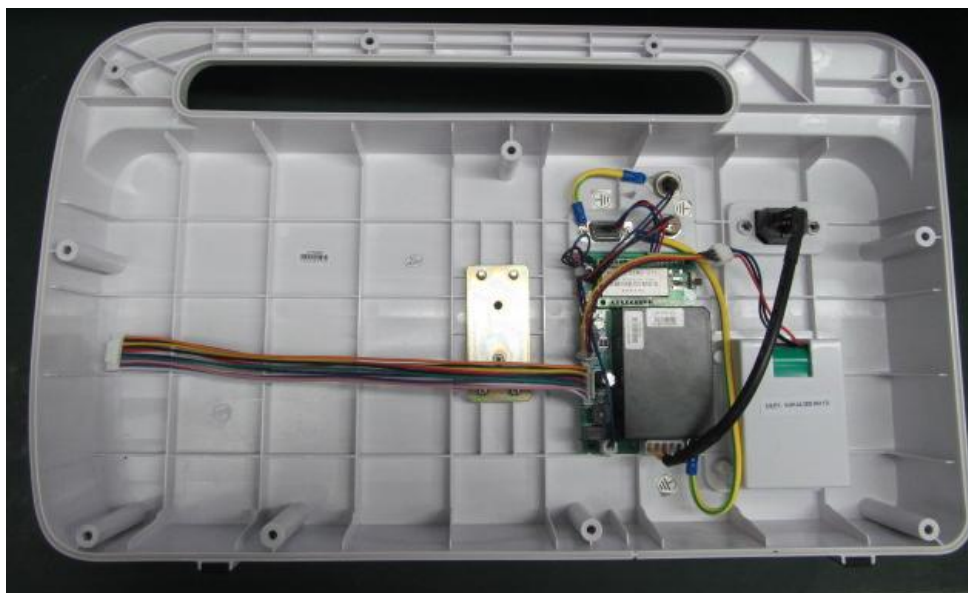


Figure 4 Internal Construction(2)

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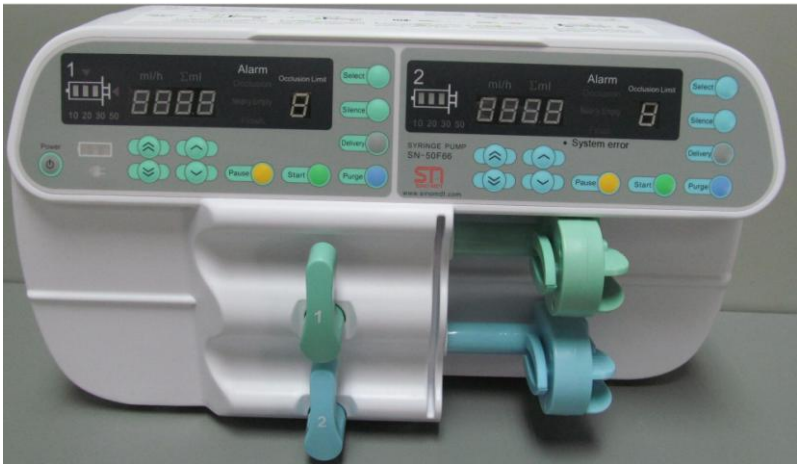


Figure 5 SN-50F66 Syringe Pump

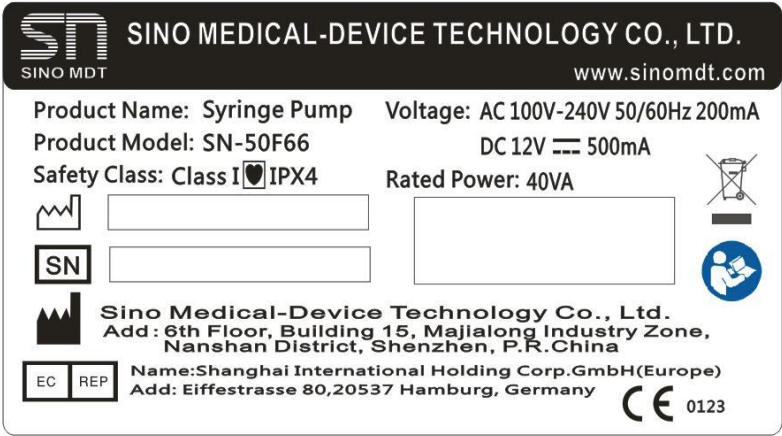


Figure 6 The label of SN-50F66 Syringe Pump

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Figure 7 SN-50F66R Syringe Pump


**SINO MEDICAL-DEVICE TECHNOLOGY CO., LTD.**
www.sinomdt.com


| | |
|----------------------------|-------------------------------------|
| Product Name: Syringe Pump | Voltage: AC 100V-240V 50/60Hz 200mA |
| Product Model: SN-50F66R | DC 12V 500mA |
| Safety Class: Class I IPX4 | Rated Power: 40VA |





**Sino Medical-Device Technology Co., Ltd.**
Add: 6th Floor, Building 15, Majialong Industry Zone,
Nanshan District, Shenzhen, P.R.China

**EC REP**
Name: Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

**CE** 0123





Figure 8 The label of SN-50F66R Syringe Pump

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Figure 9 SN-50T66 Syringe Pump

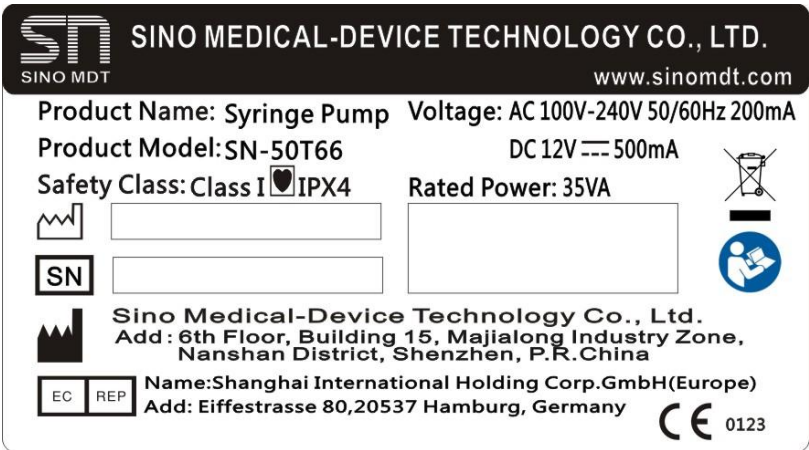


Figure 10 The label of SN-50T66 Syringe Pump

Test Report Photo

Photos and Explanations



Figure 11 SN-50C66 Syringe Pump

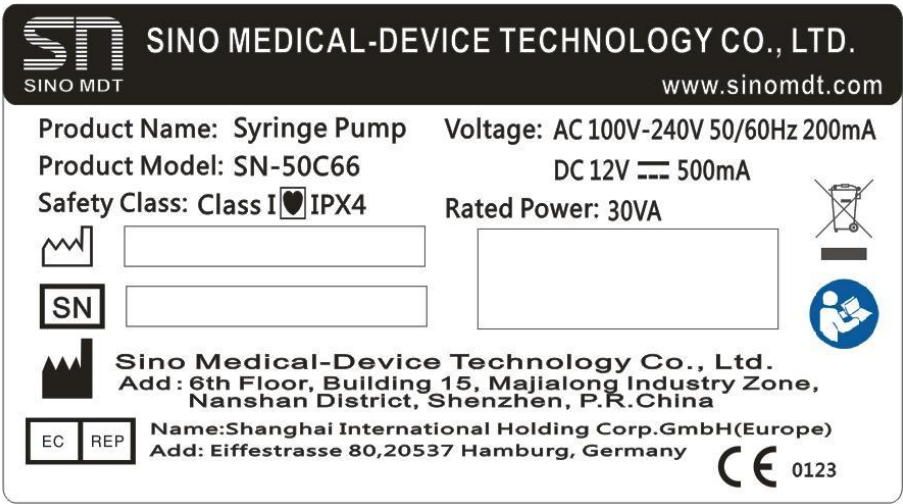


Figure 12 The label of SN-50C66 Syringe Pump

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Figure 13 SN-50C66R Syringe Pump

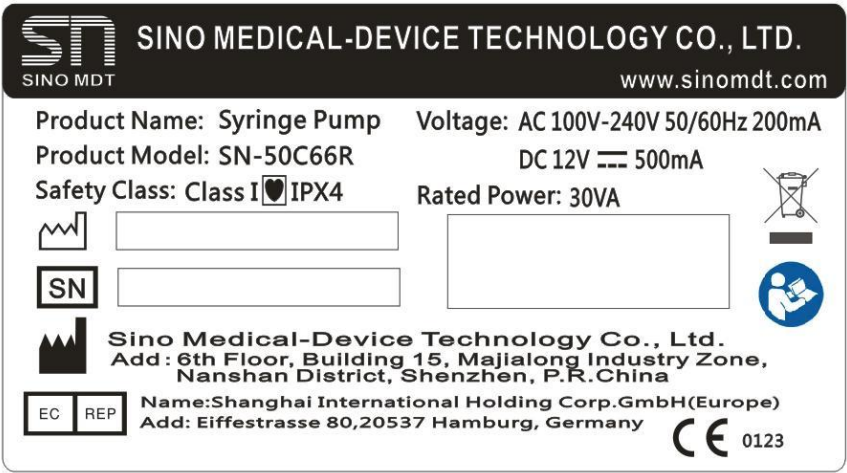


Figure 14 The label of SN-50C66R Syringe Pump

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Figure 15 SN-50C66T Syringe Pump

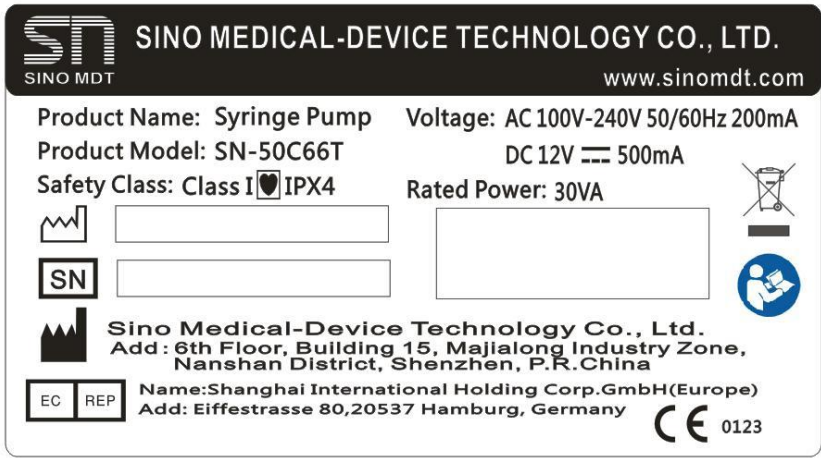


Figure 16 The label of SN-50C66T Syringe Pump

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Figure 17 SN-50C66TR Syringe Pump

**SINO MEDICAL-DEVICE TECHNOLOGY CO., LTD.**
www.sinomdt.com

| | |
|---|---|
| Product Name: Syringe Pump | Voltage: AC 100V-240V 50/60Hz 200mA |
| Product Model: SN-50C66TR | DC 12V 500mA |
| Safety Class: Class I IPX4 | Rated Power: 30VA |
|  | |
|  | |
|  | Sino Medical-Device Technology Co., Ltd. Add: 6th Floor, Building 15, Majialong Industry Zone, Nanshan District, Shenzhen, P.R.China |
|  | Name: Shanghai International Holding Corp. GmbH (Europe) Add: Eiffestrasse 80, 20537 Hamburg, Germany |
| |  0123 |





Figure 18 The label of SN-50C66TR Syringe Pump

**Guangzhou Medical Instruments Quality Surveillance and
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Test Report Addendum

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| Samples' Descriptions |
|--|
| <p>Syringe Pump is a series of products with high injection accuracy and stable flow rate, developed by Sino Medical-Device Technology Co., Ltd. It's composed of motor & actuator, lead screw, pusher head and syringe clamping device.</p> |
| Types and Specifications or Other Explanations |
| <p>By information and sample inspecting, the type SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR and SN-50T66R are in accord in principle, structure of circuit, they differ only in appearance and some auxiliary functions. So the type SN-50T66R can cover the type SN-50F66、SN-50F66R、SN-50T66、SN-50C66、SN-50C66R、SN-50C66T、SN-50C66TR.</p> |