**Serial number of product technical requirements for medical device**

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**RF Generator**

1. **Model/specification**
   1. Technical parameters: See Table 1.
   2. Accessories: See Table 2.
   3. See Table 3 for the schematic diagram and description, type, material and dimension of each model
   4. Software release version: Master Ⅱ Software B (same as the software full version).
      1. Master software is referred to as Master Ⅱ Software, and the version number is expressed in English letters. The bipolar display of the host shall display the version number in numerical value. The value corresponds to a letter in the alphabet, and the letter matches the position sequence of the alphabet; for example, the letter A represents the number 1, and the letter R represents the number 18; on the bipolar display, 18 means that the master software version is R. Version number B is displayed as 2 on the bipolar display.

Table 1: Technical parameters

|  |  |
| --- | --- |
| **Physical properties**  Width  Depth  Height  Weight | 40.5 cm  40.5 cm  20 cm  8.65 kg |
| **Operating environment**  Temperature range  Humidity range  Atmospheric pressure | +10℃~+40℃  15 ~ 75% (non-condensing)  700hPa 〜1060hPa |
| **Storage environment**  Temperature range  Humidity range  Atmospheric pressure | 40℃ ~+70℃  10% ~ 100% (non-condensing)  500hPa ~1060hPa |
| **Acoustic frequency**  ACE cutting, pure cutting and blend cutting  Standard coagulation, cut coagulation and arc coagulation  Standard and macro-bipolar  **Prompt tone frequency**  Power limit ("Beep")  Mistake ("Beep Beep")  COM ("Beep Beep Beep") | 840Hz±10%  520Hz±10%  480Hz±10%  1980HZ+10%  1980Hz±10%  2550Hz±10% |
| **Fuse type and rated value** | 2 pieces, both with specifications as F10.0/250V |
| **Electric properties** |  |

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| --- | --- |
| Rated working voltage  **THIS DOCUMENT IS PROVIDED BY THE APPLICANT/THE REGISTRANT**  Rated working frequency | 100-240VAC  50-60HZ |
| **Variation of output power**  The variation of output power is the function of variation of input power | <5% |
| **Features of output power**   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | Mode | | Power (W) | Allowable error of output (rated load) | Rated load (Ω) | Maximum open circuit voltage (Vp-p) | Working frequency (rated load) | Vibration factor (rated value at rated load) | | Monopolar cutting | ACE cutting | 15 | 20% | 200 | 1500 | 400kHz | 1.4 | | Pure cutting | 300 | 20% | 300 | 3000 | 400kHz | 1.4 | | Blend cutting | 200 | 20% | 300 | 4000 | 400kHz | 3.0 | | Monopolar coagulation | Arc | 120 | 20% | 500 | 6000 | 22 kHz @ 2.5 µs pulse  with base frequency of 400 kHz | 8.0 | | Standard | 120 | 20% | 500 | 5000 | 32 kHz @ 2.5 µs pulse  with base frequency of 400 kHz | 6.9 | | Cutting coagulation | 120 | 20% | 500 | 5000 | 30 kHz @ 2.5 µs pulse  with base frequency of 400 kHz | 7.1 | | Bipolar | Standard | 80 | 20% | 100 | 360 | 400kHz | 1.4 | | Macro- bipolar | 80 | 20% | 100 | 760 | 400kHz | 1.4 | | |
| **Volume**   |  |  |  | | --- | --- | --- | | Mode | Frequency | Adjustable volume | | Pure cutting | 840Hz±10% | 40 to 65 dB | | ACE cutting | 840Hz±10% | 40 to 65 dB | | Blend cutting | 840Hz±10% | 40 to 65 dB | | Standard coagulation | 520Hz±10% | 40 to 65 dB | | Cutting coagulation | 520Hz±10% | 40 to 65 dB | | Arc coagulation | 520Hz±10% | 40 to 65 dB | | Bipolar (Standard & Macro-bipolar) | 480Hz±10% | 40 to 65 dB | | Power limit prompt ("Beep") | 1980Hz±10% | > 65 dB not adjustable | | Mistake ("Beep Beep") | 1980Hz±10% | > 65 dB not adjustable | | COM ("Beep Beep Beep") | 2550Hz±10% | > 65 dB not adjustable | | |
| **Note** | |
| Ace cutting: Advanced Cutting Effect, making use of electrotome to automatically identify impedance to ensure consistent output.  Arc: Arc coagulation, achieving coagulation of targeted tissue by spraying electric arc.  Cutting coagulation: coagulation with cutting function. | |

Table 2: Accessories

|  |  |
| --- | --- |
| Model | English description |
| Electrosurgical Generator | |
| 1000 | Mega Power Electrosurgical Generator |
| 1400 | Monopolar Footswitch (3 Meter Cable) |
| 1450 | Bipolar Footswitch (3 Meter Cable) |
| Reusable Foot Cable | |
| 0075 | Reusable Foot Control Cord |
| Skintact Cool Contact electrosurgical Grounding Plates w/ NH 04 gel | |
| 0850C | Adult Disposable Patient Return Electrode with **Cord** - Standard |
| 0855C | Adult Disposable Patient Return Electrode with **Cord** - Monitoring |
| 0865C | Pediatric Disposable Patient Return Electrode with **Cord** -Monitoring |
| 0855 | Re-CORDable Disposable Patient Return Electrode - Monitoring |
| 0875 | Re-CORDable Reusable Cable - Monitoring |

Table 3: Schematic diagram description, type, material and dimension

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| REF# | Description | Type | Dimension  Length × width [cm] | Schematic diagram | Material |
| 0850C | Adults,  monolithic,  with 3-meter cord. | Standard | 20 × 11.2 |  | Back of 0855C & 0855-mesh  Back of other models-PE foam material  Adhesive-medical acrylic adhesive  Conductive material-aluminum  Gel-hydrogel  Release paper-silicide foil |
| 0855C | Adults,  Bilithic,  with 3-meter cord. | Monitoring | 14.1 × 15.7 |  |
| 0855 | Adults,  Bilithic,  no cord. | Monitoring | 14.1 × 15.7 |  |
| 0865C | Children,  Bilithic,  with 3-meter cord. | Monitoring | 13.5 × 11.2 |  |

1. **Performance indicators**
   1. Main technical parameters
      1. Output power: See Table 1 for output power, with allowable error of ± 20%.
      2. Working frequency: See Table 1 for working frequency, with allowable error of ± 10%.
      3. Acoustic frequency: See Table 1 for the acoustic frequency of each mode, with allowable error of ± 10%.
      4. Pulse width: See Table 1 for pulse width, with allowable error of ± 10%.
   2. Adjustable volume: The adjustable volume of each mode shall comply with the requirements of Table 1.
   3. Foot switch requirements (1400 type foot switch and 1450 type foot switch)
      1. The foot switch shall have excellent water-proof performance and shall be qualified in the withstand voltage test.
      2. The starting force of the foot switch shall not be less than 10 N and shall not be greater than 50 N.
      3. The actions of the foot switch shall be smooth without jamming or blocking. The contactor shall be able to close and interrupt well.
      4. The structure of the foot switch shall be firm.
      5. The mechanical structures of foot switch shall be able to withstand a force of 1350 N for 1 minute while no over-bending or crack occurs.
      6. The foot switch shall be still available after being subjected to three times of free falling from the height of 1 m and no live parts shall be accessible, and the foot switch can pass the withstand voltage test.
      7. The service life of the foot switch shall not be less than 25000 cycles.
      8. A clamping device to prevent cords from being pulled out and a protector to prevent scratches of cords shall be mounted at the outlet of cords of foot switch. When the cords are clamped by the clamping device, the cords shall be capable to bear the pulling force of 59N. The displacement of cord shall not be more than 2mm when pulling the cords with such force for 1s at a time for 100 cycles.
      9. The foot switch shall be stable when placed on the flat ground.
   4. Appearance
      1. The housing of equipment shall be neat and attractive; the surface shall be clean and tidy with uniform color and free from scars, cracks, etc.
      2. There shall be no coating peeling or rusting on the panel of the equipment, and the words and marking on the panel shall be clear and visible.
      3. The plastic parts of equipment shall have no blistering, cracking, deformation or perfusion spillage.
      4. The controlling and regulating mechanism of equipment shall be flexible and reliable; the fasteners shall not loosen.
   5. Electrical safety: It shall comply with the requirements of GB 9706.1-2007 and GB 9706.4-2009. For the safety characteristics, see Annex A.
   6. **Requirements for Patient Return Electrodes**
      1. Appearance: The surface shall be clean and free from spots, as well as the rough surface causing damages.
      2. Connector: The connector shall be clear and reliable without looseness.
      3. Connection firmness: The connections between connectors shall withstand a force of 40 N without fracture.
      4. Fitting performance: It shall be free from looseness and the combined machines have good service performance.
      5. Dimension: 14.1cm × 15.7cm, with allowable error of ± 10%.
   7. Requirements for the cord of Patient Return Electrodes
      1. Appearance: The surface shall be clean and have no processing defects.
      2. Connection firmness: The connections between connectors shall withstand a force of 40 N without fracture.
      3. Fitting performance: It shall be free from looseness and the combined machines have good service performance.
   8. Electromagnetic compatibility: It shall comply with the requirements of YY 0505-2012 and Clause 36 in GB 9706.4-2009.
2. **Test methods**

Test conditions and equipment

Test conditions

1. Ambient temperature range: +10℃ ~ +40℃
2. Relative humidity range: 15%~75% (non-condensing)
3. Atmosphere pressure range: 700 hPa~1060 hPa
4. Power supply: 100~240 VAC 50-60 Hz

Test equipment

Adjustable stabilized voltage supply

High frequency electrotome tester (such as Dynatech454A or equivalent), with load of 25 Ω, 50 Ω, 100 Ω, 150 Ω, 200 Ω, 250 Ω, 300 Ω, 400 Ω, 500 Ω and 600 Ω.

High frequency electrotome tester with high frequency leakage current.

Withstand voltage tester for electrical equipment.

Earth impedance tester.

Environmental conditions test chamber for electrical equipment.

* 1. Main technical parameters
     1. Output power: Conduct the test according to the method specified in GB 9706.4-2009 Medical electrical equipment-Part 2: Particular requirements for the safety of high frequency surgical equipment; the result shall comply with the requirements of 2.1.1.
     2. Working frequency: Operate the device, and use high frequency electrotome tester to measure the working frequency; the result shall comply with the requirements of 2.1.2.
     3. Acoustic frequency: Operate the device, and use high frequency electrotome tester to measure the acoustic frequency; the result shall comply with the requirements of 2.1.3.
     4. Pulse width: Operate the device, and use an oscilloscope to measure the pulse width; the result shall comply with the requirements of 2.1.4.
  2. Adjustable volume

Make the measurement by using sound level meter at 1 meter away from the front, back, left and right side of equipment; the result shall comply with the requirements of 2.2.

* 1. Foot switch test: Conduct the test according to the methods specified in YY 91057-1999.
  2. Appearance: Perform direct observation and operation for verification.
  3. Electrical safety test: Conduct the test according to the methods specified in GB 9706.1-2007 and GB 9706.4-2009.
  4. Test methods for Patient Return Electrodes
     1. Appearance: Perform visual inspection for verification; the result shall comply with the requirements of 2.6.1.
     2. Connector test: Conduct the test for verification; the result shall comply with the requirements of 2.6.2.
     3. Connection firmness test

Apply a static pulling force of 40 N between each connector for 15 s; the result shall comply with the requirements of 2.6.3.

* + 1. Fitting performance test: Operate the device for verification; the result shall comply with the requirements of 2.6.4.
    2. Dimensions of Patient Return Electrodes: Use a standard/special measuring tool to make measurement.
  1. **Test methods for cord of Patient Return Electrodes**
     1. Appearance: Perform visual inspection for verification; the result shall comply with the requirements of 2.7.1.
     2. Connection firmness: Apply a static pulling force of 40 N between each connector for 15 s; the result shall comply with the requirements of 2.7.2.
     3. Fitting performance: Operate the device for verification; the result shall comply with the requirements of 2.7.3.
  2. Electromagnetic compatibility: Conduct the test according to the methods specified in YY 0505-2012 and Clause 36 in GB 9706.4-2009.

**Annex A**

Main Safety Characteristics of Product

Classification according to the type of protection against electric shock: Class I equipment;

Classification according to the degree of protection against electric shock: Type CF applied part;

Classification according to the degree of protection against liquid ingress: Host: IPX0; foot switch: IPX8;

This equipment may not be used in the flammable anesthetic gas mixed with air, oxygen or nitrous oxide;

Classification according to the operation mode: intermittent operation: 10s On, 30s Off;

Rated voltage and frequency of equipment: 100-240 VAC, 50-60 Hz;

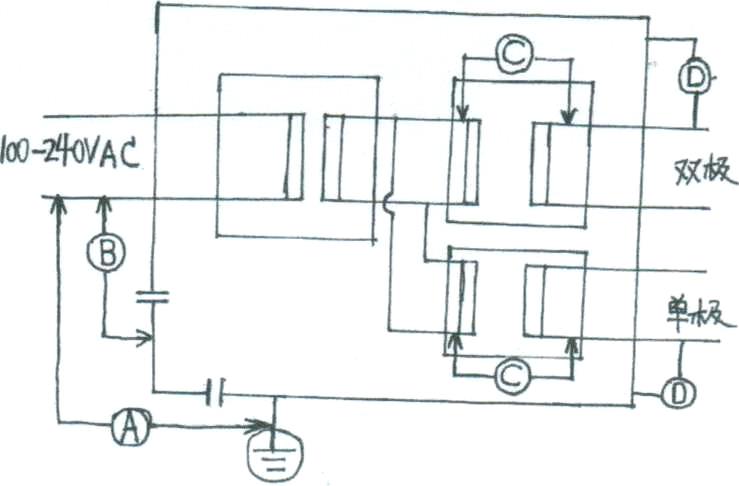
Input power of equipment: 550 W;

This equipment has defibrillation-proof applied part;

The equipment has no signal output or input part;

Non-permanently installed equipment;

Electrical insulation diagram: See the figure below.



Monopolar

Bipolar

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Position | Insulation path | Reference voltage | Test voltage requirements | Creepage distance requirement | | Air clearance requirement |
| A | A-a1 | ac 240V | ac 1500V | 4.0mm | | 2.5mm |
| B | A-a2 | ac 240V | ac 4000V | 8.0mm | | 5.0mm |
| C (bipolar) | B-a | ac 269V | ac 4076V | | 12.0mm | 7.0mm |
| D (bipolar) | B-d | ac 269V | ac 1538V | | 4.0mm | 4.0mm |
| C (monopolar) | B-a | ac 2122V | ac 9244V | | 32.0mm | 18.0mm |
| D (monopolar) | B-d | ac 2122V | ac 4122V | | 6.0mm | 6.0mm |