

---

# **INFANT RADIANT WARMER**

**CCR-4000A**

**INSTRUCTION FOR USE**

## Content

|  |        |
|--|--------|
| 1 Complete machine identification .....                            | - 2 -  |
| 2. Notes .....   | - 4 -  |
| 3. Terms and definitions .....                                     | - 10 - |
| 4 Installation .....   | - 13 - |
| 4.1 Removing the box .....   | - 13 - |
| 4.2 Installation .....   | - 13 - |
| 5 Overview .....   | - 16 - |
| 5.1 Scope of application .....                                     | - 16 - |
| 5.2 Main components of the products .....                          | - 16 - |
| 5.3 Function identification of different product models .....      | - 16 - |
| 5.5 Basic technical parameters .....                               | - 18 - |
| 5.6 Normal working environment .....                               | - 20 - |
| 6. Main structure and inspection .....                             | - 21 - |
| 6.1 Radiation head .....   | - 21 - |
| 6.2 Infusion rack .....  | - 21 - |
| 6.3 Tray .....   | - 21 - |
| 6.5 Machine foot .....   | - 22 - |
| 7 Function introduction .....                                      | - 22 - |
| 7.1 Temperature control mode .....                                 | - 22 - |
| 7.2 Fault alarm function and description .....                     | - 24 - |
| 8 Functional check and use method .....                            | - 28 - |
| 8.1 Function and usage method of the controller .....              | - 28 - |
| 8.2 Test of the alarm function of the controller .....             | - 37 - |
| 8.3 Use method of the skin temperature sensor .....                | - 38 - |
| 9. Other functions of the product .....                            | - 38 - |
| 9.1 Light for jaundice treatment .....                             | - 38 - |
| 9.2 Electric power attractor .....                                 | - 41 - |
| 9.3 T combination resuscitation / air oxygen mixing .....          | - 45 - |
| 9.5 Pulse and blood oxygen monitoring device .....                 | - 56 - |
| 9.6 Auxiliary skin temperature monitoring .....                    | - 60 - |
| 10 Daily maintenance and maintenance .....                         | - 60 - |
| 10.1 Overview .....  | - 60 - |
| 10.2 Cleaning .....  | - 61 - |
| 10.3 Reassembly after cleaning .....                               | - 62 - |
| 11 Fault analysis and troubleshooting .....                        | - 63 - |
| 12. Transportation and storage .....                               | - 64 - |
| 12.1 Environmental conditions for transportation and storage ..... | - 64 - |
| 12.2 Transportation .....  | - 64 - |
| 12.3 Storage .....   | - 64 - |
| 13 Commitment and statement .....                                  | - 64 - |
| 13.1 Commitment .....  | - 64 - |
| 13.2 statement .....   | - 65 - |
| 14 List of vulnerable parts .....                                  | - 65 - |
| Appendix 1 Packing list .....                                      | - 65 - |
| Appendix 2 circuit .....   | - 66 - |

# 1 Complete machine identification

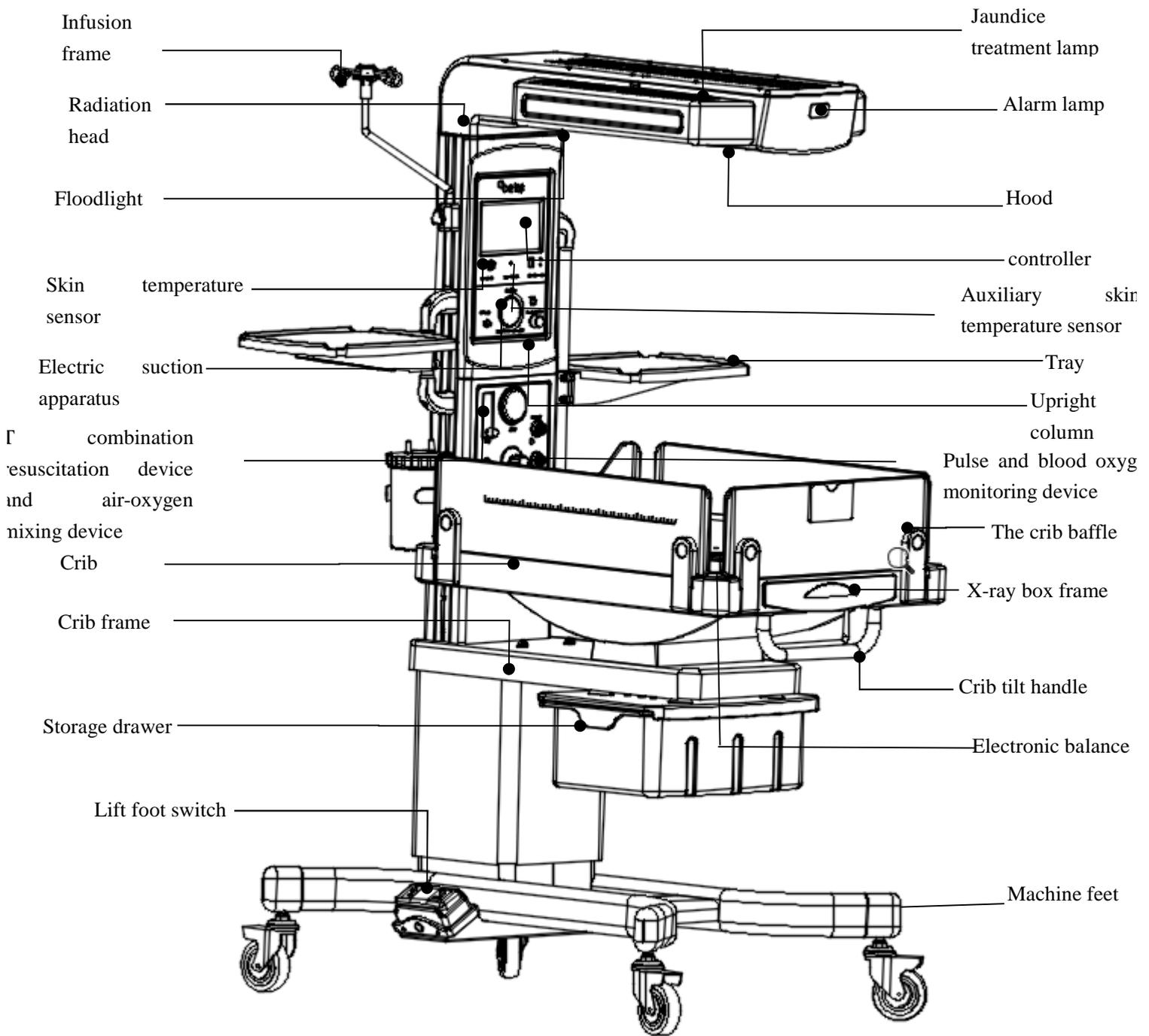


Figure 1

## Function description of parts

| order no | Part name                  | Function declaration   |
|----------|----------------------------|--|
| 1        | Radiation head             | Main functional components of the equipment, built-in far infrared ceramic heater; radiation head temperature is high, pay attention to avoid scald.   |
| 2        | Controller                 | The main control components of the equipment adopt LCD touch screen, and the functions of the equipment can be switched and adjusted through user operation. The controller has various fault self-check and alarm functions. The constant temperature time of the baby radiation insulation platform is within 1 hour. Please start up 1 hour in advance. |
| 3        | Skin temperature sensor    | A signal sensing device comprising a connecting portion with the device for detecting the temperature of an infants skin.  |
| 4        | Jaundice treatment lamp    | A neonatal jaundice treatment device (LED light source) controlled by a controller (photo therapy lamp is optional).   |
| 5        | Floodlight                 | For device lighting at night or during care.   |
| 6        | Hood                       | Prevent medical workers from accidentally touching the far-infrared ceramic heater.  |
| 7        | Upright column             | The bearing column of the radiation head is equipped with guide rails on the two sides, which can be installed with infusion racks, trays, suction bottles, etc.   |
| 8        | Infusion frame             | For hanging the infusion bottles, the maximum load bearing of the infusion rack is 2 Kg.   |
| 9        | Tray                       | Medical devices such as injection pump and infusion pump can be placed, and the maximum bearing capacity of the tray is 2 Kg.  |
| 10       | Crib                       | Platform for baby, containing mattress. The maximum bearing of the crib tray was 10 Kg.  |
| 11       | Crib frame                 | The carrier of the crib.   |
| 12       | Crib baffle                | The baby protective baffle can be turned down and can be removed and cleaned.  |
| 13       | X-ray box frame            | For placing the X-ray boxes.   |
| 14       | Crib tilt handle           | Open the lock to adjust the tilt Angle of the crib to meet the clinical needs.   |
| 15       | Electric suction apparatus | It is used to remove neonatal amniotic fluid, airway secretions, oral mucus, etc.  |
| 16       | Suction bottle             | Store the liquid attracted by the electric attractor when in operation.  |
| 17       | under-chassis              | The whole machine carrier, equipped with 4 universal casters, 2 of which 2 can be locked (optional lift foot).   |

|    |   |   |
|----|---|---|
| 18 | Storage drawer  | For the storage of common items.  |
| 19 | Alarm lamp  | It is used as a light-emitting indicator for the alarm with an alarm output.  |
| 20 | Electronic balance  | Easy to measure newborn weight and detect weight trends.  |
| 21 | T combination resuscitation device and air-oxygen mixing device | Provide a controlled, stable peak inspiratory pressure (PIP) and positive end-expiratory pressure (PEEP) to ensure functional residual volume (FRC), improve lung compliance, and improve oxygenation |
| 22 | Auxiliary skin temperature sensor                               | A signal sensing device comprising a connecting portion to the device for the auxiliary detection of infant skin temperature.   |
| 23 | Pulse and blood oxygen monitoring device                        | Used to monitor arterial oxygen saturation and pulse rate   |

## 2. Notes

- I This product is free for one year from the date of purchase, except in one of the following cases:
  - a) The user ignores the operation and maintenance instructions in this manual.
  - b) Damage caused by failure to follow the cleaning and maintenance methods specified in the instruction manual.
  - c) Failure caused by the replacement or use of parts not designated by the Company or repairs not made by the personnel of the Company or not authorized by the Company.
  - d) Access the accessories and devices that do not meet the safety requirements of the product, and change the resulting safety performance, product performance and parameters.
  - e) Damage caused by irresistible external causes (such as natural disasters, fire, over voltage, etc.).
  - f) Wear and natural wear of consumables (example: fuse, bulb, etc.) and consumables (example: bed covers, etc.).
  - g) Fault or damage caused by the operating environment, including electrical conditions and installation conditions not meeting the requirements described in this specification.
- I The operating manual of this product is combined with the technical manual. Before using the baby radiation thermal table (hereinafter referred to as the thermal table), please read and understand the contents of the manual carefully.
- I This thermal platform belongs to class I BF ordinary equipment, the operation mode is continuous operation.
- I Equipment shall not be used in the mixture of flammable anesthetic gas and air or a mixture of oxygen or nitrous oxide and a strong electromagnetic field.
- I The equipment is designed not to change the original operation mode and set parameters of the equipment after the power supply failure and power failure of the equipment occur, and no safety danger will occur.

- I It should be operated under the guidance of a medical staff or professionally trained person familiar with the use of a thermal table. During the use of the thermal platform, it should be supervised by medical staff, and observe and record the temperature of the baby at any time.
- I Do not use the thermal table in direct sunlight or to receive other heat sources, air conditioning, or air convection.
- I It is prohibited to use this equipment in places where combustible anesthetics present. Do not use yl ether, alcohol, or other flammable substances.
- I When using the thermal table, preheating should be conducted at least 1 hour in advance, without placing the patient before constant temperature. The heating time of the thermal platform (11°C higher than the ambient temperature) is not more than 1 hour.
- I Do not use the skin temperature sensor on the back or anus of the baby as a thermometer. The skin temperature sensor probe should be attached near the belly button (or according to clinical medicine regulations).
- I The skin temperature sensor metal surface must be in direct contact with the infant skin surface to provide accurate monitoring information on the infant skin surface temperature. If the sensor metal surface is not in direct contact with the infant skin, it may cause the infant temperature overcooling or overheating.
- I The distance between the crib and the radiant head heater has been fixed by design. Do not change the distance between them; When the bed surface is tilted horizontally, the temperature uniformity will become larger and the end near the radiant cover is higher.
- I Please use the infant temperature control mode. Due to the influence of various external heat sources (including open phototherapy lamp) or the change of environmental temperature, will affect the temperature of the baby, so to use the infant temperature control mode, effectively fix the skin temperature sensor, pay close attention to the change of the baby temperature. Independent monitoring of the infant temperature by the controller is the main control mode, but the operator leaving the infant to keep the device in an unmanaged state is dangerous. The instrument also can not identify the difference between the baby cold skin (fever) and high body temperature or low body and skin temperature (low temperature), the user should monitor the baby actual body temperature.
- I For cleaning and disinfection of the insulation table.
- I The maximum capacity of the infusion rack is 2 Kg, the tray is 2 Kg, the crib is 10 Kg, and the radiation head is 10 Kg.
- I The equipment that does not meet the safety requirements shall not be used together with this equipment. The following points must be considered when selecting the relevant equipment:
  - a) The product has been certified to meet the GB9706.1 general safety requirements.
  - b) There is evidence that the equipment has been tested by relevant national or international standards and has been recognized.
  - c) When using the auxiliary equipment, the relevant safety requirements and use methods of the auxiliary equipment shall be observed.
  - d) The consistency and variability on the temperature may be affected when using other auxiliary devices on the thermal insulation table.
- I The horizontal tilt angle was  $\pm 12^\circ$ .
- I If the thermal platform issues power failure, over temperature, temperature deviation, sensor failure and other warning information, and cannot be eliminated or smell the coke, strange smell, please stop using the thermal platform immediately! Relevant inspection and maintenance should be carried out by qualified personnel.
- I When the over temperature alarm occurs, the instrument will automatically cut off the heating power supply and cannot restore the reheating. Please restart the power in time and strengthen the observation.

- I The equipment shall be placed in an environment without strong magnetic field interference, otherwise, the normal use of the equipment may be affected.
- I Normal working environment: ambient temperature 18-30°C, relative humidity 30-75%, air flow rate less than 0.3 m/s; if users cannot provide normal working environment, it will affect temperature control accuracy and bring safety risks, special attention should be paid to it.
- I When the thermal table is not used for six months and is used again, the safety of the mechanical structure and function of the equipment should be checked.
- I The controller is equipped with a standard 6F22 9V carbon battery, usually does not need to take out. When the controller display shows that the battery power is only one grid, pay attention to the polarity when replacement, and it shall be operated by qualified personnel.
- I Environmental protection requirements: the replaced battery and other consumer products should not be discarded at will, and should be handled according to the local laws and regulations on environmental protection.
- I Infants should pay attention to the loss of water in the body when using the thermal table for a long time.
- I When the thermal platform is not used temporarily, it is recommended to store it in a room with temperature (-40- ~ 55) °C, relative humidity not more than 90%, no vibration, no corrosive gas and good ventilation.
- I To prevent the baby from falling, the user should regularly check the pin and baffle closure, and should not open the crib baffle when using.
- I The thermal platform shall be kept horizontally without shaking, and the caster shall be locked when used. The inclination of the whole machine shall not be greater than 5°, and the inclination of the whole machine shall not be greater than 10° when moving.
- I When moving the thermal platform, in order to prevent accidents, at least two people should operate, and the power plug must be unplugged before moving.
- I Do not place quilts or blankets around the baby, which may cause a warm table temperature change, which can affect the temperature of the crib and cause damage.
- I To confirm that the power supply meets the power supply requirements listed in the electrical nameplate of the thermal station, the power plug must be plugged into a single-phase three-wire power supply network with protective grounding. If there is any doubt about the grounding connection, please do not use this equipment.
- I Do not change the three-core power plug to the two-core power plug, thus losing the grounding protection function, and do not use the power extension line (box).
- I Due to the hazard of electric shock, maintenance services must be performed by qualified maintenance personnel.
- I The performance parameters of the thermal platform have been tested and adjusted at the factory. If the user needs to master or repair them, please contact the company for the adjustment method.
- I Given this product is mainly used for baby insulation care, therefore, keep the equipment in good condition and normal working condition is very important, suggest the hospital equipment management department to strengthen regular inspection, monthly or quarterly to check the use of thermal function, found that the problem timely repair in time, ensure the safe and effective operation.

#### **Product service life:**

- I The life period of this product is 8 years from the date of user purchase and use. Any electrical products will be the end of the risk of life, warm platform used for several years, there will be electrical aging phenomenon, affecting the normal use. The company suggests that the thermal platform should be replaced after 8 years of normal use.
- I The service life of the heater is about 4 years. After the use expires, these components should be replaced as a whole. Before use, check whether the heater is effectively fixed, whether there are unsafe factors such as

cracks, to avoid external force collision.

- I In order to ensure the effect of light treatment, when the irradiation light source exceeds the expected service life (after the total bilirubin irradiance  $E_{bi}$  decay of 25%), the light source must be replaced overall, and the service life of the LED light-emitting diode is about 30,000 hours.
- I The service life of the temperature sensor is more than 2 years; after 2 years, the user shall check the display accuracy of the sensor according to relevant regulations, standards or calibration specifications, and contact the manufacturer for calibration or replacement after the deviation is found.
- I The service life of electric suction device is 3 years (including electromagnetic pump, suction line, negative pressure gauge, etc.); After expiration, contact the manufacturer for replacement.

#### Description of electromagnetic compatibility information for medical electrical equipment:

- I Warning: The baby radiation insulation platform shall be installed and used according to the EMC information provided in the instruction manual. For the specific information, see the requirements in Table 201, Table 202, Table 204 and Table 206.
- I This equipment cannot be used in a place with strong electromagnetic field generation.
- I Equipment susceptible to magnetic field interference shall not be placed near the equipment and may interfere with them.
- I The maximum length of the skin temperature sensor cable used by the device is 200cm.
- I Warning: In addition to the transducers and cables sold by the manufacturer of the platform as spare parts for internal components, the use of unspecified accessories, transducers and cables may result in increased emission or decreased immunity of the equipment or system.
- I Warning: This equipment should not be used close to or stacked with other equipment. If it must be close or stacked, the configuration used.

Table 201 Guide and manufacturer statement — electromagnetic emission — for all equipment and systems

| Guidelines and manufacturer statements  |                |  |
|---|----------------|--|
| The infant radiation thermal table is intended to be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in such electromagnetic environment: |                |  |
| launching test  | compliance     | Guide for the electromagnetic environment —  |
| radio-frequency emission<br>GB 4842   | Group 1        | The baby radiation thermal platform uses RF energy only for its internal functions, so it has a very low RF emission and has little interference with nearby electronic devices. |
| radio-frequency emission<br>GB 4842   | A class        | The infant radiation thermal table is suitable for use in all non-domestic and facilities not directly connected to the residential public low voltage supply grid.              |
| harmonic emission<br>GB 17625.1   | not applicable |  |
| Voltage fluctuation / flicker emission<br>GB 17625.2  | not applicable |  |

(Corresponding to Table 201 in YY0505-2012)

Table 202 Guide and manufacturer claims — electromagnetic immunity — for all equipment and systems

| Guide and manufacturer declare — electromagnetic immunity   |  |  |  |
|---|--|--|--|
| The infant radiation thermal table is intended to be used in the following specified electromagnetic environment, and the purchaser or user shall ensure that it is used in this electromagnetic environment: |  |  |  |
| immunity test   | IEC 60601 Test level   | In line with the level   | Guide for the electromagnetic environment —  |
| electrostatic discharge<br>GB/T17626.2  | ± 6 kV contact discharge<br>± 8 kV air discharge   | ± 6 kV contact discharge<br>± 8 kV air discharge   | The ground shall be wood, concrete or tile, and the relative humidity shall be 30% less  |
| Electric fast transient pulse population<br>GB/T 17626.4  | ± 2 kV to the power cord<br>± 1 kV for the input / output lines  | ± 2 kV to the power cord<br>± 1 kV for the input / output lines  | Grid power shall be of quality used in typical commercial or hospital settings   |
| surge<br>GB/T 17626.5   | ± 1 kV line to line<br>The ± 2 kV line faces the ground  | ± 1 kV line to line<br>The ± 2 kV line faces the ground  | Grid power shall be of quality used in typical commercial or hospital settings   |
| Voltage temporary drop, short time interruption and voltage change on the power input line<br>GB/T 17626.11   | <5% UT, for 0.5 cycles (On UT,> 95% down)<br>40% UT, which was continued for 5 cycles<br>(On UT, 60% down)<br>70% UT, which was continued for 25 cycles<br>(On UT, 30% down)<br><5% UT, which was continued for 5s<br>(On UT,> 95% down) | <5% UT, for 0.5 cycles (On UT,> 95% of down)<br>40% UT, which was continued for 5 cycles<br>(On UT, 60% down)<br>70% UT, which was continued for 25 cycles<br>(On UT, 30% down)<br><5% UT, which was continued for 5s<br>(On UT,> 95% of down) | Grid power shall be of quality used in typical commercial or hospital settings. If the user of the infant radiant thermal unit needs continuous operation during power interruption, the unit is recommended to use uninterruptible power supply or battery power supply |
| Power frequency magnetic field (50 Hz / 60 Hz)<br>GB/T 17626.8  | 3 A/m  | 3A/m   | The power frequency magnetic field shall have the horizontal characteristics in a typical commercial or hospital environment   |
| Note: UT is the AC net voltage before the test voltage is applied.  |  |  |  |

(Corresponding to Table 202 in YY0505-2012)

Table 204 Guide and manufacturer statement — electromagnetic immunity — for non-vital support devices and systems

| Guide and manufacturers statement — electromagnetic immunity  |                      |                        |                               |
|---|----------------------|------------------------|-------------------------------|
| The infant radiation thermal table is intended to be used in the following specified electromagnetic environment and the purchaser or user shall guarantee its use in this electromagnetic environment: |                      |                        |                               |
| immunity test   | IEC 60601 Test level | In line with the level | Guide for the electromagnetic |

|   |   |  | environment — —   |
|---|---|--|---|
| <p>RF conduction<br/>GB/ T 17626.6</p> <p>radio-frequency radiation<br/>GB/ T 17626.3</p>   | <p>3 V rms<br/>150 kHz ~ 80 MHz</p> <p>3V/m<sup>c</sup>、10V/m<sup>d</sup><br/>26 MHz~ 1 GHz<br/>3V/m<sup>e</sup>、10V/m<sup>f</sup><br/>80MHz ~ 2.5GHz</p> | <p>3 V rms</p> <p>3V/m<sup>c</sup>、10V/m<sup>d</sup><br/>26 MHz~ 1 GHz<br/>3V/m<sup>e</sup>、10V/m<sup>f</sup><br/>80MHz ~ 2.5GHz</p> | <p>Portable and mobile RF communication devices should not be used closer to any part of the infant radiation insulation pad than the recommended isolation distance, including cables. The distance shall be calculated by the formula corresponding to the transmitter frequency.</p> <p>Recommended isolation distance<br/><math>d=1.2 \sqrt{P}</math></p> <p><math>d=1.2 \sqrt{P}</math> 26 MHz~ 800 MHz<br/><math>d=2.3 \sqrt{P}</math> 800 MHz~ 2.5GHz</p> <p>In formula:<br/><i>P</i> — According to the maximum rated output power of the transmitter provided by the transmitter manufacturer, the unit is watt (W);<br/>The recommended isolation distance of <i>d</i> — is in meters (m).</p> <p>The field strength of the fixed RF transmitter is measured by using the electromagnetic field survey<sup>a</sup>. To determine that, in each frequency range<sup>b</sup> Should be lower than the conforming level.</p> <p>Interference may occur near the equipment marking the following symbols.</p>  |
| <p>Note 1: High frequency band 1 formula at 80 MHz and 800 MHz frequency points.</p> <p>Note 2: These guidelines may not be suitable for all situations, and the electromagnetic transmission is affected by the absorption and reflection of buildings, objects, and human bodies.</p>   |   |  |   |
| <p><sup>a</sup>The field strength of stationary transmitters, such as wireless (peak / cordless) telephone and ground mobile radio, amateur radio, amplitude and FM radio and television radio, etc, is not accurately predicted in theory. In order to evaluate the electromagnetic environment of the fixed RF transmitter, the survey of the electromagnetic field should be considered. If the field strength of the site is higher than the applicable RF compliance level mentioned above, the infant radiation insulation platform shall be observed to verify its normal operation. If abnormal performance is observed, supplementary measures may be required, such as readjust the orientation or position of the infant radiation thermal table.</p> <p><sup>b</sup>In the entire frequency range of 150 kHz ~ 80 MHz, the field intensity should be lower than 3V / m.</p> <p><sup>c</sup>Continuous continuously according to the expected function specified in the baby radiation insulation platform at the level of 3V / m and the frequency of 26 MHz ~ 1 GHz.</p> |   |  |   |

<sup>d</sup>At the level below or equal to 10V / m, the frequency is 26 MHz ~ 1 GHz according to the expected function specified by the infant radiation insulation table or no dangerous safety failure.

<sup>e</sup>In the entire range of frequency 80MHz~2.5GHz, at the immunity test level of 3V / m, operate continuously according to the expected function specified by the manufacturer.

<sup>f</sup>Over the entire range of frequency 80MHz~2.5GHz, operating continuously at the 10V / m immunity test level, or for a failure that does not create a safety hazard.

Table 206 Recommended isolation distance between Portable and mobile RF communication devices and equipment or systems — for non-life support devices and systems

| Recommended isolation distance between portable and mobile RF communication equipment and infant radiation insulation table   |  |   |                                  |                                   |
|---|--|---|----------------------------------|-----------------------------------|
| The infant radiation thermal table is intended to be used in controlled electromagnetic environments with RF radiation harassment. Depending on the maximum rated output power of the communication equipment, the buyer or user may prevent electromagnetic interference by maintaining the minimum distance between the portable and mobile RF communication equipment (transmitter) and the infant radiation insulation table as recommended below |  |   |                                  |                                   |
| Maximum rated output power of the transmitter<br>W  | Isolation distance / m for the different frequencies of the corresponding transmitter        |   |                                  |                                   |
|   | 150 kHz~80 MHz<br>(Except for the engineering and medical frequency band)<br>$d=1.2\sqrt{P}$ | 150 kHz~80 MHz<br>(Engineering and medical frequency band)<br>$d=1.2\sqrt{P}$ | 80 MHz~800MHz<br>$d=1.2\sqrt{P}$ | 800 MHz~2.5GHz<br>$d=2.3\sqrt{P}$ |
| 0.01  | 0.12   | 0.12  | 0.12                             | 0.23                              |
| 0.1   | 0.38   | 0.38  | 0.38                             | 0.73                              |
| 1   | 1.2  | 1.2   | 1.2                              | 2.3                               |
| 10  | 3.8  | 3.8   | 3.8                              | 7.3                               |
| 100   | 12   | 12  | 12                               | 23                                |
| For the maximum rated output power of the transmitter not listed in the above table above, the recommended isolation distance d, in m (m) can be determined by the formula in the corresponding transmitter frequency bar, where P is the maximum rated output power of the transmitter provided by the transmitter manufacturer in watts (W).  |  |   |                                  |                                   |
| Note 1: used at 80 MHz and 800 MHz.   |  |   |                                  |                                   |
| Note 2: This guide may not be suitable for all situations, where the electromagnetic propagation is affected by the absorption and emission of buildings, objects, and human bodies.  |  |   |                                  |                                   |

(Corresponding to Table 206 in YY0505-2012)

### 3. Terms and definitions

#### I Baby radiant thermal insulation table

An electric power device including a radiant heat source to maintains thermal balance in an infant patient with direct radiation energy in the infrared range of the electromagnetic spectrum.

**I controller**

A temperature sensing controller that maintains a temperature between two specific values and may be set by the operator.

**I Infant control mode (servo control)**

An operating mode that approaches the user-set temperature value. In this operating mode, the power output changes automatically with the infants temperature.

**I manual mode**

A mode of operation regulated by the user, in which the heater output is output at a fixed energy level or a partial energy level at the maximum output.

**I preheat**

A preheating that keeps the mattress at a certain temperature, in which the heater output is output in a predetermined program.

**I Skin temperature sensor**

A signal sensing device comprising a connecting portion with the device for measuring the temperature of an infant's skin.

**I Set the temperature**

The temperature that is set on the controller.

**I Test device temperature**

Place one test device (simulating the temperature after the human body receives radiation energy) at the center point of the mattress surface and four equal points of the mattress surface (see Figure 2).

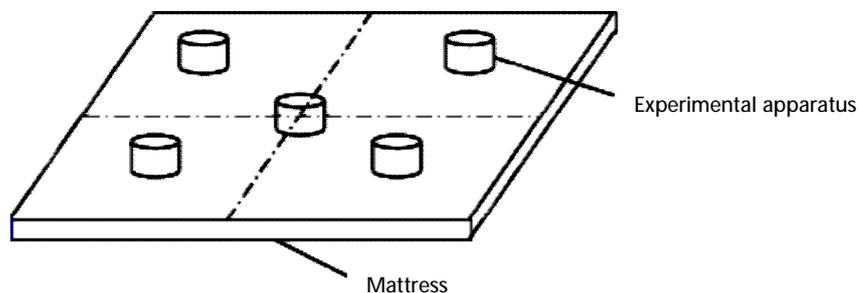


Figure 2

**I The constant temperature state**

The temperature is set in the middle of the device mattress to a change of no more than 1°C per hour.

**I Average temperature of the test device**

Take the average temperature value of the middle of each test device during the period of constant temperature.

**I Temperature control accuracy**

The difference between the temperature determined by the skin temperature sensor and the controlled temperature.

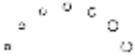
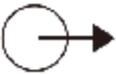
**I Bed surface temperature uniformity**

Maximum difference between the average temperature at the center point of the test device and the average temperature of the other four test units.

**I The APGAR score-timing function**

According to the APGAR scoring principle, the 1min, 5min and 10min time prompts were provided.

## Symbols, signs

| Symbols and signs   | explain  | Symbols and signs   | explain   | Symbols and signs   | explain  |
|---|--|---|---|---|--|
| I 类   | Class I equipment                                    |    | Type BF equipment   |    | alternating current (AC)                       |
|    | pay attention to!<br>Consult random files            |    | Manufacturing date  |    | identification of product                      |
|   | Total power supply is connected                      |    | Total power is disconnected                               |    | Protective grounding (earth)                   |
|    | Wear a blindfold                                     |    | Negative pressure regulation direction                    |    | On (only in part of the device)                |
|    | Skin temperature                                     |    | Auxiliary skin temperature                                |    | Controller off                                 |
| MAX-P   | Preset the maximum pressure delivered to the patient | PIP   | Control the inspiratory pressure delivered to the patient |   | The air inlet connects to the air source       |
|  | Air port to the patient                              |  | Controller open   |  | Disconnect (used only in a part of the device) |

## 4 Installation

### 4.1 Removing the box

Warm table is for integral carton packaging. Avoid scratching the surface of the machine or damaging the parts when unpacking.

When opening the foam, open the top foam first (see Figure 3).

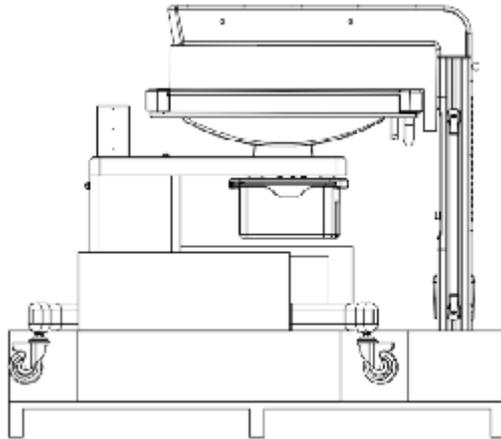


Figure 3

### 4.2 Installation

The installation of the equipment shall be completed by 2 persons familiar with the product, and the installation tools shall be placed in the packaging bag of the instruction manual.

Please check the integrity of the parts, accessories and data against the packing list.

#### 4.2.1 Installation of crib baffle

1、 Place the crib baffle parallel to the crib surface (see drawing 4.1), insert into the slot of the hinge seat, and keep this direction down to the bottom of the slot.

2、 Turn the crib baffle vertically to the crib surface and press down (see Figure 4.2)

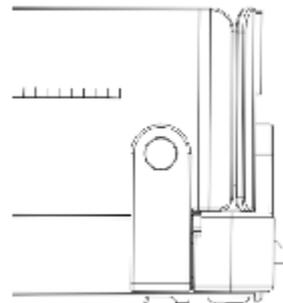
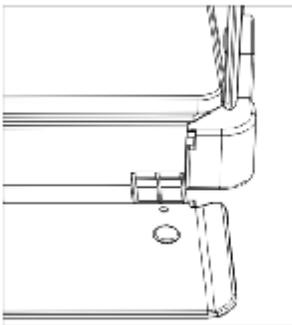


Figure 4.1 Figure 4.2



Attention

There are four crib panels, with a card slot as the front panel. When installing the rear gear panel, you need to tilt the crib toward the front to the maximum angle.

#### 4.2.2 Installation of the columns (see Figure 5)

1. Use a 5mm hexagonal wrench to spin out the 6 M 6 X1 6 inner hexagonal round head screws fixed on the pin column.
2. Insert the upper column assembly into the foot column.

3. Use the M 6 X1 6 hexagonal round head screw to tighten the upper column, and connect the lift power supply with the lift foot.



Attention

It must be ensured that the radiation head and the rear post remain vertical, otherwise the

temperature uniformity of the baby bed surface will be affected.

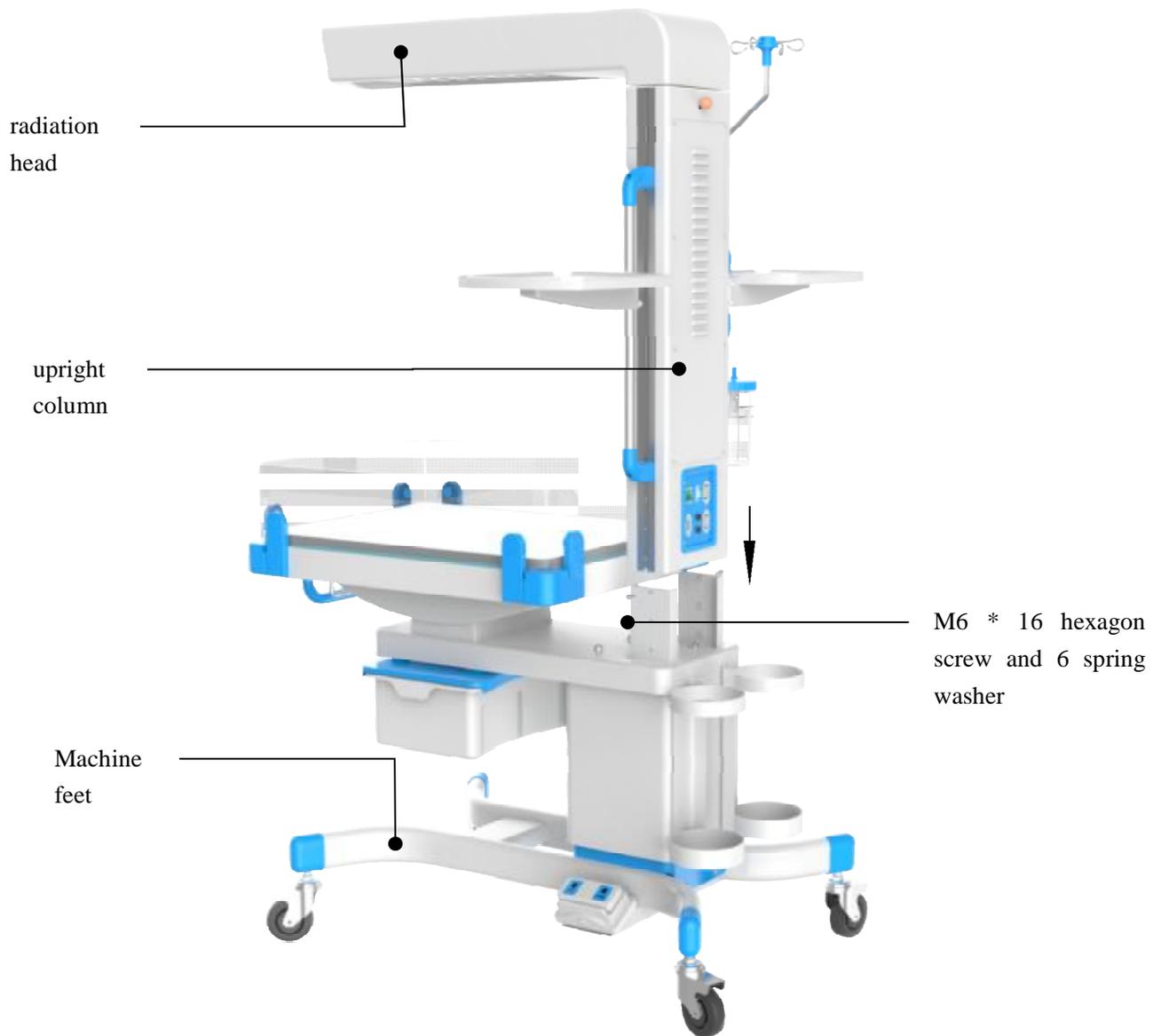


Figure 5

#### 4.2.3 Installation of the infusion rack

1. Insert the infusion holder into the mounting hole of the infusion holder and tighten the fixing knob (see Figure 6).
2. Use the socket wrench to adjust the height of the infusion holder.

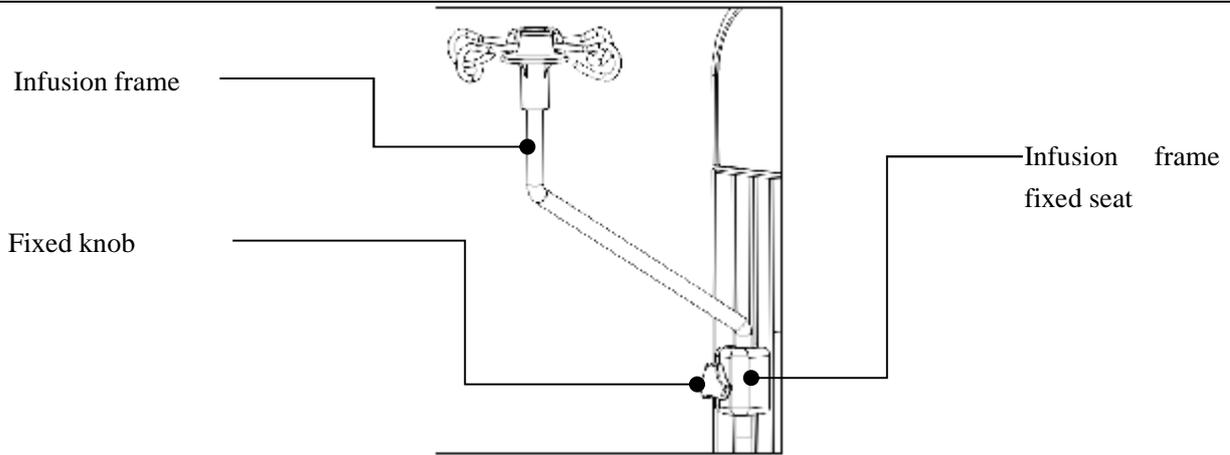


Figure 6

#### 4.2.4 Installation of the tray

1. Use 4mm hexagon wrench to pre-install M 5 X40 hexagonal stud,  $\phi$  5 spring washer,  $\phi$  5 flat washer.
2. Install the tray on the tray fixture, and reset it with the M 5X40 hexagonal stud,  $\phi$  5 spring washer and  $\phi$  5 flat washer. When tightening the front hexagonal stud, you need to rotate the tray back, and rotate the back hexagonal stud forward (see Figure 7).

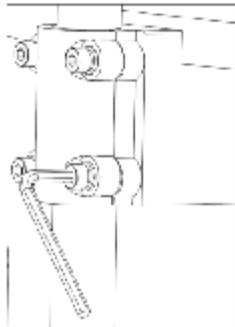


Figure 7

#### 4.2.5 Installation of the jaundice treatment lamp

Install as shown in Figure 8, align the two gourd holes on the light box at the two fixed screws on both sides of the radiating head, and then push the screws into the hoist hole as shown in Figure 9. When the fixed screw and the hanging lamp change from the installation state of FIG. 9.2 to FIG. 9.3, it indicates that the hanging lamp has been installed.

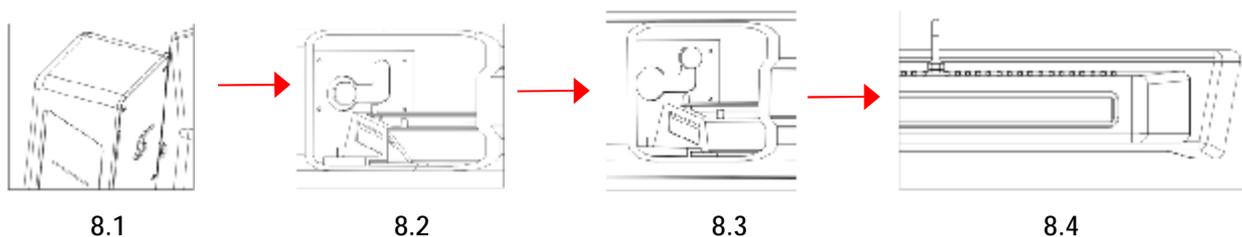


Figure 8

#### 4.2.6 Installation of the Electric Suction assembly

1. Use the screwdriver to spin out the M3X12 cross groove sink head screw preinstalled on the column side groove.
2. Use the M3X12 cross screw (see Figure 9.1).
3. Connect the suction catheter to the suction port on the suction device panel (see Figure 9.2).
4. Connect the suction tube to the suction port on the liquid storage bottle (see Figure 9.3).



**Attention** When connecting the silicone tube of the suction port, it should be connected to one end of the overflow valve.

The middle section of the suction catheter is equipped with filters and the air filter should be replaced frequently (it must be replaced after each patient); the suction soft catheter should be cleaned and disinfected at any time (it is recommended to replace it after 300 times), and the replaced parts should be destroyed centrally.

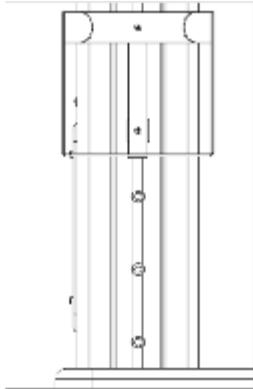


Figure 9.1

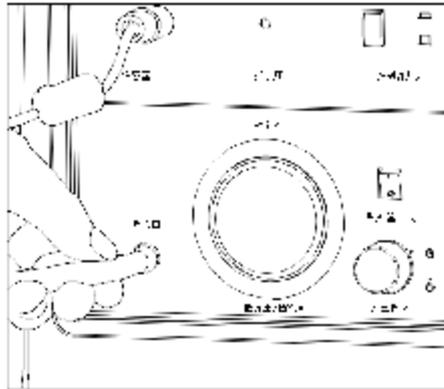


Figure 9.2



Figure 9.3

## 5 Overview

### 5.1 Scope of application

This product is suitable for open care, rescue and temperature regulation for newborns. Taboo: No.

### 5.2 Main components of the products

The products are mainly composed of radiation head, controller, crib frame, foot, skin temperature sensor, tray, infusion frame, electric lift foot (optional), jaundice treatment lamp (optional), electronic scale (optional), T combination resuscitation device and empty oxygen mixing device (optional), pulse oxygen monitoring device (optional), auxiliary skin temperature sensor (optional).

The adds the following configuration: electric suction.

### 5.3 Function identification of different product models

| major function \ model   | CCR-4000A                               | BRW-4000B |
|--|---|-----------|
| human-computer interface                                       | LCD LCD display, touch screen operation |           |
| Baby control   | ▲                                       | ▲         |
| manual mode  | ▲                                       | ▲         |
| APGAR reckon by time   | ▲                                       | ▲         |
| The RS-232 interface   | ▲                                       | ▲         |
| headlamp   | ▲                                       | ▲         |
| electric suction apparatus                                     | --                                      | ▲         |
| jaundice treatment lamp  | Optional                                | Optional  |
| Electric lift foot   | Optional                                | Optional  |
| X-ray box frame  | ▲                                       | ▲         |
| Storage drawer   | ▲                                       | ▲         |
| T combination resuscitation device, empty-oxygen mixing device | Optional                                | Optional  |
| electronic balance   | Optional                                | Optional  |

|   |          |          |
|---|----------|----------|
| Pulse and blood oxygen detection device | Optional | Optional |
| Assisted skin temperature detection     | Optional | Optional |

Note: Please read this manual according to the selected model!

- heating-rate curve

At the ambient temperature of 21°C ~26°C, the target temperature is set as the maximum value, and the infant bed surface temperature rises by 11°C

as illustrated in following figure:

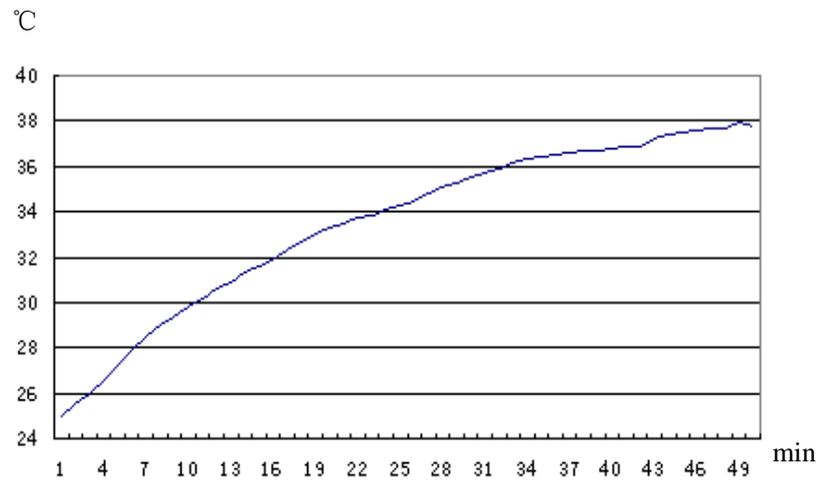


Figure 1 0

## 5.5 Basic technical parameters

| Order no | Model  |  |  |
|----------|--|--|--|
|          | Technical parameter  |  |  |
|          |  | CCR-4000A  | BRW-4000B  |
| 1        | temperature resolution   | 0.1℃   |  |
| 2        | Skin temperature control range   | 32.0～37.5℃   |  |
| 3        | Skin temperature and ultra temperature alarm                                 | 38.5 ±0.1℃   |  |
| 4        | Temperature display range  | 5℃～65℃   |  |
| 5        | Skin temperature sensor accuracy   | ±0.2℃  |  |
| 6        | Temperature control accuracy   | ≤0.5℃  |  |
| 7        | Bed surface temperature uniformity   | ≤2℃  |  |
| 8        | Temperature deviation alarm  | ±1℃  |  |
| 9        | APGAR Timing (s)   | The timing error should not be greater than ±4s at 1 min, 5min and 10min.  |  |
| 10       | The APGAR acoustic-light cue   | At 50s to 1min, 4min50s to 5min, 9min50s to 10min and display synchronous sound prompt; the timer shall be manually reset in any of its cumulative times |  |
| 11       | Radiation head level adjusts the angle                                       | ±90° (Adjustable and locked)   |  |
| 12       | Bed surface tilt adjustment angle  | ±12° (stepless adjustable)   |  |
| 13       | Center illumination of bed surface   | ≥700 lx  |  |
| 14       | Tray carrying capacity   | ≤2Kg   |  |
| 15       | Infusion frame bearing capacity  | ≤2Kg   |  |
| 16       | The infusion frame adjusts the height  | 180～200 mm   |  |
| 17       | Lift foot stroke   | 0～180 mm   |  |
| 18       | Suction limit negative pressure value KPa                                    | --   | <sup>+1</sup><br>18 KPa<br><sub>-5</sub>                               |
| 19       | Transient pumping rate, L / min  | --   | 1 ±0.5 L/min   |
| 20       | Negative pressure adjustment range, KPa                                      | --   | 1 ~ arbitrary adjustment in the range of limit negative pressure value |
| 21       | Total bilirubin irradiance crest value E <sub>bi</sub>                       | 1700±25% μW/cm <sup>2</sup> (The vertical distance between the light source plane and the effective test surface is 80cm)                                |  |
| 22       | Total bilirubin irradiance homogeneity                                       | E <sub>bimin</sub> /E <sub>bimax</sub> = G <sub>2</sub> > 0.4  |  |
| 23       | Range of the main radiation spectrum (blue light wavelength) of phototherapy | 400nm～550nm  |  |
| 24       | Phototherapy controller timing function                                      | The phototherapy controller has the function of current time timing and cumulative time timing   |  |
| 25       | consumed power   | 800VA  |  |
| 26       | heating-up time  | ≤1h  |  |

|    |   |   |
|----|---|---|
| 27 | Foot switch waterproof grade                                      | I PX3   |
| 28 | T. Gas source requirements for combined resuscitation units       | Capacity greater than 100L gas cylinder or gas supply system, pressure: 0.3MPa~0.4MPa   |
| 29 | T combination recovery unit flow adjustment                       | 0~15L/min   |
| 30 | Adjust the oxygen concentration of the empty oxygen mixing device | 21%~100%  |
| 31 | MAX-P   | 0 to 15 LPM gas flow exceeding 6 KPa  |
| 32 | T combination resuscitation unit gas source fault hearing alarm   | If the air source or oxygen source is interrupted or the pressure difference exceeds 0.1MPa, an auditory alarm shall be generated. The alarm level shall not be no less than 60dB (A), and the alarm time shall last at least 60s |
| 33 | PIP adjustable range  | 5 LPM gas flow rate: 0.2~2.7KPa (2cmH2O~27cmH2O), tolerance of $\pm 10\%$   |
| 34 |   | 8 LPM gas flow rate: 0.4~3.6KPa (4cmH2O~36cmH2O), tolerance of $\pm 10\%$   |
| 35 |   | 10 LPM gas flow rate: 0.6~4.2KPa (6cmH2O~42cmH2O), tolerance of $\pm 10\%$  |
| 36 |   | 15 LPM gas flow rate: 1.2~5.7KPa (12cmH2O~57cmH2O), tolerance of $\pm 10\%$   |
| 37 | PEEP adjustable range   | 5 LPM gas flow rate: 0.03~0.6KPa(0.3cmH2O~6cmH2O), with tolerance of $\pm 10\%$   |
| 38 |   | 8 LPM gas flow: 0.08~1.4KPa(0.8cmH2O~14cmH2O), tolerance $\pm 10\%$   |
| 39 |   | 10 LPM gas flow rate: 0.1~1.7KPa (1cmH2O~17cmH2O), tolerance of $\pm 10\%$  |
| 40 |   | 15 LPM gas flow rate: 0.25~2.3KPa(2.5cmH2O~23cmH2O), with tolerance of $\pm 10\%$   |
| 41 | Measurement range of the electronic scale                         | 0.1~8Kg   |
| 42 | Electronic scale resolution                                       | 5g  |
| 43 | Electronic scale accuracy   | $\pm 50g$   |
| 44 | The SpO <sub>2</sub> display range                                | 1~100%  |
| 45 | Accuracy of the SpO <sub>2</sub> measurement                      | $\pm 3\%$   |
| 46 | The SpO <sub>2</sub> display resolution                           | 1%  |
| 47 | The SpO <sub>2</sub> calibration range                            | 70~100%   |
| 48 | The SpO <sub>2</sub> alarm upper limit setting range              | 50~100%   |
| 49 | The SpO <sub>2</sub> alarm lower limit setting range              | 45~95%  |
| 50 | PR indication range   | 30-240bpm   |
| 51 | PR certainty of measurement                                       | $\pm 3bpm$  |

|    |                                    |           |
|----|------------------------------------|-----------|
| 52 | The PR displays the resolution     | 1 bpm     |
| 53 | Scope of PR calibration            | 25-240bpm |
| 54 | PR alarm upper limit setting range | 80-240bpm |
| 55 | PR alarm lower limit setting range | 35-180bpm |

Note: Please read this manual according to the selected model! The operation mode of the attractor is the intermittent attraction.

#### 5.6 Normal working environment

- a) Power supply voltage:  $\sim 220 \pm 22V$ ,  $50 \pm 1H z$ .
- b) Ambient temperature:  $18^{\circ}C \sim 30^{\circ}C$  (the control temperature is at least greater than the ambient temperature of  $3^{\circ}C$ ).
- c) Relative humidity: 30%~75%.
- d) Atmospheric pressure: 70 kPa  $\sim$  106 kPa.
- e) The ambient air flow rate is less than 0.3 m/s.
- f) In a place where the air flow is relatively static, without direct sunlight and other heat sources of influence.

## 6. Main structure and inspection

### 6.1 Radiation head

1. Check whether the protective cover is loose, confirm that the ceramic plate is not loose and installed reliably (s drawing 1 1).

2. Ensure that the jaundice treatment lamp is not loose and the fixation screw has been fastened.



Figure 1 1

### 6.2 Infusion rack

1、 Hook no loose, deformation and other phenomena.

2、 Confirm that the screws are fastened and the fixing knob is tightened (see Figure 12)

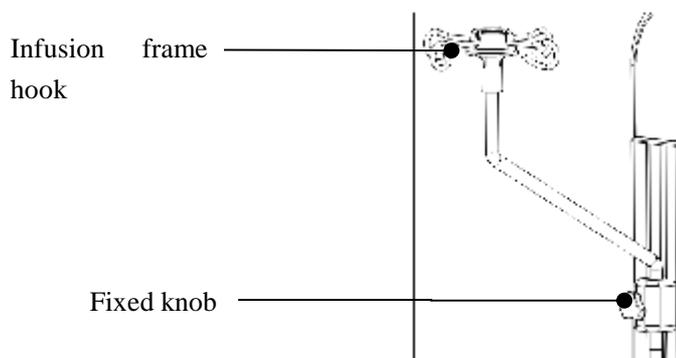


Figure 1 2

### 6.3 Tray

1. Ensure that the screws of the tray are fastened and without loosening.

2. Check the tray for no deformation, no surface fracture and cracking phenomenon (Figure 1 3).

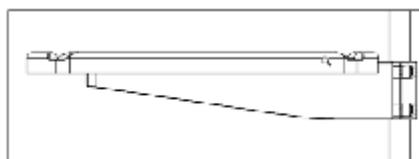


Figure 1 3

## 6.4 Infant bed body

- 1、 Check the crib baffle without deformation and surface fracture or cracking (see Figure 1 4).
- 2、 Make sure that the crib baffle is firmly installed and not loose.

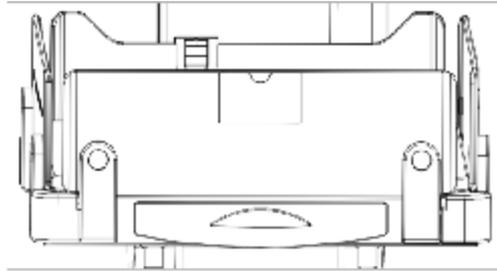


Figure 1 4

## 6.5 Machine foot

Confirm that the casters are intact, free, undamaged, flexible, complete and reliably connected (see Figure 1 5).

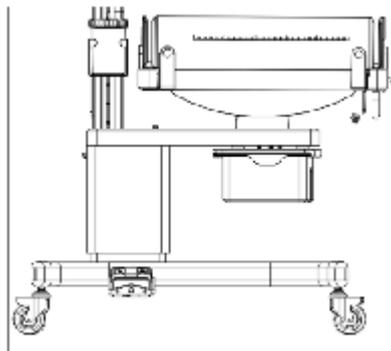


Figure 1 5

## 7 Function introduction

The warm platform is an open nursing platform, making it easier for medical staff to approach the baby and win precious time for rescue.

A far infrared heater is installed on the radiation cover of the thermal table, and the heat is radiates radiated to the mattress, which can effectively reduce the incidence of neonatal swelling. The skin temperature sensor is close to the baby skin, and the servo control of the controller enables the baby skin temperature to reach and maintain the temperature set by the medical staff.

Note: the so-called servo control refers to: the temperature control system automatically skin temperature sensor with the temperature value set by the operator, calculation, get one or several control signals to automatically adjust the power of the thermal platform far infrared heater, to gradually eliminate the deviation between the sampling value and the set value, so that the baby skin temperature to reach the temperature set by the operator.

### 7.1 Temperature control mode

The temperature control mode of the thermal platform is divided into: manual mode and infant control mode (ser

control).

### 7.1.1 Preheat

Preheat is a fixed type of program operation mode.

In this state, the system will output heat according to the predetermined program, and after a period of operation (the initial preheating operation time is about 5 and a half minutes), the system will automatically enter the infant control mode.



**Attention** During preheating, the baby is not allowed to be placed on the baby mattress to avoid the risk of high temperature output; preheating is generally only used for the preheating process of the initial startup.

### 7.1.2 Infant control mode (servo control)

In this mode, the operator sets the skin temperature to be maintained by the baby, and the controller samples through the skin temperature sensor to automatically adjust the output power of the far infrared heater and radiates to the baby, so as to affect and adjust the required body temperature of the baby. The value of infant skin temperature can be set to 32°C to 37.5°C.



**Attention** This control mode is the main and most basic working mode of the thermal platform.

In this control mode, please ensure that the skin temperature sensor is correctly and reliably attached to the baby skin, and pay close attention to the baby temperature, to prevent the sensor from falling off, and do not cover blankets and other objects on the sensor.

The operator should set the skin temperature control value correctly according to the clinical needs.

When the baby is in fever or shock, this mode should not be used in order to avoid incorrect heat output, resulting in too cold or overheating, it is recommended to use "manual mode".

### 7.1.3 Manual mode

The manual mode shall output the heat at the heating ratio set by the operator, which is intended for short rescue rewarming of the patient. In some clinical cases, when the patient urgently needs the thermal platform, and the warm platform does not complete the preheating temperature, the operator can use the manual method to quickly heat the thermal table to the required temperature.

The proportion of manual heating output can be set to 0-100%. The operator can set the heating ratio through the man-machine interface. The "Heating indication" indicates the proportion of heating power, and each grid represents 10% heating power.

After 15 minutes of manual work, sound and light prompts (horn warning, man-machine interface hand icon shining) are issued to attract the attention of medical staff. At this time, there are two choices: A: If the "noise" of the man-machine interface is not pressed within two and a half minutes, the manually set heating power will be replaced by a 30% constant heating power. B If you press the "silence" button of the man-machine interface, you can maintain the manual mode for another 15 minutes, clear the beep alarm at the same time, and then continue to select A and B.



**Attention** In this control mode, infants are not allowed to be placed on the mattress, avoiding the risk of high temperature output.

If there is a baby on the thermal platform, the heating output ratio is not controlled by the temperature measured by the skin temperature sensor. Close attention should be paid to the

fluctuation of the baby body temperature, and the baby should not be in an unattended state.

## 7.2 Fault alarm function and description



Attention

- 1) Equipment alarm can reduce the risk of use, but absolute safety cannot be guaranteed. At any time, hospital personnel must watch the equipment in use while there, and the sound and light alarm state of the equipment can be effectively found within 4 meters of the equipment.
- 2) Due to safety needs, the parameters of the alarm function have been preset by the manufacturer when leaving the factory, and the user cannot change them. Power supply loss or power recovery will not change the preset parameters of the alarm function.
- 3) When any alarm of the thermal table, the sound level of the baby mattress shall not exceed the A-weighted sound pressure level of 80dB, and the sound level of the auditory alarm shall be at least 3m in front of the control device.

The alarm state can be divided into physiological alarm state and technical alarm state, specifically as follows:

- 1) Physiological alarm status: skin temperature deviation alarm.
- 2) Technical alarm status: power failure alarm, sensor fault alarm and over temperature alarm.

7.2.1 Fault alarm category and alarm status description are shown as follows:

| order no | Alarm status                     | state description   | remarks  |
|----------|----------------------------------|---|--|
| 1        | Power alarm                      | Open the controller, when there is no power supply, the alarm starts, the alarm indicator light is on, and the horn emits a continuous alarm sound.(If the main control board has no battery or the battery power is too low, the power failure alarm fails. When the power failure alarm occurs, please check the power supply).   | Built-in battery power supply to implement the alarm, press the "sound pause" button can not pause the sound.  |
| 2        | Sensor fault alarm               | <p>1. Short circuit or open circuit inside the temperature sensor (not inserted).</p> <p>2. When the sampling temperature is always lower than the set value of 3.5℃ or the sensor sampling value violates the logic, the alarm will start. The alarm indicator light is shining, the horn emits a continuous alarm sound, and the interface alarm information is shining for display.</p> <p>Under the infant control mode, before the skin temperature sensor is not placed accurately, the alarm starts, the alarm indicator flashes, the horn emits a continuous alarm sound, and the interface alarm information is displayed.</p> | Press the "sound pause" button to temporarily stop the sound alarm. If the fault is not eliminated within 5 minutes, the sound alarm will be automatically restored. |
| 3        | Skin temperature deviation alarm | Under the infant control mode, when the temperature measured by the skin temperature sensor is higher   | Press the "sound pause" button to temporarily  |

|   |                              |  |   |
|---|------------------------------|--|---|
|   |                              | <p>than the skin temperature set value of 1°C, the alarm starts, the alarm indicator light flashes, the horn emits a continuous alarm, and the interface alarm information is displayed brightly.</p> <p>Under the infant control mode, after the temperature is stable, when the temperature measured by the skin temperature sensor is lower than the skin temperature set value of 1°C, the alarm starts, the alarm indicator light flashes, the horn emits a continuous alarm sound, and the interface alarm information is displayed.</p> | <p>stop the sound alarm. If the fault is not eliminated within 5 minutes, the sound alarm will be automatically restored.</p> |
| 4 | Over temperature alarm       | <p>When the temperature of the thermal platform rises to 39°C interval, the alarm starts, the alarm indicator light flashes, the horn emits a continuous alarm sound, and the alarm information of the interface is displayed.</p> <p><b>Note: When the over temperature alarm, the heating pipe cut off the power supply will not automatically resume heating, and should be restarted.</b></p>  | <p>Press the "sound pause" key, can not temporarily stop the sound alarm, restart the boot to stop the sound alarm.</p>       |
| 5 | The sound alarm is suspended | <p>When the alarm sound appears, press this key to temporarily cancel the alarm sound. If the fault is not removed within 5 minutes, the alarm sound will be restored.</p>   | <p>audible alarm pause, and can not visual alarm pause.</p>   |

Note: The sound pause ala  bol



- Attention
- 1) When any alarm (sound and light) occurs, the baby should be immediately removed, stop using, and the relevant technology or equipment pipe should be notified. Management personnel to deal with. And make the prohibited mark on the thermal table, and use it after the fault is solved.
  - 2) When the fault alarm occurs, the equipment will automatically cut off the heating power supply (except for the lower deviation alarm).
  - 3) Shut alarm signal: when the over temperature alarm occurs, even if the fault has been eliminated, the heating pipe will not automatically restore the heating, and should be restarted.
  - 4) Non-bolt alarm signal: except for the bolt alarm signal, other fault alarms will be automatically restored after troubleshooting Heating of the power supply control.

## 7.2.2 Confirmation of alarm status is as below:

| order number | Alarm status                     | Determination of the alarm status  | remarks   |
|--------------|----------------------------------|--|---|
| 1            | Power alarm                      | When the equipment emits a long sound alarm, and the "power off" indicator light on the control board is always on, other digital display and indicator lights are not on. The device enters the "power off" alarm state.  | The inherent delay of the device alarm status is within 1 second; the operator is within 1 m in front of the device.                  |
| 2            | Sensor fault alarm               | When the device issued "di di... didi, didi....." sound alarm, in addition to the red alarm indicator flashing light, the alarm information display box has "skin temperature sensor fault" display. The device enters the "Sensor Failure" alarm state.                                   | The inherent delay of the device alarm status is within 30 seconds; the operator is within 1 m in front of the device.                |
|              |                                  | When the device issued "di di... di, didi... di,..." sound alarm, in addition to the red alarm indicator flashing on the display, alarm information display box has "skin temperature sensor placement error" display. The device enters the "Sensor Failure" alarm state.                 |   |
| 3            | Skin temperature deviation alarm | When the device issued "didi... didi, didi....." sound alarm, in addition to the red alarm indicator flashing light, the alarm information display box has "high skin temperature alarm" display. The device enters the Temperature Deviation alarm state.                                 | The inherent delay of the alarm status of the device is within 2 seconds; the operator is within 1 m in front or side of the device.  |
|              |                                  | When the device issued "didi... didi, didi....." sound alarm, in addition to the red alarm indicator flashing light, the alarm information display box has "low skin temperature alarm" display. The device enters the Temperature Deviation alarm state.                                  |   |
| 4            | Over temperature alarm           | When the device issued "di di... di, di di, di....." sound alarm, in addition to the red alarm indicator flashing light, the alarm information display box has "over temperature, cut off heating, repower can be reset" display. The equipment enters the "over temperature" alarm state. | The inherent delay of the alarm status of the device is within 30 seconds; the operator is within 1 m in front or side of the device. |

## 7.2.3 Alarm status priority, visual alarm and auditory alarm signal features are shown as follows:

| Alarm status | priority | Visual alarm status   |                   |            | auditory alarm status             |                  |                           |
|--------------|----------|-----------------------|-------------------|------------|-----------------------------------|------------------|---------------------------|
|              |          | Indicator light color | flicker frequency | duty cycle | Number of pulses within the pulse | Pulse group time | Interphase of pulse group |
|              |          |                       |                   |            |                                   |                  |                           |

|                                  |      |        |              |      |       |      |           |
|----------------------------------|------|--------|--------------|------|-------|------|-----------|
|                                  |      |        |              |      | group |      |           |
| Power alarm                      | low  | yellow | Often bright | 100% | --    | --   | Long song |
| Sensor fault alarm               | tall | red    | 2Hz          | 50%  | 10    | 2.8s | 6.5s      |
| Skin temperature deviation alarm | tall | red    | 2Hz          | 50%  | 10    | 2.8s | 6.5s      |
| Over temperature alarm           | tall | red    | 2Hz          | 50%  | 10    | 2.8s | 6.5s      |

Note: High Priority alarm display  Middle Priority alarm display  Low Priority alarm display icon:   
 The feature diagram of the acoustic perception alarm signal is as follows:

The feature diagram of the auditory alarm signal is as follows:  
 High-priority alarm tone:

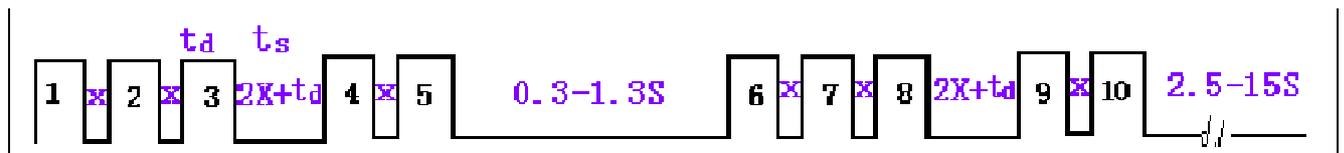


Figure A Characteristic representation of the pulse group of the auditory alarm signal

Table 1. Characteristics of the pulse interval:

| model clauses                           | Module setting | Standard requirements |
|---|----------------|-----------------------|
| Between the 1-2 pulses                  | 80ms           | 50~120ms              |
| Between the 2-3 pulses                  | 80ms           | 50~120ms              |
| Between the 3-4 pulses                  | 290ms          | 2x+td                 |
| Between the 4-5 pulses                  | 80ms           | 50~120ms              |
| Between the 5-6 pulses                  | 500ms          | 0.35 s ~ 1.30 s       |
| Between the 6-7 pulses                  | 80ms           | 50~120ms              |
| Between the 7-8 pulses                  | 80ms           | 50~120ms              |
| Between the 8 - 9 pulses                | 290ms          | 2x+td                 |
| Between the 9 - 10 pulses               | 80ms           | 50~120ms              |
| High-priority pulse population interval | 3s             | 2.5 s to 15.0 s       |

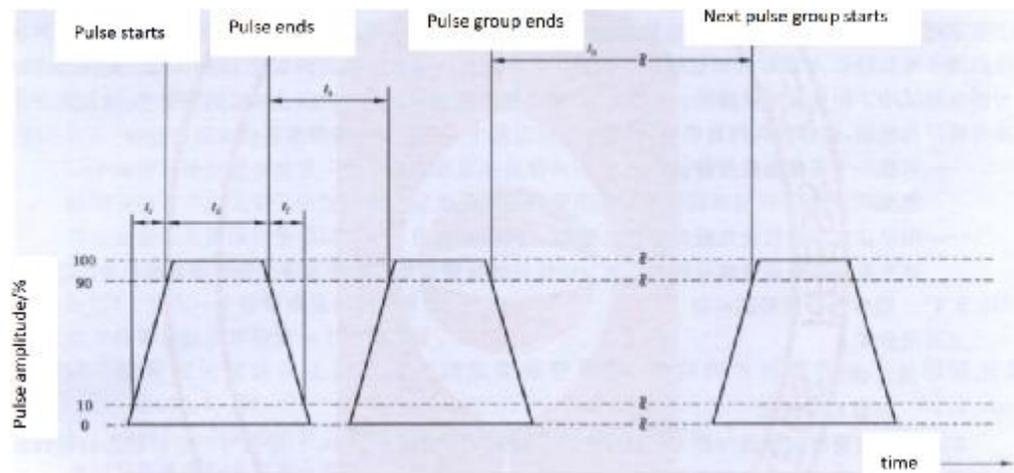
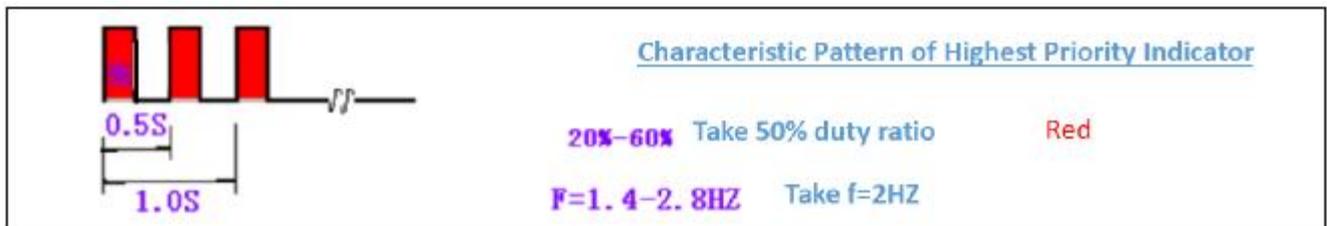


Figure B Graphic representation of the temporal characteristics of the auditory alarm signals

Table 2. Time characteristics:

| model clauses                      | Module setting | Standard requirements   |
|------------------------------------|----------------|-------------------------|
| rise time $t_r$                    | 20mS /15.4%    | 10%~20% $t_d$           |
| The pulse effective duration $t_d$ | 130mS          | 100~200mS               |
| drop-out time $t_f$                | 20ms           | $< 60mS \leq t_s - t_r$ |
| High-priority pulse interval $t_s$ | 80ms           | 50~120ms                |

The visual alarm signal features is as follows:



## 8 Functional check and use method



**Attention** Functional check shall be performed before first use or after each cleaning or maintenance!

During the examination, the baby should not be placed in the crib, in case of accidents.

Do not use the following inspection or find any foreseeable damage information. Relevant maintenance services must be performed by qualified personnel.

Ensure that the power supply meets the power specification indicated on the nameplate. In order to ground the thermal platform correctly and reliably, the power cord must be connected to the single-phase three-wire power socket, and the extended power cord should not be used.

### 8.1 Function and usage method of the controller

L) The thermal console controller of this series adopts touch screen and integrates man-machine operation. The touch display area is the main operating function of the

controller, "Skin temperature sensor socket" is used to connect the skin temperature sensor, "total power indicator" is used to indicate whether the device is on (main power switch is on), "controller switch" is used to open and close the controller; the controller panel is shown in the figure below.

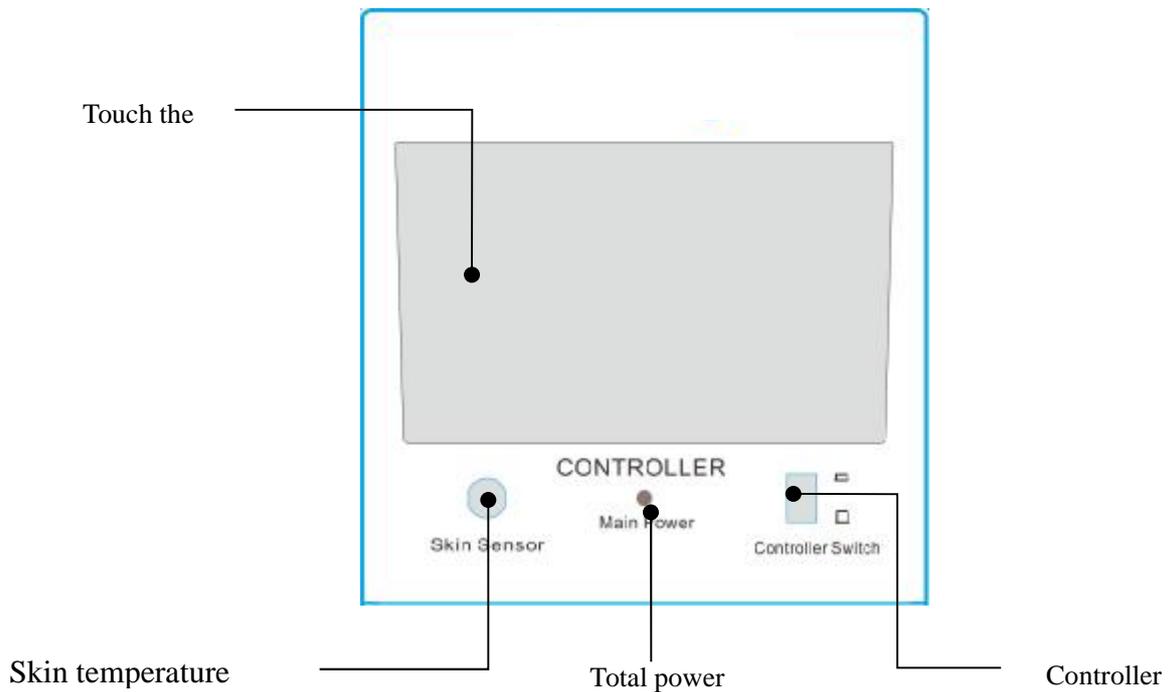


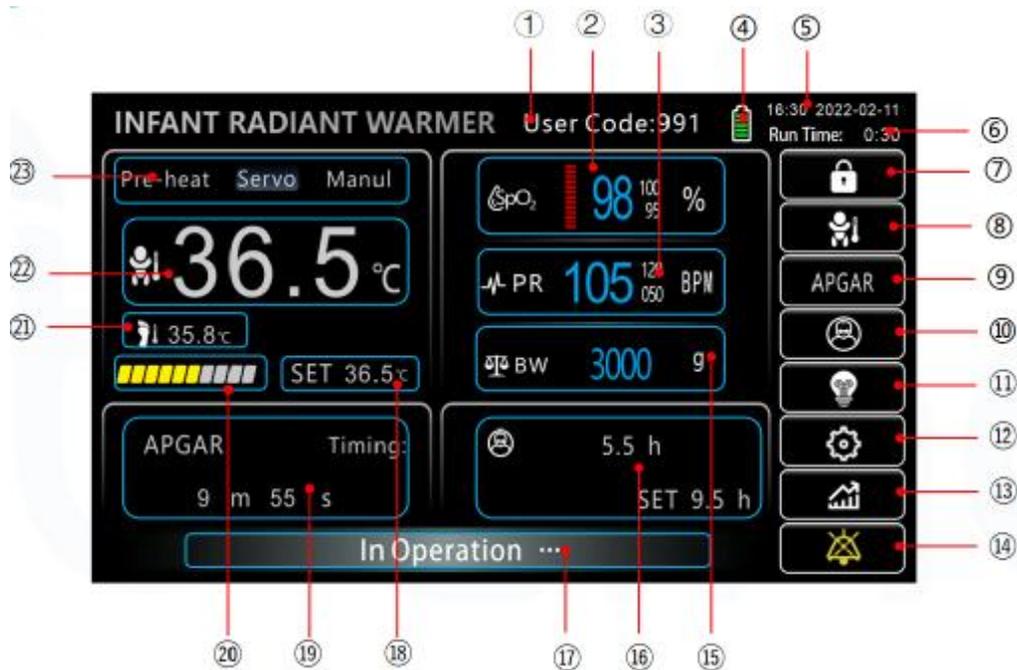
Figure 1 6

2) Power on the equipment and turn on the main power switch, press the controller switch and the controller runs the self-test; as shown in the figure below.



System Self-Test Initialization Interface (Figure Description: 1 7)

3) If the controller self-checks everything normally, it will enter the equipment operation main interface; the function of the controller main interface is as follows:



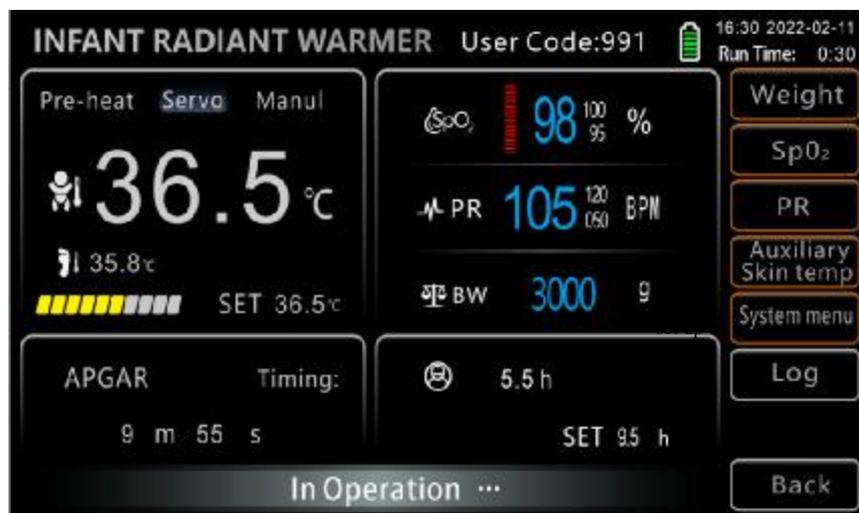
Main interface (Figure 1 8)

The function description table of the system main interface is as follows:

| Illustration number | Function and representation area    | explain   |
|---------------------|-------------------------------------|---|
| ①                   | Alarm indication area               | This area displays the alarm indication that may occur during the operation of the system, and the display of the relevant area becomes highlighted red when an alarm occurs. From left to right, the skin temperature sensor, skin temperature deviation, skin temperature sensor over temperature, and manual prompt. |
| ②                   | Blood oxygen showed the area        | This area displays the blood oxygen saturation information  |
| ③                   | Pulse display area                  | This area displays the relevant information of the pulse  |
| ④                   | Battery power area                  | Indicate the battery power information of the controller mainboard, and it will be shown in red when the battery power level is less than 10%. Please pay attention to replace the battery in time.   |
| ⑤                   | System date and time display area   | This area shows the date and time of the system.  |
| ⑥                   | Run time length display area        | This area shows the total running time running after the device is turned on: minutes   |
| ⑦                   | "Screen lock" touch button          | Press this key to lock and unlock the screen.   |
| ⑧                   | The "Skin Temperature" touch button | Press this key will enter the skin temperature setting interface.   |

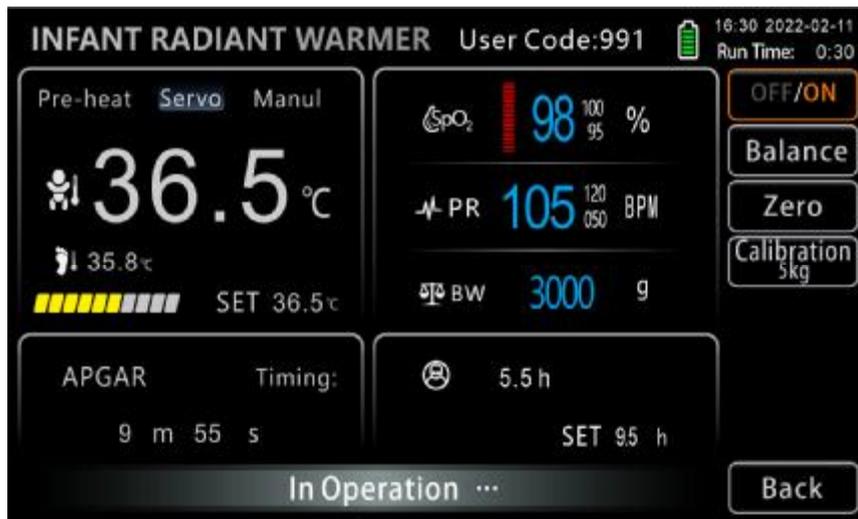
|   |   |   |
|---|---|---|
|   | touch button                                  |   |
| ⑨ | The "APGAR" touch button                      | Press this key to enter the APGAR setting interface.  |
| ⑩ | The " Phototherapy touch button               | Press this key to enter the phototherapy setting interface.   |
| ⑪ | The "Lighting" touch button                   | Press this key to turn on and off the lights of the device. This key is not limited by the screen lock, and you can also adjust the illumination of I, and file.                      |
| ⑫ | Touch button                                  | This key can be set for symmetrical weight, blood oxygen and pulse rate, auxiliary skin temperature matching function or set the system parameters and view the log                   |
| ⑬ | The Curve touch button                        | Press this key to enter the curve setting interface.  |
| ⑭ | "Silencing" touch button                      | Press this key to temporarily eliminate the alarm sound for 5 minutes. The manual mode is the operation key to continue running manually. This key is not limited by the screen lock. |
| ⑮ | Weight display area                           | This area shows the weight of the baby in units: grams  |
| ⑯ | Phototherapy information area                 | This area displays information about phototherapy, including set time, treatment time, and cumulative time.   |
| ⑰ | Alarm text information area                   | Display the relevant text information and prompt of the alarm.  |
| ⑱ | Set the temperature                           | Show the set temperature of the controller.   |
| ⑲ | APGAR information area                        | This area displays relevant information about APGAR.  |
| ⑳ | Heating power indication                      | Indicates the actual operating power of the radiator, with a total of 10 grids, and each grid represents 10%.   |
| ㉑ | Auxiliary skin temperature sensor temperature | Display the actual measured temperature of the auxiliary skin temperature sensor.   |
| ㉒ | Skin-sensor temperature                       | Shows the actual measured temperature of the skin sensor.   |
| ㉓ | Equipment operating mode indication           | This area displays the working mode of the device, where the current working mode is displayed in bold and highlighted.   |

4) When pressing the "Settings" button on the main interface, enter the following menu interface.



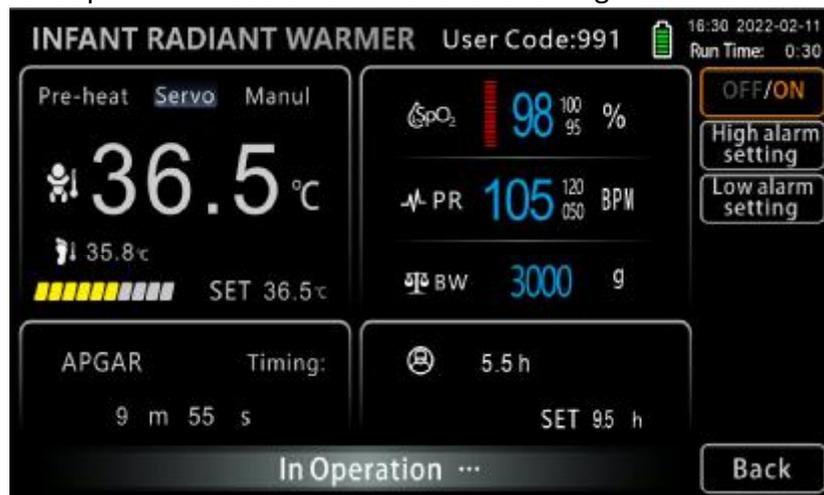
Menu interface (Figure illustration: 19)

- a) Click the "Weight" button to enter the following interface;



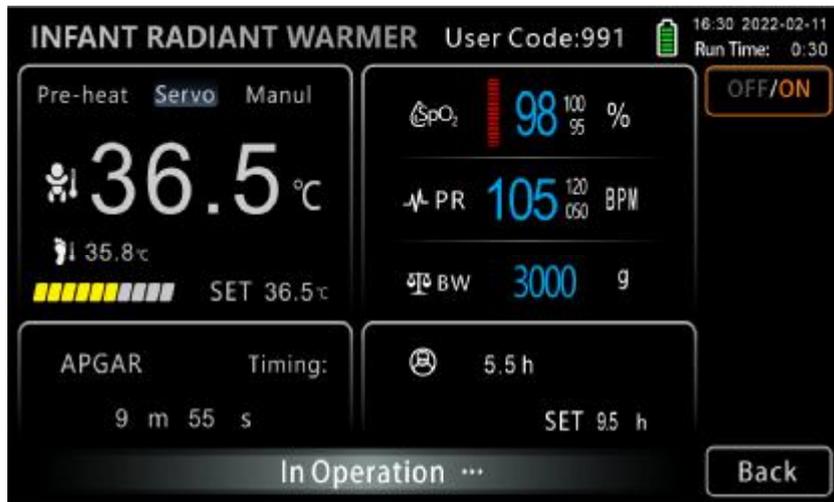
Click "OFF / ON" to choose to open or close the electronic scale function, and click "Balance" button to stably weigh the heavy value. Before weighing, click "Zero" button to zero, before weighing, place a 5kg weight on the bed surface, and then press "Calibration 5kg" button to calibrate the weighing accuracy (if the weighing is not accurate)

- b) Click the SpO<sub>2</sub> or PR button to enter the following interface:



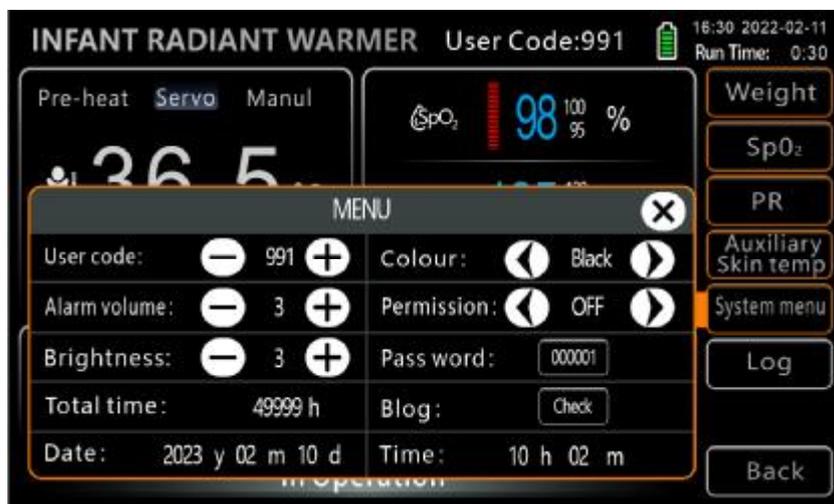
Click OFF / ON to select the SpO<sub>2</sub> or PR function on or off, and click High alarm setting or Low alarm setting to set the alarm upper or lower limit.

- c) Click the "Auxiliary Skin temp" button to enter the following interface:

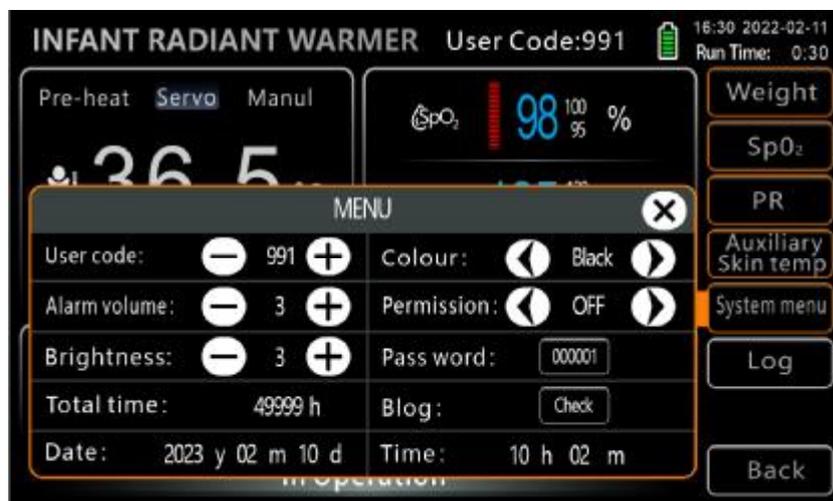


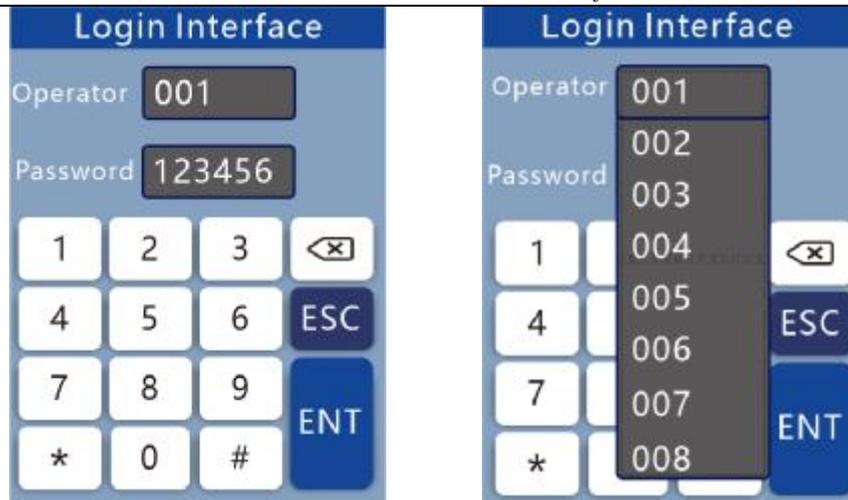
Click OFF / ON to turn the auxiliary skin temperature monitoring function on or off

d) Click the "System menu" button to enter the following interface;



Through this menu, the user can set the user code, adjust the alarm volume, adjust the lighting illumination, view the cumulative use time of phototherapy, set the date and time, switch the background color of the main interface, the password setting, the alarm log or work log to view, open or close the user permission





Note: ① After opening the operation permission, you need to enter the password to operate the device each time you start the machine;

② In order to avoid affecting the normal use, please carefully open the use permission!

③ Permission opening method: after switching the operation authority from "OFF" to "ON", the upper login interface will pop up in the operator

In the box, you can select 001,002,003,004,005,006,006,007,008. The default passwords are 000001,000002,000003,000004,000005,000006,000007,000008 respectively. For example, the password corresponding to the account number "001" is "000001".

④ Password modification: After the permission is opened, the password corresponding to each account number can be changed to a 6-bit password. Please keep it in mind after modification.

⑤ 008 account is advanced authority account, can also change the password of other accounts, modify must remember, if forgotten, please contact the manufacturer to restore the factory password setting.

⑥ Press the Back button to return to the main interface:

5) After pressing the "Skin Temperature" touch button on the main interface (which is used to set the working mode of the system and the manual input settings and servo temperature settings); as shown in the figure below.



Figure 2 8

6) When pressing the "APGAR" touch button on the main interface, enter the APGAR menu interface (this interface is used for opening and clearing the APGAR function); as shown in the figure below.

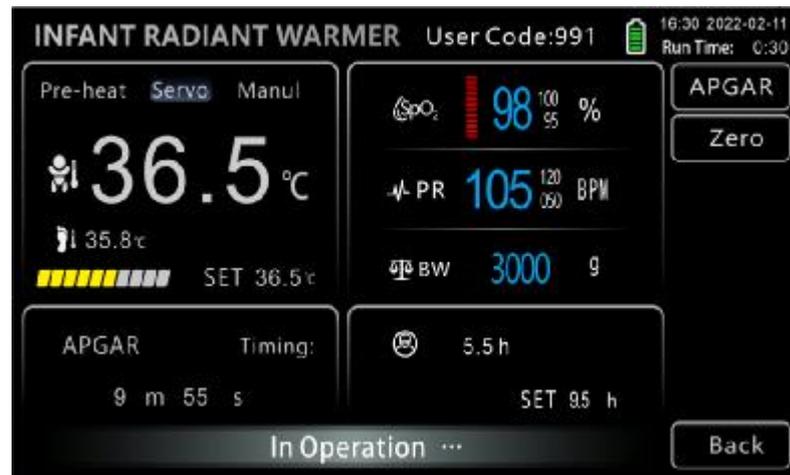
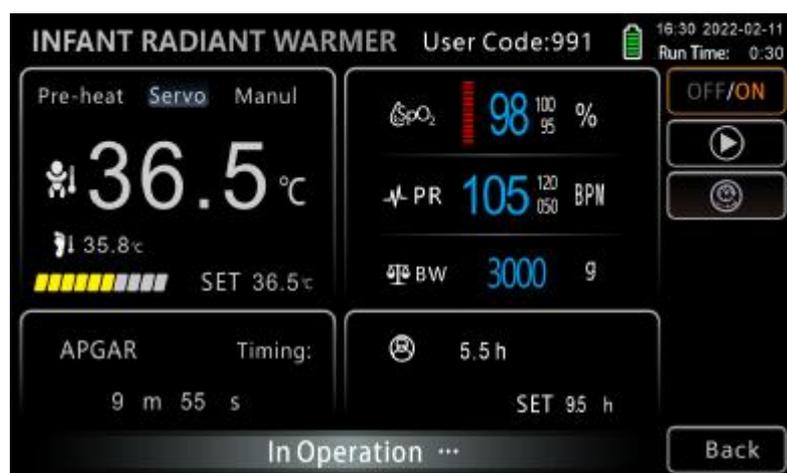


Figure 2 9

- ① Press APGAR, the APGAR timer starts working, and the display window starts timing. Run to 50 seconds to 1 minute, 4 minutes and 50 seconds to 5 minutes, 9 minutes and 50 seconds to 10 minutes, will be respectively sound and light prompt for 10 seconds.
- ② If you need to pause, press the "APGAR" key; repeatedly open or pause timing.
- ③ If you do not need to continue to use, press the "timing" or "zero" key to turn to the timing function.

**⚠ Attention** The APGAR timer no longer gives sound and light prompts after 1,5 or 10 minutes, and the APGAR timer automatically enters the pause mode. After pressing the Zero button, click the APGAR button again to enter the APGAR timing mode

7) Click the "Light therapy" touch button to enter the following interface



Click OFF / ON to turn phototherapy on or off, or click the Start / Pause button to start or suspend treatment. After phototherapy is turned off, click the Time button to set the treatment time.

7) When pressing the "Curve" button on the main interface, enter the curve menu interface (this interface is used for the device to view and clear the skin mild heating power curve within 96 hours, and select the blood oxygen and pulse rate monitoring

function, with the view and clear of the blood oxygen and pulse rate curve within 96 hours); as shown in the figure below.

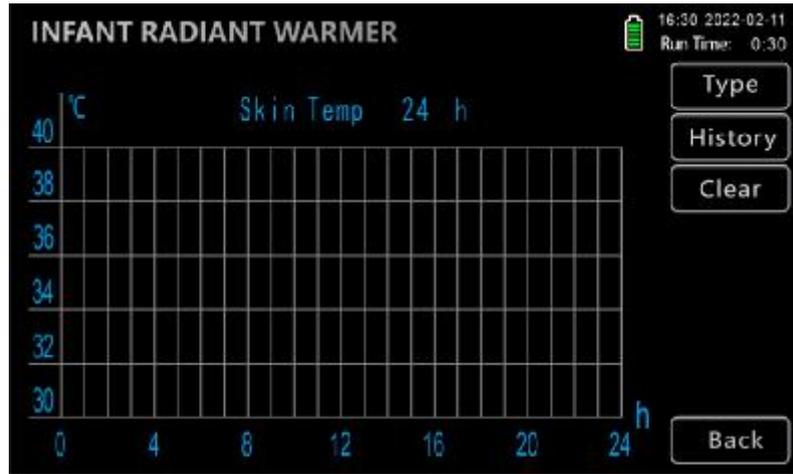


Figure 3 0

## 8.2 Test of the alarm function of the controller

 Attention During the controller alarm function test.

### 1) Check the power-off alarm function

 Attention When the controller is energized, unplug the power supply line, and the equipment should appear "power off" alarm. The alarm indicator light is shining, and the horn will emit continuous alarm sound.

In normal use, ensure that the battery used for alarm inside the controller has sufficient power; if the alarm battery is insufficient, the equipment will not appear the sound and light alarm warning when the power supply is cut off. If the battery is used for a year or has a power failure alarm for more than 10 minutes, the battery should be replaced in time.

### 2) Check the skin temperature sensor fault alarm

In the infant control mode, pull off the skin temperature sensor plug, the equipment should be able to appear the "skin temperature sensor fault" alarm, the alarm signal light shines, and the horn emits a continuous alarm sound.

**Important:** When pulling out the skin temperature sensor, you must hold the skin temperature sensor plug with your hand, and do not pull off the skin temperature sensor by pulling the wire, so that it is easy to break the sensor cable.

### 3) Check the skin temperature deviation alarm

In the skin temperature control mode, the control temperature is set to 35°C, under the constant temperature state, the skin temperature deviation alarm test can be conducted. Soak the skin temperature sensor probe into the water cup with a water temperature of 37°C. When the skin temperature display value reaches 36.1°C, the equipment should be able to appear "high skin temperature alarm" display, the alarm signal light shines, the horn emits a continuous alarm sound, and the radiation head will cut off the heating.

In the skin temperature control mode, the control temperature is set to 35°C, under the constant temperature state, the skin temperature deviation alarm test can be conducted. Dip the skin temperature sensor probe into the water cup with a water temperature of 33°C. When the skin temperature display value reaches 33.9°C, the equipment should be able to appear the "low skin temperature alarm" display, the alarm signal light shines, and the horn emits a continuous alarm sound.

 Attention The temperature sensor probe shall not be immersed in constant temperature water for a long time. Put the sensor probe until the water temperature is constant. Soak the probe in water for as little as 15min to avoid affecting the service life of the sensor.

### 4) Check the skin temperature over temperature alarm

Set the baby temperature at 37.5°C, reach constant temperature state, and then the skin temperature sensor probe into the water temperature of 39°C, when the skin temperature display value reached 38.5°C, the equipment should be able to appear "over temperature, cut off heating, heavy power can be reset" display, according to the alarm signal lamp shining, horn continuous alarm sound, radiation head cut off the heating.

 Attention The temperature sensor probe shall not be immersed in constant temperature water for a long time. Put the sensor probe until the water temperature is constant. Soak the probe in water for as little as 15min to avoid affecting the service life of the sensor. During the over temperature alarm, the heater needs to be reenergized (turn off and turn on the controller power again) to work.



**Attention** If there is no conformity to the above phenomenon, technicians must be asked to debug or repair.

When you alarm, press the "silencing button" to eliminate the alarm sound, but this noise is temporary. If there is no troubleshooting within 5 minutes, The alarm will sound again until troubleshooting. Over-temperature alarm and system alarm can not eliminate the alarm sound.

### 8.3 Use method of the skin temperature sensor

The skin temperature sensor probe must make effective contact with the baby skin, and ensure that the "skin temperature" display area can accurately display the baby skin temperature. If the skin temperature sensor probe from the baby skin, the sensor measured the temperature is not expected baby skin temperature, and may be the bed air temperature or contact object temperature, this will change the heating output ratio, resulting in the phenomenon of overheating or too cold baby, may cause serious consequences.

The metal surface of the skin temperature sensor should be close to the baby skin and fixed with medical tape. If the baby sleeping position is supine or lateral, it is recommended to stick the skin temperature sensor probe between the sword bone of the baby abdomen and the belly button; if the baby sleeping position is prone, it is recommended to stick the skin temperature sensor probe to the kidney part of the baby back.

When pulling out the skin temperature sensor from the controller, hold the sensor seat (see Figure 31) and do not pull out to avoid damage to the sensor.

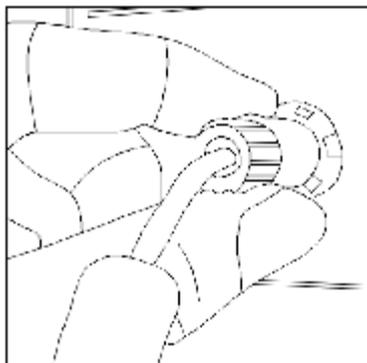


Figure 31



**Attention** The skin temperature sensor measures the baby skin temperature. If necessary, please measure the baby actual body temperature;

Pay close attention to whether the skin temperature sensor can effectively contact the baby skin, so as not to fall off;

The skin temperature sensor should not be placed under the baby body, and the probe should not cover blankets and other items to avoid temperature error.

## 9. Other functions of the product

### 9.1 Light for jaundice treatment

The jaundice treatment lamp is suitable for reducing the bilirubin concentration in newborns.

Neonatal jaundice is to point to the clinical phenomenon of skin, mucosa and sclera yellow dye caused by the increase of bilirubin level in blood in neonatal period. It is a common symptom in neonatal period, most of which is caused by increased serum without bilirubin. Blue light irradiation in the spectral wavelength range of (400 to 550) nm is the most common treatment of neonatal jaundice. Phototherapy allows formation of induced ducible and unbound bilirubin structural isomers. Formation of these bilirubin isoforms is more hydrolyzed than the original compounds, and less accessible to the CNS, passing through the liver and excreted through bile and urine faster than the original form of unbound bilirubin.

#### 9.1.1 Notes

- | A warm table equipped with phototherapy lamp, in the use of phototherapy lamp, the baby should be naked, the use of qualified eye cover to cover the baby eyes, and to use diapers to cover the baby's genitals. Medical staff should not look directly at the light source or be under blue light for a long time.
- | Phototherapy lamp does not need debugging and preheating, can be used directly. Phototropic isomers of bilirubin may cause the effects of toxic effects. The bilirubin values should be measured regularly to observe the effect of treatment.
- | The infant should be placed within the effective irradiation area on the bed surface to achieve optimal treatment results. The vertical distance between the phototherapy lamp and the bed surface is fixed, and changing the distance will affect the total bilirubin irradiance.
- | The operator should understand and pay close attention to the phototherapy equipment in the hyperthermal device (e. g., infant incubator, infant radiation thermal sink, heating mattress), and the impact on the heat supply and the patient's body temperature.
- | The use of phototherapy lamp may affect the temperature control performance of the thermal platform, and may also affect the baby's body temperature. Baby control mode should be used, and the observation should be strengthened. Phototherapy may accelerate water evaporation in infants.
- | No use of flammable agents, including preservatives, cleaning agents, etc., for phototherapy equipment. Do not store drugs and injections in light radiation areas. Phototherapy lamps should not be used in the presence of combustion gases (e. g. oxygen, nitrogen oxide, anesthetic gas).
- | When the total bilirubin irradiation  $E_{bi}$  decreases by 25%, the overall light source should be replaced. Please purchase the same light source from the manufacturer, and the use of other light sources will affect the safety and treatment effectiveness.
- | The service life of phototherapy light source is about 3000 hours, after the service period expires, these components should be replaced overall; the light source of LED phototherapy instrument (model: RL-1D4DBC60-0) shall be purchased from the company.
- | In order to achieve a better treatment effect, the phototherapy instrument light transmission board should be kept clean.
- | During illumination, operators do not look directly or view the beam through an optical instrument. Other infants near the phototherapy device can be protected by using an opaque cloth barrier to avoid the effects of light. If the operator is under the irradiation of the phototherapy instrument for a long time, it may also be affected, please pay attention to avoid and pay attention to the protection.
- | The phototherapy instrument needs no preheating time and can be used after opening. However, to test the accurate data, the measurement should be made after 30min turned on.
- | The phototherapy instrument does not need the debugging time, and can be used after opening.
- | The working noise of the phototherapy instrument is 60dB. If there is abnormal noise, please stop the use and report for maintenance.
- | The vertical distance between the phototherapy device and the bed surface is 80cm and the distance between the two is not adjustable.

I To prevent the patient from leaving the effective surface, users should check the patient position regularly to achieve better treatment results.

### 9.1.2 Effective irradiation area

The effective irradiation area of the light on the bed surface is 38cm 25cm (see Figure 3 2), and the effective area is in the positive center of the bed surface. During phototherapy, the patient should be placed within the effective irradiation area.

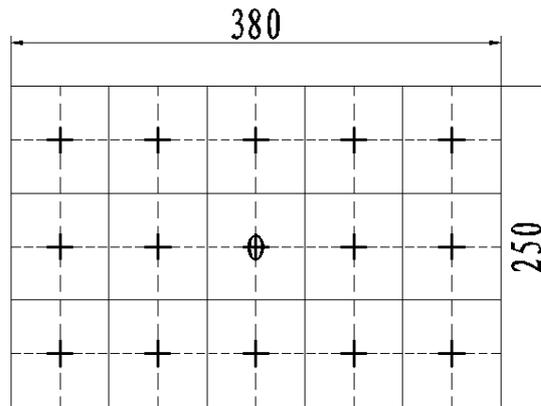


Figure 3 2

The illustration illustrates the average with a wavelength range of 320nm – 550nm with a wavelength interval of 5nm

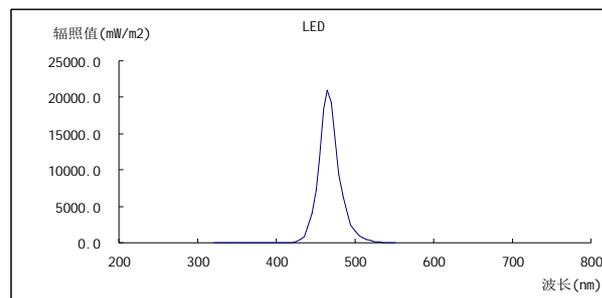


Figure 3 3

Wavelength wavelength between 320nm and 550nm

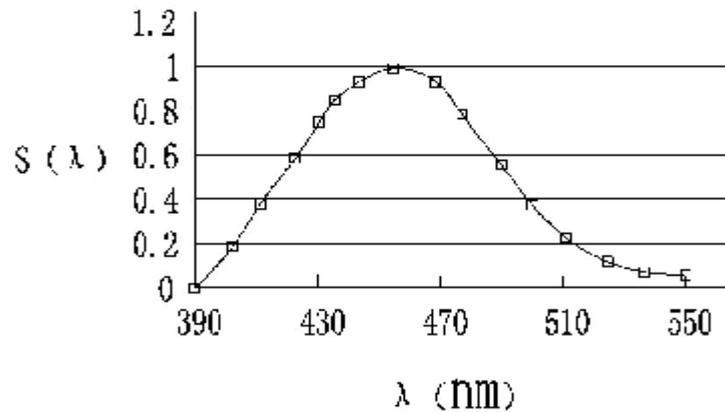


Figure 3 4

### 9.1.3 Use method of phototherapy

- Check the connection of the input power supply and the communication lines.
- Through the "phototherapy" sub-menu in the operating interface of the thermal console, set and control the treatment time and set time can be displayed in the phototherapy information area of the main interface.
- If you need to pause during treatment, press the "Start / pause" key, the phototherapy light will go off, and press the "Start / pause" key again to continue treatment, as shown in the figure below.
- When setting the treatment time, press the "OFF / ON" button to turn off the phototherapy, and then press the "Time" button to enter the treatment time.

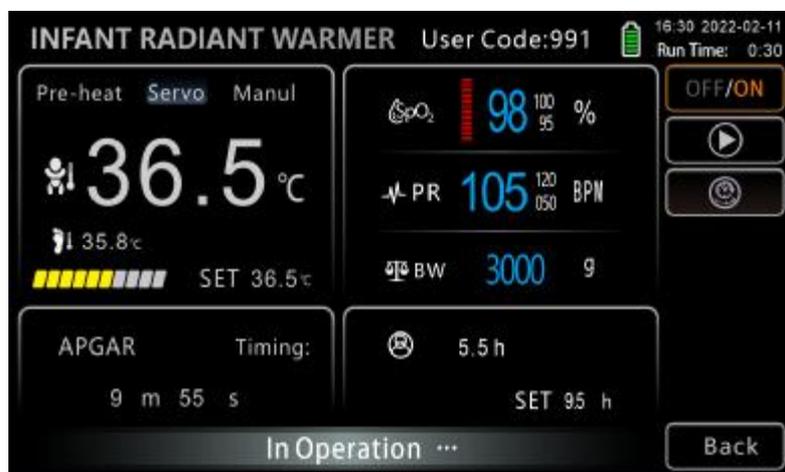


Figure 3 5

## 9.2 Electric power suction

Electric suction device is suitable for removing neonatal amniotic fluid, airway secretions, oral mucus, etc.

Working principle: when the leather bowl of the solenoid valve is reciprocated, the suction valve and the exhaust valve are opened and closed respectively, so that the suction port continuously generates negative pressure (negative pressure pump in the suction port), and the exhaust port generates positive pressure; the

negative pressure regulator can be stepless pressure according to clinical needs, through the negative pressure indicator; through the negative pressure line, the negative pressure attraction on the application port. Negative pressure pump is a one-way, oil-free plastic pump, without refueling.

### 9.2.1 Notes

- l Suction operation mode: continuous operation.
- l The suction shall be placed for use in an environment without strong magnetic field interference.
- l The suction device shall be cleaned and disinfected before use. Please replace the suction catheter, filter and other parts provided by the manufacturer.
- l Disposal of waste (including machine scrap) according follow the local regulations; do not discard and pay attention to environmental protection.
- l The filter device is in the middle section of the suction catheter, and the user can plug and replace it by himself.
- l The suction bottle is equipped with overflow valve, which will automatically stop suction during overflow. Please empty the storage bottle before the liquid is full, and open the cap counterclockwise.
- l If any liquid or solid suction negative pressure pump, please contact the manufacturer for repair.
- l When the suction works, it may produce a certain amount of noise.

### 9.2.2 Use method of the suction

- a) Ensure the correct connection according to the drawing 3 6, the external connection of the suction device (ensure that the cap of the collection container bottle is tightly rotated);

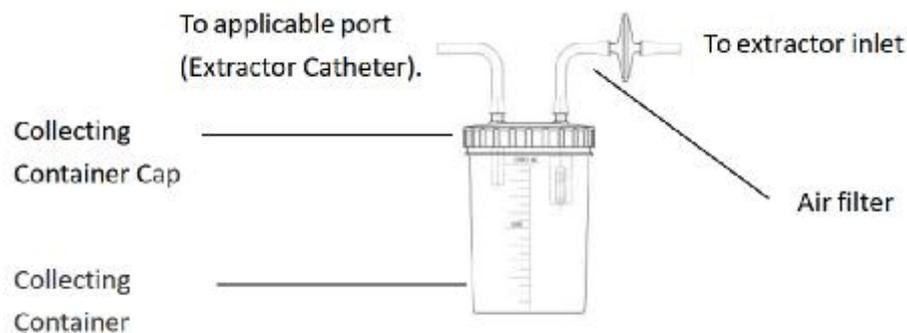


Figure 3 6

- b) The suction tube is configured by the user. Please use the suction tube complying with Chinese regulations / standards (obtain registration certificate); please treat the disposable suction tube according to the requirements of disposable products. The inner diameter of the suction catheter is 6mm and all joint suction tubes suitable for this size; the manufacturer provides a suction catheter link head for the suction tube with the same inner diameter of the suction catheter (6mm). The suction bottle is 1000ml (one).

- c) Turn the negative pressure regulator clockwise, block the application port and open the power switch on the suction panel to check the closure of each connection. The negative pressure indicator of the working suction should be able to reach the specified negative pressure value, proving that the connecting points of the suction have good sealing performance and can be applied to work. If the negative pressure value specified by the equipment cannot be reached, please carefully check each connection again for leakage. (If the problem can not be found after repeated inspection, please contact the factory or report for repair)

**⚠ Attention** Due to long-term use, aging or cracks may occur, which will reduce the negative pressure value or no negative pressure; please contact the supplier or manufacturer to replace a new suction catheter.

- d) Turn on the power switch and block the sputum suction tube;
- e) Adjust the "negative pressure adjustment knob" (the right-handed negative pressure value increases) and observe the negative pressure indicator so that the negative pressure reaches the required negative pressure value (see figure 37).
- f) Adjust the negative pressure: (see Figure 37) Block the suction port, open the suction switch, and adjust the negative pressure regulating valve. The reading on the negative pressure meter should change within the range of 2 kPa ~ limit negative pressure value. In clinical use, the negative pressure regulator is used to control the negative pressure value required for suction. The negative pressure increases when the negative pressure regulating valve rotates clockwise. In clinical application, it is forbidden to operate the negative pressure regulator at will to change the negative pressure value and cause clinical danger. If the negative pressure display may be inaccurate after the negative pressure meter or the impact of external force, contact the dealer or manufacturer for replacement.

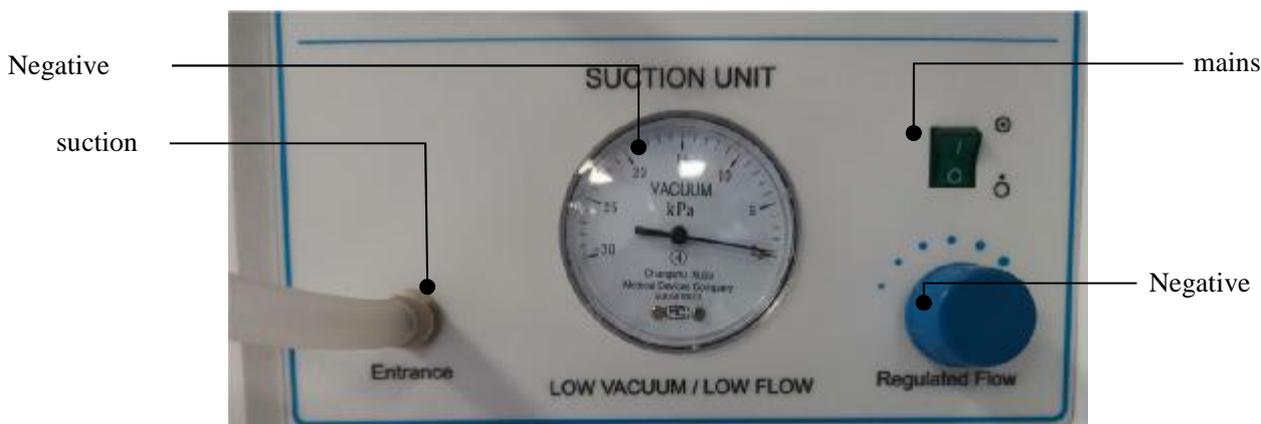


Figure 3 7

- g) Check and test the overflow device

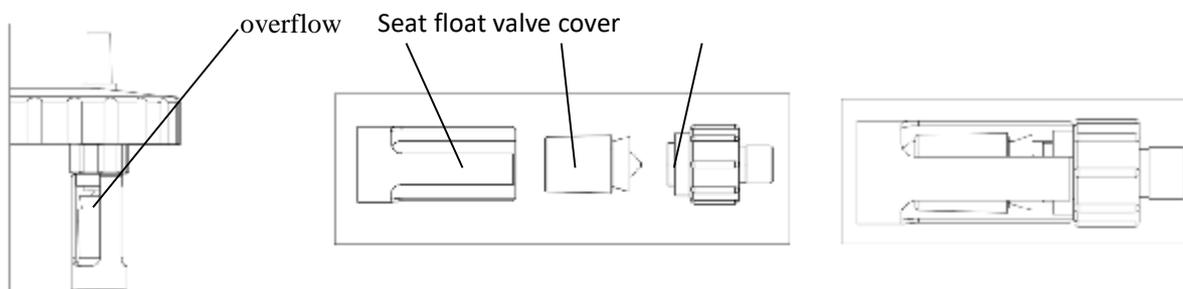


Figure 38 Figure 39

- I Open the bottle cap, clean the seat cover, and press the overflow leather bowl on the flat float. The overflow leather bowl should be free of warping, tearing and other defects, and should be connected with the float intact. Floating should be flexible in the valve seat, without resistance rolling phenomenon.
- I Carry the bottle cap, make the float vertical contact with the water surface, slowly move down the

bottle cap, the float should be able to float in the valve seat.

- | Hold the cap, connect the suction catheter to the suction port, tighten the regulating valve and run the suction device.
- | Extend the suction soft catheter into a clear bucket, or simulate the normal use situation, and inhale the liquid into the liquid storage vial with the overflow device. The level rise will drive the float until the valve port is closed and the attraction stops automatically. The final liquid level will change with the attraction method.
- | Release the regulating valve, close the suction switch, open the cap, and empty the liquid in the bottle. When capping the cap, the float shall be at the bottom of the seat and open.
- | If the above conditions, it means that the overflow device is working normally and can be used in clinical practice.



Attention

A) If the liquid level continues to rise after the overflow device is closed, there are two possible situations: (1) due to the remaining negative pressure in the liquid storage bottle. (2) The valve port is not completely closed. Treatment: In the former case, when the suction catheter leaves the suction liquid, the liquid level in the storage bottle will no longer rise; in the latter case, the liquid level will still rise, so carefully observe. When the storage bottle is nearly full, immediately lift the suction catheter, close the suction actor, stop the suction, and find out the cause for the failure of the valve opening.

B) the float after closing the suction stops. But due to the negative pressure in the pipe, the float may still be sucked in the valve port. At this time should relax the regulating valve or close the suction device, that is, release the negative pressure in the pipeline, let the float fall according to the weight. It is strictly prohibited to pull the float by hand to prevent the rubber valve piece from the float.

C) Remove the negative pressure and open the bottle cap only after shutdown.

D) No use of the suction device when removing the overflow device.

(h) make use of

- | Before use, check the suction device according to the installation and debugging procedures to ensure that its performance is intact, and then connect the disinfected suction soft catheter and sputum suction tube can be put into use.
- | In use, the negative pressure can be used to adjust to the required negative pressure value with the regulating valve, and often pay attention to the height of the liquid level in the storage bottle.
- | More than 900ml is not allowed. If the liquid level exceeds 1000ml to the calibration capacity (the whole machine is still applicable within 10 degrees), stop attracting and use the liquid storage bottle after emptying and cleaning. The posterior stage liquid storage bottle serves as the suction aid bottle to prevent the liquid from entering the pump body.



Attention

a) If the liquid level continues to rise after the closing mechanism of the overflow device moves, see "Check and test the overflow device" for the treatment method.

b) The use of the suction shall be conducted under the guidance of the medical staff and according to the scope of use of the instructions. If you have any questions, please contact the supplier or the manufacturer

### 9.2.3 Replacement of air filter and suction soft catheter

Appearance of air filter (see Figure: 4 0)

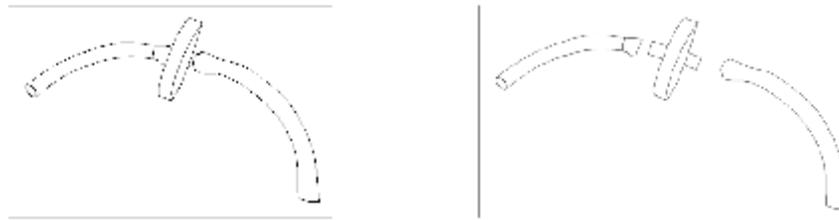


Figure 4 0

If the air filter is inhaled into foam or filled with dust, the color of the filter film will change from light to dark, and it will also cause the suction at the pipeline entrance to significantly reduce or even disappear. At this time, it should be replaced with the air filter of the factory in time.



- Attention
- The closure of the medium overflow device and pipe blockage will also cause the decrease or disappearance of the suction in the device, but the negative pressure value shown by the negative pressure meter rises.
  - The air filter should be replaced frequently (monthly replacement is recommended, after each patient when necessary); the suction catheter should be cleaned and disinfected at any time (it is recommended to replace after 300 times); the replaced parts should be destroyed centrally.

### 9.3 T combination resuscitation / air oxygen mixing (for optional T combination resuscitation and air oxygen mixing)

9.3.1 Notes: T combination resuscitation device / empty oxygen mixing device: "Pediatric CPAP Continuous Sustained Positive Airway Pressure System", where continuous positive pressure flow is delivered into the airway with a nasal cover or nasal plug, and the machine giving oxygen in this way is called the CPAP ventilator. It ensures that under spontaneous breathing conditions, patients should have stable respiratory driving force and appropriate tidal volume, and artificially apply a certain degree of positive pressure in the airway during the whole respiratory cycle, so as to prevent airway atrophy, increase functional residual volume, improve lung compliance, and improve oxygen cooperation. In this mode, the ventilator only maintains a certain amount of positive airway pressure, without mechanical ventilation. Limited to patients with spontaneous breathing.

- I Functional checks must be performed before using the device (see "Chapter 152. Instructions for Installation Connections and Functional Testing").
- I Please follow the instructions in "Chapter 165. Disinfection Methods" to prevent infection or bacterial infection.
- I The T combination resuscitation / empty oxygen mixture can be used only if you have been medically trained and received technical guidance from respiratory equipment, and improper use may result in serious physical injury.
- I Only the T combination resuscitation device / empty oxygen mixture device can be used in newborns and children with spontaneous breathing to provide continuous positive pressure ventilatory support.
- I If the oxygen source fails, the T combination resuscitation device / air oxygen mixture will produce an audible alarm to prompt the medical staff  
The prepared oxygen concentration and flow output may change significantly.
- I If the pressure difference of the air source exceeds 0.1MPa, the T combination resuscitation device / air oxygen

mixture device will generate an audible alarm. In this case,

The oxygen concentration and flow output of the equipment will change significantly.

- I Please monitor patient gas using marketed YY0601 compliant oxygen monitors.
- I Do not steam clean the equipment, autoclave, or place the equipment at temperatures higher than 62°C.
- I Do not immerse the T combination resuscitation / nO mixture assembly in liquid decontamination for cleaning.
- I Do not block or remove the alarm posts at any time.
- I The adjustment results of the oxygen concentration should be checked using the oxygen monitor.
- I Only allow our company manufacturer or its authorized professionals to perform maintenance measures, such as inspection and Maintenance operation.
- I To prevent damage to breathing, the respiratory system should be connected only to clean, dry medical grade gas sources.
- I Clean, dry medical grade gas shall be used while operating the T combination resuscitation device / empty oxygen mixture device. Contaminated or wet can cause the undesirable operation. Medical air shall comply with grade F compressed air specified in the Pharmacopoeia, and the water content shall not exceed neonatal / pediatric continuous gas. The dew point of the channel positive pressure respiratory support system is not less than 5°C of the minimum ambient temperature.
- I The moisture content of medical air or oxygen supplied to the T combination resuscitation device / empty oxygen mixture shall not exceed 5.63 mg/L.
- I When using a T combination resuscitation / empty oxygen mixture with oxygen cylinders, users are advised to use a source with wall Pressure reducing valve with consistent fitting. If the gas is exhausted in the bottle, the above practice can close the respiratory system to the wall gas source.
- I Before using the equipment, a YY0601-compliant oxygen testing equipment must be used to check the oxygen concentration of the delivered gas.
- I Patients and oxygen concentrations must also be observed continuously during ventilation.
- I Relying on the respiratory system for too long can cause respiratory muscle atrophy.

### 9.3.2 Instructions for Installation and Use:

9.3.2.1 Pipe connection: Connect the T-pipe patient pipe outlet in Fig. 42 to the outlet of FIG. 41, connect the air inlet in Fig. 44 to the air inlet in FIG. 43, and connect the oxygen inlet to the oxygen inlet in FIG. 43

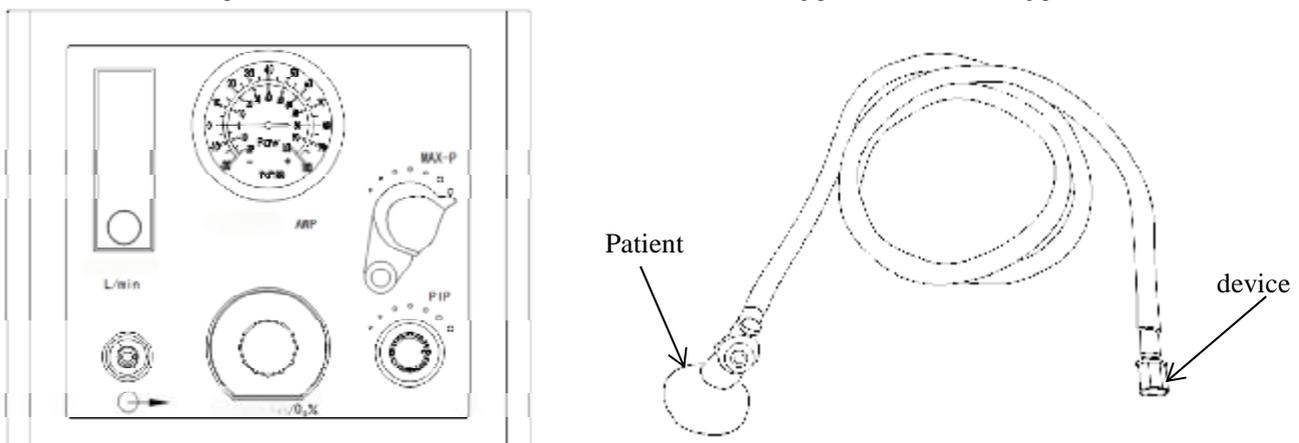


Figure 41 Figure 42: T tube patient donor trachea

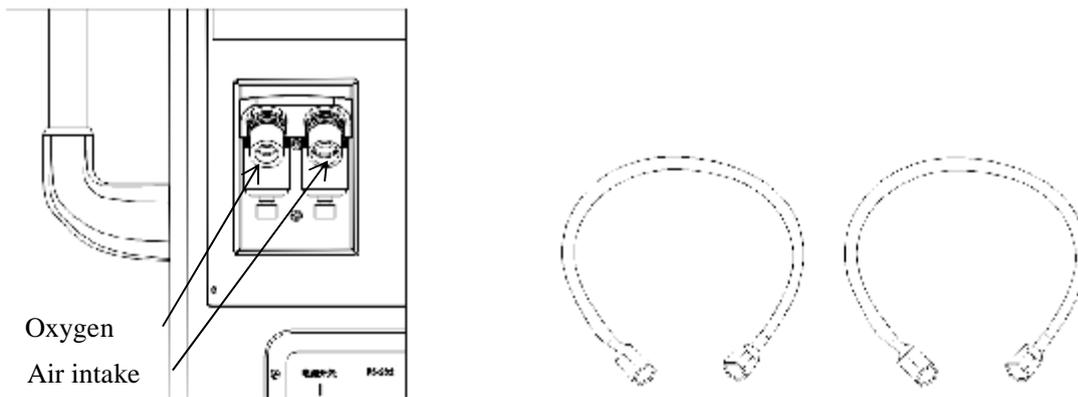


Figure 43 Figure 44: Air intake pipe (black) and oxygen intake (blue)

### 9.3.2.2 Introduction of the operation interface

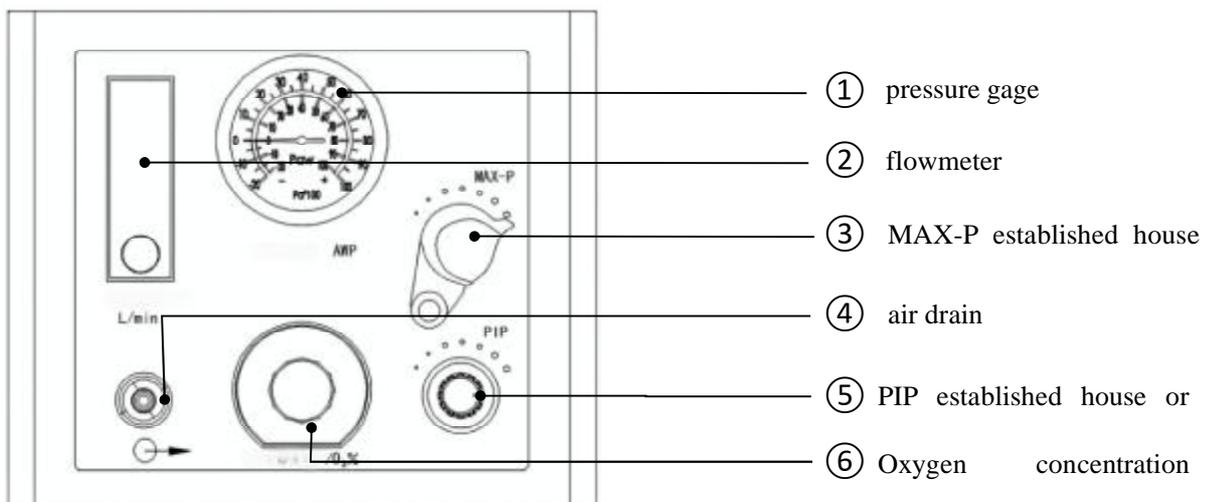
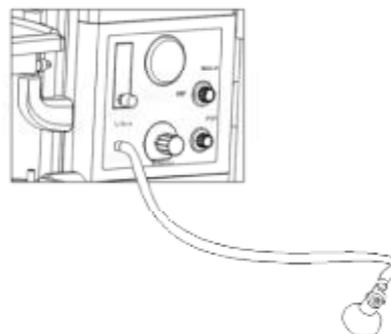


Figure 45

### 9.3.2.3 Instructions for installation, connection to gas source and function test

- ▶ T combination resuscitation device / air oxygen mixture device installation of the flow meter and pressure as far as possible. The force meter is installed vertically. So as not to affect the accuracy of the use.
- ▶ Has the air-oxygen mixer and flow meter function, need to move Force source, follow the indication through the pressure tube (oxygen tube is green OXYGEN, Air pipe is blue AIR), the connection pressure source is 0.3MPa~0.4 MPa oxygen and air sources.



- ▶ Alarm system test: connect the medical compressed air source (or oxygen source), Pressure: 0.3~0.4MPa, the alarm sound can be heard (the air source is interrupted), Adjust the oxygen source (or air source) when there is a pressure difference between them Greater than 0.15MPa, alarm alarm (differential pressure alarm), when oxygen

When the air source pressure reaches 0.3-0.4MPa, the alarm sound must be eliminated, indicating that the alarm system is working normally.

- ▶ Reverse airflow is a measure of product in normal condition and or a single fault: normal operation

Under condition or in a single fault condition without alarm, the reverse air flow should not exceed 10 ml / h; the alarm indicates

The reverse airflow shall not exceed 100 ml / h. The interval between such tests is one year.

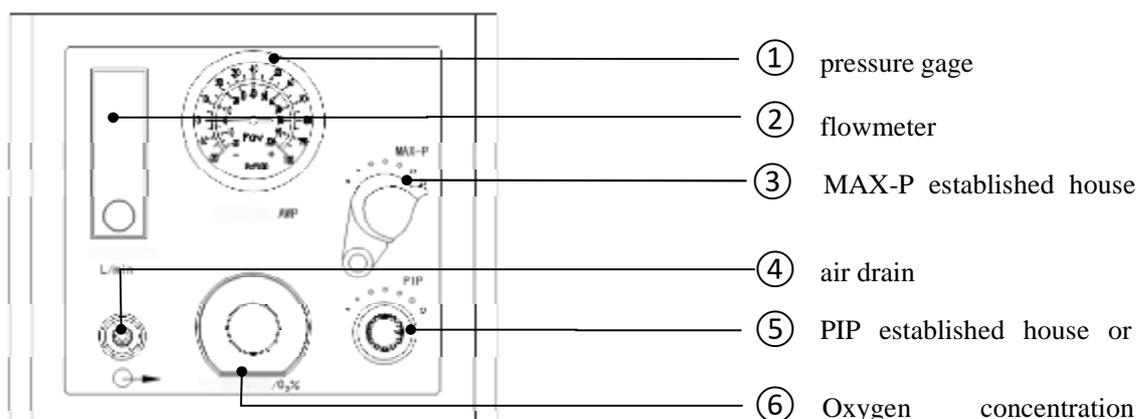
Note: When the alarm is generated, you must check whether the oxygen and air air source pressure is at 0.3MPa~0.4 MPa.

### 9.3.2.4 Circuit check

1) Connect the circuit and the simulated lung.

- ▶ Correct connected circuit / simulated lung / air source by product;
- ▶ Adjust the flow value to 8 LPM (recommended value);
- ▶ The MAX-P, PIP, and PEEP regulating valves are selected in the maximum position;
- ▶ Adjust MAX-P, PIP, and PEEP respectively to observe whether the pressure gauge is in the normal control range.

2) Recommended compliance as shown on the right side:



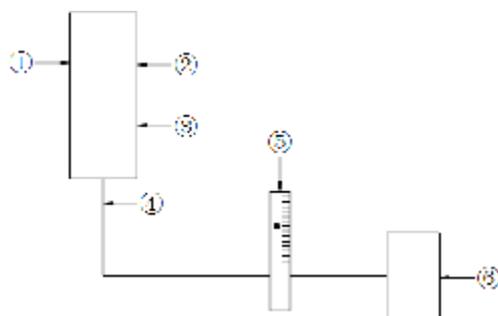
YY 0601-2009 oxygen monitor to check the delivery gas oxygen concentration

Recommended test process:

- ▶ Correct connection 0.3MPa~0.4 MPa oxygen and air two air sources, flow

Volume meter and oxygen analyzer.

- ▶ Adjust the flow value to 8 LPM (recommended value);
- ▶ Change the oxygen concentration adjustment parameters to read the oxygen concentration value;



- ▶ If it normal indicates that the circuit is connected correctly, the equipment can be used normally.

Note: 1) It is recommended to conduct a loop check on the equipment before each use.

2) Flow adjustment clockwise rotation flow reduction.

3) Whenever a gas mixer is used, an oxygen analyzer is recommended to ensure the output accuracy of the equipment.

① Oxygen input ② air input ③ air oxygen mixer ④ gas output ⑤ flowmeter ⑥ per YY0601-2009D oxygen analyzer

### 9.3.2.5 Use of the equipment

- ▶ Connect air source: correctly connect the supply pipe, connect oxygen and air high pressure pipe to is over voltage medical oxygen and medical air.
- ▶ Connect the return pipe to the gas outlet (if it is a disposable circuit, it must be effective).
- ▶ Connect the simulated lung, check the T combination resuscitation device / air oxygen mixing device according to the installation and debugging procedures, to ensure its good performance;
- ▶ Please check whether the pressure gauge reading is zero, if no, please correct after use.
- ▶ check settings

Adjust the supply flow from 0 to 15 LPM per demand

#### 1) Set the upper limit of inspection air pressure (MAX-P)

- ① Cover the PEEP spin cap with your thumb and place the PIP valve clockwise  
To rotate to the end.
- ② Rotate the MAX-P valve clockwise or counterclockwise to set the required gas  
Pressure upper limit.

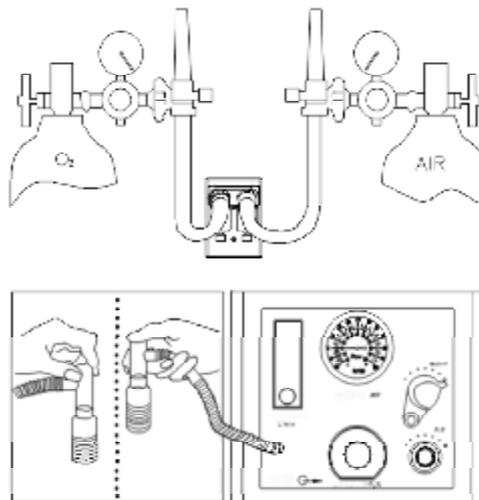
#### 2) Set the inspiratory peak pressure PIP

Cover the PEEP cover with the thumb

The clockwise direction rotates until the pressure gauge shows the pressure value and required  
The PIP values were consistent.

#### 3) Set EP PEEP / CPAP

Adjust the PEEP / CPAP flap and observe the pressure gauge to get the desired end-breath  
Positive pressure: PEEP / CPAP.



- ▶ Check the oxygen concentration of the delivery gas at the intended set points (21%, 30%, 40%, 50%) according to the recommended oxygen concentration test method

Degree of conducting the necessary tests.(P. r. n)

- ▶ Remove the simulated lung connection mask or trachea for normal use.

Check the oxygen concentration of the delivered gas at the intended settings (21%, 30%, 40%, 50%, 50%) following the recommended oxygen concentration test method

Degree of conducting the necessary tests.(P. r. n)

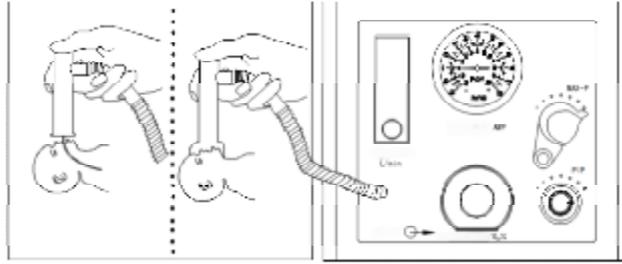
- ▶ Remove the simulated lung connection mask or trachea for normal use.

Recommended use

- 1) Adjust the gas supply flow, oxygen concentration, PIP, PEEP / CPAP as required;
- 2) Install the resuscitation mask on the circuit pipe and then cover the baby  
The mouth and / or nose. Or connect the circuit tube to the airway cannula.

## 3) Place your thumb on the PEEP / CPAP flap for inhalation

Exhale, thus performing resuscitation.



- ▶ In use, you can adjust the oxygen concentration values and flow values, PIP and PEEP / CPAP value, and often test the oxygen concentration value and carbon dioxide value to meet the temporary Bed requirements (recommended with blood gas analyzer, oxygen concentration monitor, blood oxygen Real-time monitoring of saturation and carbon dioxide tester).

Statement: A mask that does not allow the patient to breathe spontaneously; the dead space must not exceed 10.5ml

Note 1: Connect the recommended disinfection pipeline circuit or the recommended one-time circuit;

Note 2: The use of T combination resuscitation device / air-oxygen mixing device should be under the guidance of medical personnel and strictly according to the scope of use of the instructions

Please contact the supplier or manufacturer if in doubt.

#### 9.3.2.6 Stop

After installation, debugging or use, the gas source should be turned off first, the pipeline must be disinfected and standby, and the equipment should be treated with dust proof.

#### 9.3.3 Product maintenance and maintenance methods

1) T combination resuscitation device / air oxygen mixing device should be inspected by qualified technicians within the interval recommended by the manufacturer

2) T combination resuscitation device / air oxygen mixing device must be regularly checked by qualified technical personnel, the recommended interval:

Six months.

3) Description of any maintenance performed by the user: T combination resuscitation device / air oxygen mixture device is of precise pure mechanical design

Product, users are not recommended to carry out any maintenance, in the daily water of the gas supply system must be discharged, after use must be completed

Remove the residual gas from the system.

4) Before shutdown, it is recommended to cut off the gas supply source, adjust the oxygen concentration value to the 21% position, and adjust the flow value to the closed state, PIP and PEEP /

The CPAP is adjusted to the initial state.

5) After shutdown, remove all kinds of pipes and disinfect them for standby. Clean the surface of the equipment and prevent dust.

6) The surface of the equipment shall be wiped with a micro-wet cloth soaked in disinfectant to prevent the liquid from entering the equipment.

7) The removed parts of the airway should be cleaned and disinfected within 24h to avoid the growth and reproduction of pathogenic microorganisms and cause cross-infection.

Remove the airway parts, first clean thoroughly with soapy water, washing powder or clean washing solution, all sputum, blood and oil

And other residual dirt removal, and then rinse with warm water, clean water wash, dry after disinfection. The patient breathed the airway, air valve, and thinning

All airway parts such as water device, direct passage, elbow and pressure transmission tube can be disinfected by soaking 1:1000 fresh clean solution for 30min.

8) When the equipment is not in use, it should be placed in a dry and clean place, and run once regularly (usually half a year).

#### 9) Troubleshooting

| order number | fault phenomenon                         | analysis of causes   | The exclusion method   | remarks  |
|--------------|--|--|--|--|
| 1            | Generate alarm sound                     | 1) Lack of pressure of oxygen source supply<br>2) Lack of air source pressure<br>3) The pressure difference is too large | 1) Check the oxygen source<br>2) Check the air source<br>3) Check the pressure                                       | 1) No oxygen<br>2) No air<br>3) Adjust the pressure                      |
| 2            | The traffic value is too low             | 1) Air leakage through the pipeline connection<br>2) Improper adjustment parameters<br>3) Fault                          | 1) Check the pipeline<br>2) Readjust the parameters<br>3) Contact with the manufacturer                              | 1) Correct connection<br>2) Maintenance by professionals                 |
| 3            | There is no traffic output               | 1) Gas supply interruption<br>2) Flow value is not set<br>3) Fault   | 1) Check the gas source<br>2) Adjust the flow value<br>3) Contact with the manufacturer                              | 1) Check the gas source<br>2) Maintenance by professionals               |
| 4            | The oxygen concentration is not accurate | 1) The pressure difference is too large<br>2) Internal fault   | 1) Check the pressure<br>2) Contact with the manufacturer  | 1) Check the gas source<br>2) Maintenance by professionals               |
| 5            | The PIP pressure is too low              | 1) The MAX-P setting is too low<br>2) Circuit system leakage<br>3) Internal fault  | 1) Re-verify the setting<br>2) Check the loop system<br>3) Contact with the manufacturer                             | 1) Re-set<br>2) Check the loop system<br>3) Maintenance by professionals |
| 6            | The MAX-P pressure is abnormal           | 1) The MAX-P valve problem<br>2) Circuit system leakage<br>3) Internal fault   | 1) Re-verify the setting<br>2) Check the loop system<br>3) Contact with the manufacturer                             | 1) Re-set<br>2) Check the loop system<br>3) Maintenance by professionals |
| 7            | The PEEP / CPAP pressure is abnormal     | 1) The PEEP / CPAP valve problem<br>2) PIP / MAX-P setting<br>3) Circuit system leakage<br>4) Internal fault             | 1) Re-verify the setting<br>2) Check the PIP / MAX-P<br>3) Check the loop system<br>4) Contact with the manufacturer | 1) Re-set<br>2) Check the loop system<br>3) Maintenance by professionals |

Note: Before the equipment is used again, it must be correctly connected according to the pipeline connection mode, and conduct air source connection and circuit verification.

#### 10) Check the air source differential pressure alarm and monitoring

Connect the oxygen source to make the pressure of 350 kPa, keep the flow meter open and slowly reduce the oxygen pressure until ventilation.

The system emits a whistling alarm sound to prove that the function is normal, otherwise it is abnormal.

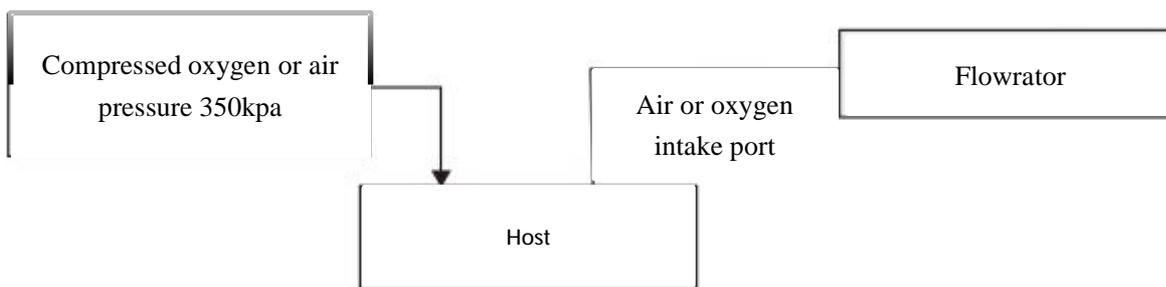
#### 11) Reverse airflow monitoring in the alarm state

The test method is as shown in the following figure below. The oxygen inlet of the ventilation system is connected to oxygen, and the air inlet is connected to the buoy flow meter to record the flow meter

Test value, which shall be <100 ml/min.

If the air intake of the ventilation system is connected to the air, and the oxygen intake is connected to the buoy flow meter to record the test value of the flow meter.

Value should be <100 ml/min.



#### 12) Reverse airflow monitoring without alarm state

The test method is shown in the following figure. The input gas source pressure is 350 kPa, and the buoy flow meter is connected between the gas source and the host to access the flow meter

The direction is consistent with the figure below (i. e. the gas source is connected to the outlet of the flow meter, and the air inlet of the flow meter is connected to the host inlet), and then will

When the flow output is completely closed, the value of both buoy flow meters should be <10ml / h.

#### 13) Check the concentration of oxygen in the conveying gas

Access to the oxygen gas source, so that the gas source pressure is 350 kPa;

Open the flow meter, so that the gas flow output of the host is 10 LPM;

Access conforming to YY0601-2009 at the host hybrid gas output port

Oxygen analyzer, adjust the oxygen concentration knob, test the concentration of each gear separately,

The concentration shall be within  $\pm 5\%$  (V / V) of the indicated value, and the deviation should not be guided

Oxygenic concentration was below 20%.

#### 14) Check the air tightness of the system

Connect the 100 ml/min flow meter at the oxygen gas input port, and then close the pediatric CPAP, when the flow display in the flow meter should be small

At 50 ml/min, leak if the meter is greater than 50 ml/min.

#### 15) Other contents that should be indicated in the instruction manual

##### ①YY0600.5-2003 Other instructions:

- ▶ T-tube patient supply pipe assembly must meet the product requirements; cylinder

The contents meet GB7144 and the cylinder valve meets the requirements of GB15382.

- ▶ MAX-P pressure test method: Connect the test lung, rotate the PIP valve clockwise to the end, and cover the PEEP / CPAP with your thumb

Cover, the observation pressure gauge shows the MAX-P pressure value.

- ▶ Oxygen concentration range: 21%~100%; if the input gas source (including oxygen and or air) pressure does not meet the pressure 0.3MPa~

At 0.4MPa, if the flow rate is not less than 15 LPM, it will affect the oxygen concentration output of the delivered gas.

The ▶ T combination resuscitation device / empty oxygen mixing device has a body weight range of a maximum of 10kg, and the delivery capacity is generally average

The ventilation guidelines indicate a tidal volume of 10 ml/kg to 15 ml/kg with a maximum delivery capacity of 150ml.

The dead chamber of the ▶ T combination resuscitation device / empty oxygen mixture device shall not exceed the T combination resuscitation device / empty oxygen mixture device

And 30% of the minimum delivery capacity.

- ▶ Inspiratory impedance: at 6L / min inspiratory flow, the negative pressure at the patient interface should be

less than 6 hPa (6cmH<sub>2</sub>O); expiratory impedance: at 6L / min

At suction flow, the negative pressure at the patient interface should not be 6 hPa (6cmH<sub>2</sub>O).

- ▶ The T combination resuscitation device / empty oxygen mixture assembly (including filled gas oxygen cylinder) that can be quickly transported to the patient requiring ventilation shall be no more than 5kg and provide high oxygen for 10min. Newborn / small

Pediatric continuous positive airway pressure respiratory support system components containing the patient connector should be less than 0.3kg.

- ▶ The pipeline with PEEP / CPAP valve in the complete component is not the complete component of T combination recovery device / air-oxygen mixing device, which

Supporting disposable parts are recommended.

- ▶ Products leave the factory with a special carton independent packaging, no transport box.

- ▶ As a T combination resuscitation device / empty oxygen mixing device assembly (including filling) that can be quickly transported to the patient requiring ventilation

Full gas oxygen cylinder) shall not exceed 5kg and can provide high concentration oxygen for 10min with minimum minute ventilation of 10 L/min.newborn

Pediatric / pediatric continuous positive airway pressure respiratory support system components containing the patient connector should be less than 0.3kg.

The components of the ▶ T combination resuscitation device / empty oxygen mixing device include the supply trachea and the disposable patient supply trachea with a T-tube,

Among them, the donor trachea is matching, and the disposable donor trachea for patients with a T-shaped tube is recommended.

The minimum delivery capacity of ▶ T combination resuscitation device / air oxygen mixture is 35ml, and the mask used is recommended.

②YY0893-2013 Technical Description:

- ▶ The pressure and flow characteristics of the delivery gas under the condition of the 0.3MPa~0.4MPa and the flow rate not less than 15 LPM:

Pressure stability does not produce any impact on oxygen concentration output, the flow is independently adjustable.

- ▶ Reverse airflow from one air inlet to another air intake in normal operating condition or in a single fault state without alarm

Reverse airflow shall not exceed 10ml/h(0.0169kPa.L/min); intake from one airflow in a single fault state indicated by the alarm

The reverse flow to the other air intake shall not exceed 100ml/min(10.13kPa.L/min).

- ▶ Available output range of output flow rate: 0 ~ 10 LPM.

- ▶ When the input pressure increases by 1.5 times, the delivery gas characteristics are not affected.

- ▶ The gas source (including oxygen and or air) must be a medical grade oil-free dry gas source, general oxygen source dry 0.05 mg/L, air source

The dew point is less than-5°C.

- ▶ Pneumatic schematic diagram:

- ▶ Operator detachable intake air pressure hose complies with YY / T 0799-2010.

- ▶ The pressure release valve must be set with parameters reasonably and timely. When the pressure exceeds the set value, the pressure valve will automatically release to ensure the safety of the patient.

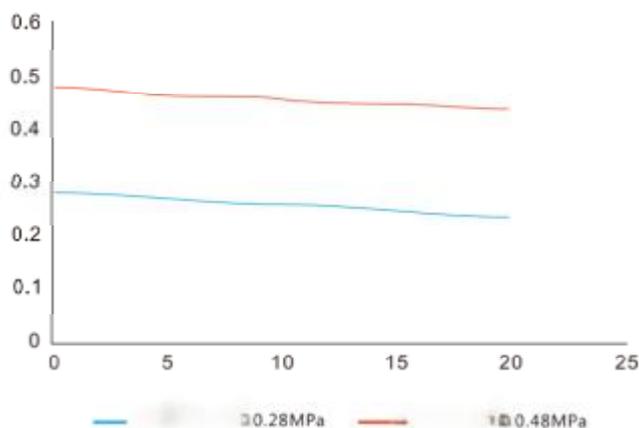
- ▶ The accuracy of the delivery of oxygen concentration: the accuracy is closely related to the pressure source of the intake air, in order to ensure that the accuracy meets the requirements, the pressure

The source must meet the medical requirements, the pressure meets the normal use conditions, and the pressure difference should not cause the alarm.

- ▶ Statement of any exhaust gas flow: the exclusion flow of the outlet is controllable under normal pressure

input conditions.

- ▶ Recommended methods for testing the flow, pressure and oxygen concentration of the gas
  - Recommended test method for conveying gas flow: test with a standard mass flowmeter;
  - Recommended test method for conveying gas: test with standard pressure gauge;
  - Recommended test method for oxygen concentration for delivery gas: test with an oxygen concentration monitor.
- ▶ Description of skim products before shipment
  - Products in the manufacturing and installation process of debris, including: grease, dirt, etc., before the factory delivery, has been used on the products and oxygen
  - The pipeline performs the necessary degreasing cleaning.
- ▶ Supporting the flow meter products in the use, adjustment of parameters, the product must be kept in a vertical position, so as not to affect the accuracy of the adjustment parameters.
- ▶ Air source pressure range for normal operation: 0.3MPa~0.4MPa.
- ▶ Product use process does not require lubricant.
- ▶ Pressure and flow characteristics of the output gas.



## 9.4, an electronic scale

### 9.4.1 Installation of the electronic scale

Align the four positioning columns at the lower end of the electronic scale assembly with the positioning hole on the tray and place them on the tray, plug the sensor connector plug through the crossing hole on the rear baffle of the bed, and connect the sensor connector plug with the 5-core sensor socket, as shown in Figure 46

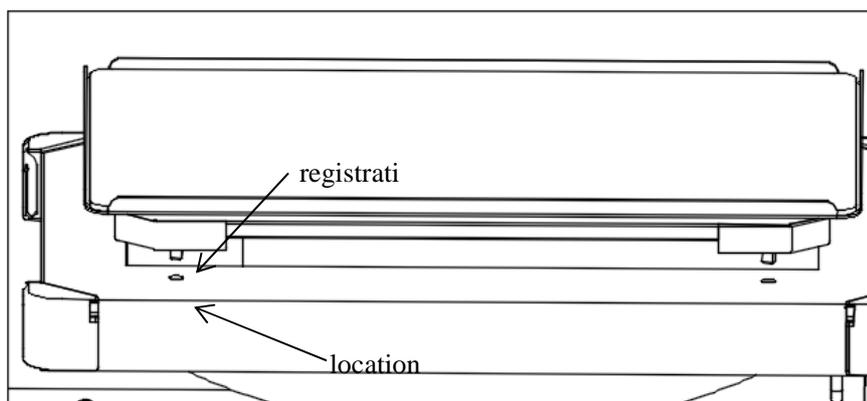


Figure 46

### 9.4.2 Function and operation of the electronic scale

9.4.2.1 The electronic scale is equipped with a sensor and a data acquisition system. The data acquisition system transmits the data measured by the sensor to the main controller of the device and displays it through the LCD screen, and has the operation functions such as balance and zero setting, as shown in Figure 47.

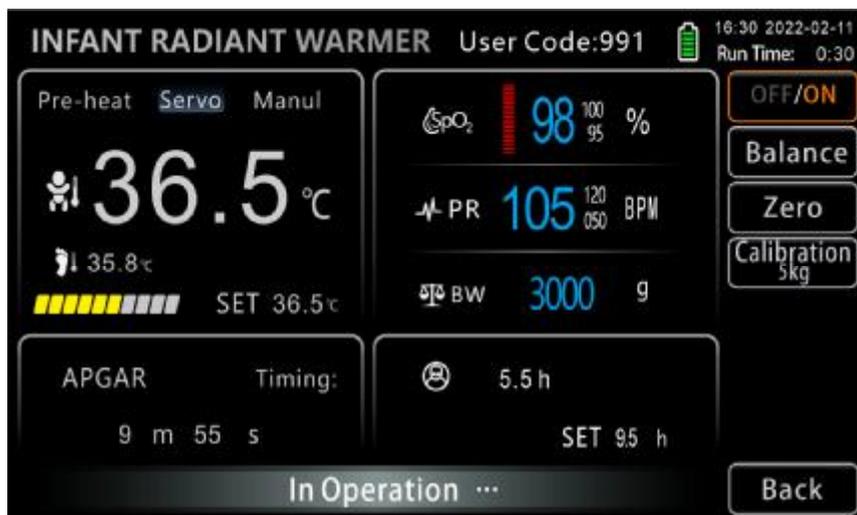
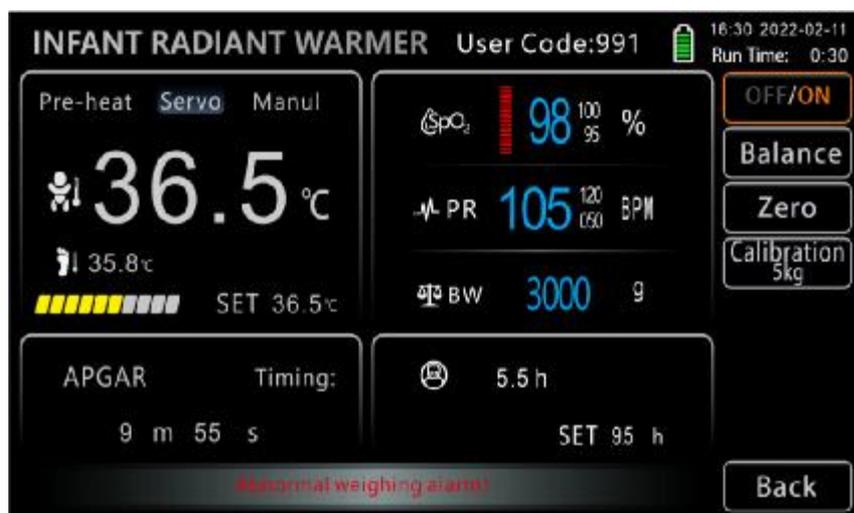


Figure 47

9.4.2.2 The weight display range of the electronic scale is 10 0-8000g, with a display resolution of 1g and a display accuracy of  $\pm 50g$ .

9.4.2.3 Calibrate the electronic scale before use and remove all items on the crib tray. At this time, the weight should be  $0 \pm 50g$ . If this range is not displayed, please press the "Zero" key to calibrate the weight display to this range. If the zero range exceeds 2000g, the "zero" button is invalid. At this time, the equipment display should appear "weighing abnormal" alarm prompt, as shown in the following figure, indicating zero failure. Please clear all items on the crib tray.



graph 48

9.4.2.4 The electronic scale can be placed into the baby at zero or (peeling), and the controller LCD screen displays the weight of the baby tested.

Note: 1. If the sensor cable of the electronic scale is not effectively connected to the controller, the weight display area is not displayed.

2. If the baby's activity affects the scale weight, press the "balance" key to stabilize the value of the scale table.

3. Before use, calibrate the electronic scale with a 5 Kg standard object, press the "5 Kg calibration" key once, and then there will be a pop-up box, and choose to agree

## 9.5 Pulse and blood oxygen monitoring device

### 9.5.1 Operation of the pulse and blood oxygen monitoring device

Before using the pulse and blood oxygen monitoring device, please read the following precautions, to ensure the accurate use of pulse, blood oxygen monitoring device, if not correctly install and use the device, there may be inaccurate measurement results, blood oxygen probe long-term compression tissue tissue necrosis or skin burns and other adverse consequences.

- ▶ The manufacturer has specified the brand, model and specification of pulse, oxygen sensor and sensor extension cord (see list of vulnerable parts), before use, medical personnel need to test the compatibility between the pulse oxygen monitoring device, pulse oxygen sensor and sensor extension cord, otherwise it may cause the equipment cannot be normal use, medical accident.
- ▶ Pulse blood oxygen monitoring device is mainly used for the monitoring of neonatal vital signs. The data or information displayed can be used for clinicians to diagnose patients, but it can not be used as the only diagnostic basis. It must also be used together with the clinical manifestations and the doctors diagnosis.
- ▶ Do not connect the pulse oxygen sensor probe with the patient in the same skin tissue for a long time, and change the connection position at least once within 4 hours. If the connection position is not changed after this time, it may lead to a wrong monitoring data or a possibility of the patients skin burns.
- ▶ When using the pulse blood oxygen sensor, please properly arrange the blood blood oxygen sensor extension line and sensor to reduce and avoid the possibility of its cable winding around the patients neck or other positions to cause harm to the patient.
- ▶ Do not place the supporting components of the pulse and oxygen testing device in any position where a drop may occur to reduce and avoid the possibility of causing harm to the patient.
- ▶ Before using the pulse oxygen detection device, make sure that the device receives the correct calibration test and operation settings.
- ▶ Do not use the device in a magnetic resonance imaging (MRI) environment.
- ▶ In order to make the pulse, blood oxygen saturation and pulse rate measurement more accurate, please keep the use of the environment quiet, no electromagnetic interference and infrared light exposure
- ▶ If an abnormal pulse and oxygen monitoring device is found, such as poor technical alarm, please stop using the device before excluding abnormal conditions.
- ▶ To avoid causing electric shock damage, please follow the following instructions:
  - Do not place this device on a surface with liquid leakage;
  - Do not soak the pulse oxygen monitoring device and accessories directly into the liquid
  - Do not disinfect the pulse oxygen monitoring device, but the pulse oxygen device can be cleaned using the method specified in this manual.

Do not use the pulse oxy monitoring device while cleaning the pulse oxy monitoring device;

- ▶ When several medical equipment used in the same patients at the same time, the leakage current may be beyond the allowable range, will cause certain risk to patients, suggest before use at the same time, first by qualified professionals test leakage current, ensure the leakage current within the safe range, ensure that the patient, operator and the surrounding environment will not cause harm. If there is still doubt, the user should consult the manufacturer for the correct way to use it.
- ▶ In the process of use, if the test data is questioned, other methods should be taken to monitor the patients pulse data and oxygen saturation, and the pulse oxygen monitoring device should be checked to determine whether the device is working abnormally
- ▶ The reason for the inaccurate oxygen saturation reading may be:

#### ① Increased levels of COHb and MetHb

For increased COHb levels: higher COHb levels above normal standards will cause higher SpO<sub>2</sub> levels. The increase is roughly equal to the COHb content.

Note: High COHb levels may also occur when SpO<sub>2</sub> is apparently normal. If elevated COHb levels are suspected, blood samples should be taken for laboratory analysis (carbon oximetry).

For the increase of MetHb levels: Based on the level value of MetHb, SpO<sub>2</sub> may decrease by approximately 10% to 15%. When MetHb levels are high, SpO<sub>2</sub> readings tend to be between the low to medium 80s range. If elevated MetHb levels are suspected, blood samples should be taken for laboratory analysis (carbon oximetry).

- ② Intravascular stain (e. g. indigo green or methylene blue)
- ③ External pigments and substances (such as nail polish, nail polish, flash powder, etc.)
- ④ Bilirubin levels are increased
- ⑤ severe anemia
- ⑥ Low-arterial blood flow and perfusion
- ⑦ motion artifacts

- ▶ Dyes that alter normal blood pigmentation or any substance containing the dye may cause erroneous readings.
- ▶ SpO<sub>2</sub> was empirically calibrated in healthy adult volunteers with normal carbon oxyhemoglobin (COHb) and methemoglobin (MetHb) levels.

▶ Do not change or remove the pulse oxygen monitoring device and its accessories, otherwise, injury or equipment damage may occur. If necessary, please return to the factory for maintenance.

- ▶ Do not place the pulse oxetry monitoring device where it can be controlled by the patient.
- ▶ Electric shock and fire hazard: before cleaning, please turn off the equipment and disconnect the power supply.
- ▶ Medical electrical equipment that may interfere with the pulse oxygen monitoring device test should not be placed near the device as it may cause the device to function properly.
- ▶ If the pulse oxy monitoring device shows the patient hypoxemia, the medical staff should take the patient blood sample to confirm the condition
- ▶ If low flow perfusion is frequently indicated, select a monitoring site for better flow perfusion, during which the patient is assessed and examined and the oxygenation status checked by other methods as indicated.
- ▶ If using a pulse oxetry monitoring device during patient phototherapy, keep the pulse oxetry sensor away from the radiation source. If the pulse blood oxygen sensor is exposed to a radiation source, it may lead to inaccurate or zero measurement readings
- ▶ Ensure that the alarm limit setting for monitoring is applicable for the patient, and that the alarm limit setting is checked before using each pulse blood oxygen monitoring device

It is possible that the data changes in the ▶ measurement may be influenced by the sampling technique and the patients physiological conditions. Any results that are inconsistent with the patients clinical status should be repeated and / or supplemented with additional test data. Blood samples are collected and submitted to the laboratory instrument before making clinical decisions, and a comprehensive understanding of the patients condition should be made.

- ▶ Do not immerse the pulse oxy monitoring device in any cleaning solution or attempt to disinfect with high pressure, irradiation, steam, gas, ethylene oxide, or any other method, which will seriously damage the pulse oxy monitoring device.
- ▶ The pulse blood oxygen monitoring device and its accessories must be disposed of in accordance with local laws.
- ▶ In order to minimize electromagnetic interference, RF electrical equipment shall not be close to the pulse blood oxygen monitoring device
- ▶ The function tester cannot be used to assess the accuracy of the pulse blood oxygen monitoring device
- ▶ High intensity light sources (e. g., fluorescent lamp, infrared) can not touch the sensor, otherwise it may cause the pulse oxygen monitoring device to obtain the reading of the patients vital signs.
- ▶ Do not wire patient cables into a tight coil or around the device as this may damage the patient cable.
- ▶ Compatibility of the pulse oxygen sensor and pulse oxygen monitoring device and specific additional information, including product performance information for patient movement and low flow perfusion monitored during the period, can be found in the Pulse Oxygen Sensor Instructions for Use

#### 9.5.2 Connection of the sensor extension cord to the equipment

Put the plug of the sensor extension cable into the SpO<sub>2</sub> interface on the side column of the device, correctly connect the prepared pulse oxygen sensor and the sensor extension line, and then open the pulse oxygen monitoring device. Over time, the SpO<sub>2</sub> display window and pulse display window will display the current value

matters need attention:

- ▶ The sensor extension line and pulse oxygen sensor shall use the accessories designated or recommended by the Company, as listed in the attachment list.

- ▶ When the main switch and the switch of the pulse oxygen monitoring device are placed in the state of "on" simultaneously, the power off time of the device is more than 30 seconds. After the power is restored, close the controller switch for several seconds and then turn on, and then the pulse oxygen monitoring device is set again.
- ▶ When the equipment main switch and the pulse oxygen monitoring device switch are simultaneously placed in the "on" state for no more than 30 seconds, the pulse oxygen monitoring device will automatically restore the setting before the power off

### 9.5.3 Connection of the sensor to the patient

- ▶ Connect the pulse oxygen sensor to the patient according to the instructions. Turn on the pulse blood oxygen detector switch

### 9.5.4 Pulse oxygen alarm upper / lower limit setting

- ▶ The SpO<sub>2</sub> and pulse value can set the upper and lower limit alarm. After exceeding the set alarm limit, the system will issue a sound and information alarm.

#### 9.5.4.1 Setting of the upper / lower limit of the SpO<sub>2</sub> alarm

- 1) Click the alarm upper limit button, open the number keyboard, enter the alarm upper limit, SpO<sub>2</sub> alarm upper limit can be set, the alarm upper limit set range is 50~100%, the level difference is 1%, click SpO<sub>2</sub> on or SpO<sub>2</sub> off to open or close the SpO<sub>2</sub> monitoring device.

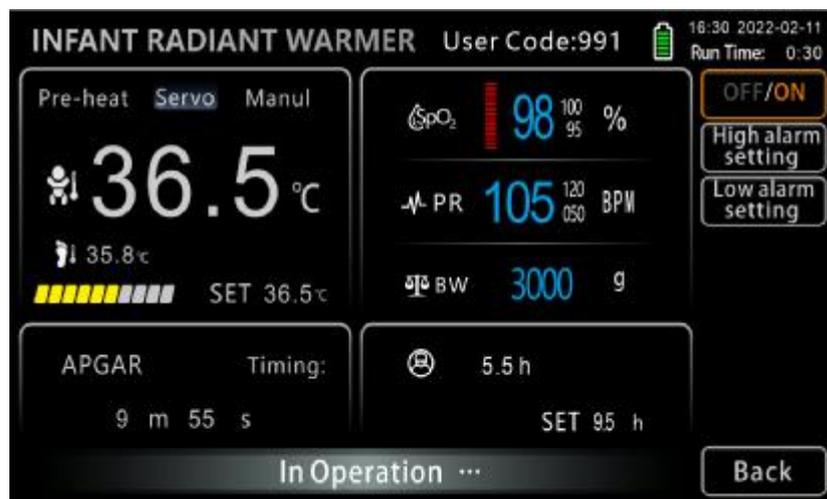


Figure 49

- 2) When the upper limit of SpO<sub>2</sub> alarm is set, click the lower limit button, the number keyboard is opened, enter the lower limit, the lower limit of SpO<sub>2</sub> alarm can be set, the lower alarm limit is 45-95%, and the grade difference is 1%.

Note: When performing positive pressure ventilation resuscitation or oxygen supply, the upper and lower limits of SpO<sub>2</sub> should be carefully selected according to clinical decisions. The wrong setting may cause hyperoxic complications (such as retinopathy).

#### 9.5.4.2 Setting of upper / lower limit of pulse rate alarm

- 1) in the lower limit of SpO<sub>2</sub> alarm is set, press the upper limit of pulse rate alarm, number keyboard open, enter the upper limit of pulse rate alarm, pulse rate alarm can be set, alarm limit range of 80~240 times / points, difference is 1 / points (long press for 5 times / points), click PR open or PR off can open or close the pulse monitoring device.

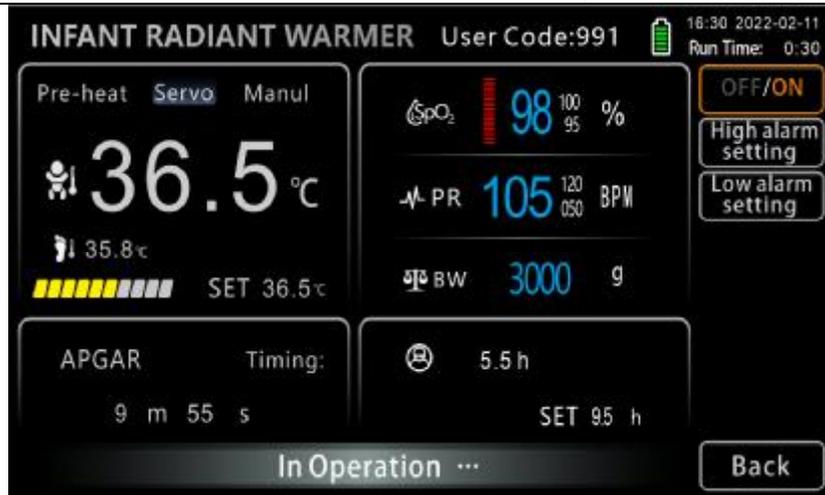


Figure 51

3) When the upper limit of pulse rate alarm is set, press the button of the lower limit of pulse rate alarm, open the number keyboard, and enter the lower limit of pulse rate alarm. The lower limit of pulse rate alarm can be set. The lower alarm limit is set at 35~180 times / minute, and the stage difference is 1 time / minute (long press is 5 times / minute).

#### 9.5.5 Setting of the averaging time of the pulse blood oxygen monitoring device

When the lower limit of the pulse rate alarm is set, the average change time of the pulse blood oxygen monitoring device can be set by pressing the key. The average time can be selected from 2~4 seconds, 4~6 seconds, 8 seconds, 10 seconds, 12 seconds, 14 seconds, 16 seconds, and set by pressing adding button or subtracting button (factory setting: 8s).

- ▶ Only the accessories / consumables provided by the company or recommended by the designated manufacturer (see the accessories list), and the reduced product safety performance caused by the accessories / consumables provided by other manufacturers will cause the equipment to achieve the intended functional use.

#### 9.5.8 Maintenance of pulse and blood oxygen monitoring device

The pulse oxygen monitoring device has passed a rigorous calibration test. During the trial period, routine maintenance of the unit shall be followed in the maintenance cycle of the medical unit. The replacement of pulse oxygen monitoring device shall be conducted by authorized qualified maintenance personnel.

#### 9.5.9 Common faults and solutions of pulse and blood oxygen monitoring devices

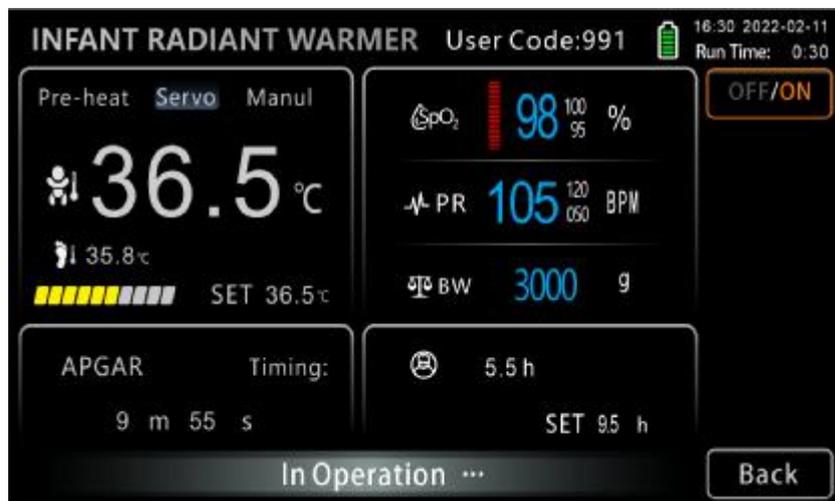
| phenomenon                   | probable cause   | resolvent   |
|------------------------------|--|---|
| The SpO 2 upper limit alarm  | The SpO 2 value displayed is above the set alarm upper limit | When the displayed SpO 2 value is lower than the set alarm upper limit value, the alarm sound and the alarm display information on the LCD screen will disappear  |
| The SpO 2 lower limit alarm  | The SpO 2 value displayed is below the set alarm lower limit | When the displayed SpO 2 value is higher than the set alarm lower limit value, the alarm sound and the alarm display information on the LCD screen will disappear |
| Pulse rate upper limit alarm | The pulse rate value is above the upper alarm limit          | When the displayed pulse rate value is lower than the set alarm upper limit value, the alarm is automatically reset   |

|   |   |  |
|---|---|--|
| Pulse rate offline alarm                | The pulse rate value displayed is below the set alarm lower limit | When the displayed pulse rate value is higher than the set alarm lower limit value, the alarm is automatically reset |
| The SpO <sub>2</sub> sensor fault alarm | Short circuit of the pulse and blood oxygen sensor occurs         | Replace the pulse and blood oxygen sensor  |
|   | Pulse, blood oxygen sensor occurs in an open circuit              |  |

## 9.6 Auxiliary skin temperature monitoring

### 9.6.1 Functions and setting of auxiliary skin temperature

Auxiliary skin temperature monitoring is mainly to monitor the skin temperature of newborn skin temperature. Click the "menu" button to enter the following "Settings" interface:



Click the "Auxiliary Skin Temperature" button to enter the following auxiliary skin temperature setting interface:

Click the "auxiliary skin temperature open" or "auxiliary skin temperature off" button to open and close the auxiliary skin temperature display.

### 9.6.2 Auxiliary skin temperature sensor alarm

When the equipment is in operation and the auxiliary skin temperature sensor is in an open state, the sensor internal short circuit, open circuit or poorly connected, the touch screen should display the "auxiliary skin temperature sensor fault" alarm prompt

## 10 Daily maintenance and maintenance

### 10.1 Overview

The cleaning, maintenance and maintenance provided in this section are instructive only. Before cleaning and maintenance, cut the mains and all wires and pipes.

Be sure to thoroughly clean and disinfect the thermal table before using it in another baby.

This thermal platform is not disinfected before delivery, and must be cleaned and disinfected before use

for the first time after purchase.

It is recommended to clean and disinfect the thermal table at least once a week. The most effective method is to remove the thermal platform first, then clean and disinfect according to the cleaning and disinfection methods required in this section, and then install these parts.

## 10.2 Cleaning

### 1.1.1 Removing before cleaning

For routine cleaning, all parts.

- a) Turn off the power supply and unplug the power supply cord;
- b) Remove the baby crib gear board, take out the baby mattress;
- c) Take out the X-ray shooting box frame;
- d) Pull off the skin temperature sensor;
- e) For the product model with electric suction device, take out the suction bottle, open the cap, and unscrew down the overflow valve on the inside of the cap.

### 1.1.2 Cleaning and disinfection

#### 1) Complete machine disinfection:

After removing the parts, the whole machine can be wiped and disinfected with a disinfectant containing 500 mg/L of effective chlorine, the action time is more than 10 min, and then wipe the surface of each part with sterile wet cloth, and then dry with sterile dry cloth. The removed parts (crib baffle and X-ray box frame) can be used by the same disinfection method as the whole machine.

Note that all the holes and depressions on the outer surface should be wiped.

Note that there is no water entering into the border when wiping the controller display.

Note that the heater has cooled while wiping the radiation head.

#### 2) Disinfection of the skin temperature sensor:

Equipped with disinfectant containing 500 mg/L of effective chlorine, wipe the sensor wire and probe with a cloth stained with disinfectant, the action time is more than 10 min, then wipe the whole sensor with sterile wet cloth, and then dry with sterile dry cloth.

Do not immerse the sensor plug or temperature probe to avoid liquid infiltration into the sensor.

#### 3) Disinfection of the infant mattress:

Baby mattress is divided into mattress core (sponge sealed plastic bag) and mattress cover (pure cotton cloth processing).

The disinfection method of the mattress inner core refers to the whole machine disinfection.

For the disinfection of the mattress covers, it is recommended to use the disinfectant containing 1000 mg/L of effective chlorine to wipe the disinfection, and the action time is more than 10 min. Then rinse into clean water, can be cleaned for many times, and finally dry for standby.

Note: a dirty baby mattress, bed cover will have the accumulation of dirt, in case of pollution should be timely cleaned and disinfected, should ensure that the baby mattress, bed cover clean. The mattress core should be cleaned and disinfected for 2-3 weeks, the mattress cover should be cleaned and disinfected for 2-3 days, and one person should be discarded when damaged. Mattress covers can be reused.

#### 4) Disinfection of suction device bottle and suction tube:

The suction device is mainly used for the attraction of amniotic fluid, including the cavity mucus or blood, and the pollution is relatively serious. Suction bottle and suction tube can be preferred for damp-heat disinfection, or soaked by chlorine-containing disinfectant.

Method 1: Soak and disinfect with chlorine-containing disinfectant. Specific steps are: cleaning-disinfection-clean-dry.

Before the suction stops, it is recommended to inhale a small amount of clean water to clean the inner wall of the pipe. The dirt in the suction bottle should be emptied in time and washed with running water; rinse the bottle cap, unscrew the overflow protector, separate the parts, and rinse with clean water. After cleaning, the suction tube and the suction bottle shall be free of dirt.

Soak the disinfectant containing more than 2000 mg/L of effective chlorine, soak the disinfectant items in the container with the disinfectant, and cover the action time for more than 15 min.

Rinse and wash clean with distilled water. Finally, dry and set aside.

Method 2: use the lower exhaust pressure steam sterilization in the damp-heat disinfection method. The operation method of sterilizer shall follow the instructions of the manufacturer, and the sterilization parameters are generally temperature 121°C, pressure 102.9 kPa and sterilization time 20 min.

Note: Cleaning method before disinfection.

When cleaning, do not wet each electrical interface.

Do not immerse the sensor plug into the disinfectant to avoid liquid infiltration into the sensor interior.



Attention Cleaning and disinfection shall be carried out after the heater is completely cooled.

Avoid liquid from entering the controller, heaters, wires and other components.

Please scrub with a soft cloth, and be careful not to scratch the surface of the equipment, especially the reflective cover.

Should not be cleaned and disinfected with alcohol.

The cloth used to clean the surface of objects should be cleaned and disinfected after each use and dried.

When the equipment is not used, it should be placed in a dry and clean place and stored dry. Under normal circumstances, it is turned on regularly once every six months. For more than one week, it should be cleaned again before use.

### 10.3 Reassembly after cleaning

Reassemble in the disassembly order as described in 10.2.1 before cleaning.



Attention After disassembly, cleaning and installation, see 8.1 "Inspection before Use" for inspection, and

it can be used only after passing it.

## 11 Fault analysis and troubleshooting

The table below lists the general faults that may occur during the life of the thermal platform. Maintenance should be carried out by trained and qualified personnel. If the cause of the fault cannot be found from the table, please contact our company or dealer for repair.

Statement: If necessary, the company may provide the circuit diagram, component list, drawing notes, correction rules and other necessary information, so that the users qualified technicians can repair the specified repair parts.

| phenomenon                              | probable cause  | resolvent  |
|---|---|--|
| There was no display and no alarm sound | The power switch is not turned on                                     | Turn on the power switch   |
|   | Electrical appliance failure or line disconnection                    | Please ask the maintenance personnel to repair it  |
| Power alarm                             | power cut   | Turn off the power switch  |
|   | The power cord is not connected                                       | Connect the power cord   |
|   | The fuse tube is damaged  | Method for replacing the fuse tube:<br>1. Turn off the power switch and unplug the power cord with the outside world;<br>2. Use a one-word screwdriver, unscrew the cap, and remove the fuse;<br>3. Place the same size fuse into the fuse seat;<br>4. Use a one-word screwdriver and tighten the cap. |
| Skin temperature sensor alarm           | The Skin temperature sensor is not connected                          | Connect the skin temperature sensor  |
|   | The internal sensor socket is detached or poorly connected            | Please ask the maintenance personnel to repair it  |
|   | Skin temperature sensor is damaged                                    | Replace the skin temperature sensor  |
| Over temperature alarm                  | The temperature control system is out of control                      | Please ask the maintenance personnel to repair it  |
|   | There is a heat source next to it                                     | Remove the heat source   |
| Skin temperature deviation alarm        | The ambient temperature is very variable                              | Control ambient temperature  |
|   | The skin temperature sensor was not in proper contact with the infant | Check the skin temperature sensor  |
|   | Skin temperature sensor is damaged                                    | Please ask the maintenance personnel to repair it  |
| Operation interface failure             | LCD screen plug-in does not contact                                   | Please ask the maintenance personnel to repair it  |
|   | LCD screen damaged  | Please ask the maintenance personnel to repair it  |

|                              |   |   |
|------------------------------|---|---|
| The temperature rises slowly | Temperature setting value is too low              | Adjust the temperature Set point  |
|                              | The ambient temperature is too low                | Increase ambient temperature  |
|                              | The heater is damaged                             | Replace the heater  |
| Do not heat                  | Please ask the maintenance personnel to repair it |   |
| No negative pressure         | Liquid or solid suction negative pressure pump    | 1, please maintenance personnel maintenance.<br>2, the overall replacement of the factory special negative pressure pump. |

## 12. Transportation and storage

### 12.1 Environmental conditions for transportation and storage

Ambient temperature:  $-40^{\circ}\text{C} \sim +55^{\circ}\text{C}$

Relative humidity: 90%

Atmospheric pressure: 50 kPa  $\sim$  106 kPa

### 12.2 Transportation

After the product is packaged, common vehicles are allowed to transport, but rain and snow splashing and mechanical collision should be avoided.

### 12.3 Storage

The packaged insulation table should be kept in the temperature of  $-40^{\circ}\text{C} \sim +55^{\circ}\text{C}$ , relative humidity not exceeding 90%, no vibration, no corrosive gas and well ventilated room.

## 13 Commitment and statement

### 13.1 Commitment

a) If the ordering company fails to work properly, repair or replace the parts within one year from the date of the purchase; after the warranty period, the corresponding service fee shall be charged. For the repair within the warranty period, if found to be improper use or man-made damage, the repair fee shall be charged according to the circumstances.

**Note:** The following materials are not covered by the warranty: temperature sensor, power cord, fuse, light bulb, battery, mattress, bed cover, etc.;

b) This "Technical Instructions for Use" serves as an important random document, as a common operation guide for the professional management of nursing staff, please be properly stored.

## 13.2 Statement

a) If the thermal platform is found in use, please contact the after-sales service center or agent of the company in time, and obtain the technical support of the company in the first time. The controller should be used as a precision instrument component. It is strictly prohibited to open and repair without authorization, otherwise, it will be treated as "artificial damage".

b) There is a "warranty card" in the attachment, please fill in the relevant content according to the requirements, and seal your company and send it back to the after-sales service center in time, so that we can establish relevant after-sales service files for you as soon as possible.

## 14 List of vulnerable parts

| Name of vulnerable and vulnerable parts |  |
|---|--|
| power line                              | 227 IEC 52 (RVV) 300/500 0.75 m <sup>2</sup> |
| fuse                                    | F 5 A L 250V                                 |
| headlamp                                | LED 12V 6.5 W                                |
| Controller battery                      | 6F22 9V                                      |
| The crib set                            | The company accessories                      |
| drip stand                              |  |
| pallet                                  |  |
| Skin temperature sensor                 |  |
| Simulated lung                          |  |
| T-tube patient donor trachea            |  |
| visor                                   |  |

## Appendix 1 Packing list

| order number | name                    | unit | quantity | remarks         |
|--------------|-------------------------|------|----------|-----------------|
| 1            | overall unit            |      | 1        |                 |
| 2            | drip stand              |      | 1        |                 |
| 3            | pallet                  |      | 2        |                 |
| 4            | Skin temperature sensor |      | 1        | In the file bag |
| 5            | power line              |      | 1        | In the file bag |
| 6            | The crib set            |      | 1        |                 |
| 7            | crib mattress           |      | 1        |                 |
| 8            | replacement tool        |      | 1        | In the file bag |
| 9            | instructions            |      | 1        | In the file bag |

|    |                              |  |   |   |
|----|------------------------------|--|---|---|
| 10 | Packing list                 |  | 1 | In the instructions                         |
| 11 | certificate                  |  | 1 | In the file bag                             |
| 12 | Fuse of the F 5 A L 250V     |  | 4 | In the file bag                             |
| 13 | jaundice treatment lamp      |  | 1 | Optional light therapy                      |
| 14 | Attractive attraction bottle |  | 1 | BRW—4000B                                   |
| 15 | Attractor suction catheter   |  | 1 |   |
| 16 | Air, oxygen intake pipe      |  | 1 |   |
| 17 | Simulated lung               |  | 1 |   |
| 18 | T-tube patient donor trachea |  | 1 |   |
| 19 | visor                        |  | 1 | Optional T-combination resuscitation device |

Note: T-tube patient supply pipe is recommended for disposable pipes, and mask is recommended for disposable accessories for a single patient

Refer to the randomization instructions.

## Appendix 2 circuit

