DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

CE 0483

DIXION

BabyGuard W-1140

Infant radiant warmer

Operator´s Manual

Manual Ver: V1.9
Release Date: August 2024
Part Number: OM_BabyGuard W-1140_V1.9

EMC INFORMATION

This section is special precautions regarding EMC. The equipment should be installed and put into service according to EMC information of this section.

ELECTROMAGNETIC COMPATIBILITY PRECAUTIONS

1. The equipment intends to use in the professional healthcare facility environment.
2. Equipment cannot be operated or exposed in RFID, X-RAY, MRI environments.
3. Pay attention to the electromagnetic environment at the scene, because the equipment may be affected by the electromagnetic environment at the scene.
4. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
5. Equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
6. If the essential performance is lost or degraded due to EM disturbances, the user might need to take mitigation measures, such as relocating or re-orienting the equipment.
7. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

CABLES SUPPLIED BY THE MANUFACTURER

NAME	MAXIMUM LENGTHS OF CABLES
Power cord	3 meters
Skin temperature sensor	1.5 meters

ESSENTIAL PERFORMANCE

1. With the INFANT RADIANT WARMER working in the BABY CONTROLLED RADIANT WARMER operation with horizontal mattress orientation in NORMAL CONDITION， the temperature as measured by the SKIN TEMPERATURE SENSOR shall not differ from the CONTROL TEMPERATURE by more than 0.5℃.

2. After STEADY TEMPERATURE CONDITIONS have been achieved, any sensed temperature deviation exceeding ±1℃ compared with the CONTROL TEMPERATURE shall cause an auditory and visual alarm to operate, and the INFANT WARMER heater shall switch off when the second temperature exceeds the CONTROL TEMPERATURE by 1℃.

3. The INFANT RADIANT WARMER shall not permit the SKIN TEMPERATURE of the PATIENT to exceed 40℃ under NORMAL CONDITION and each SINGLE FAULT CONDITION.

Guidance and manufacturer's declaration – electromagnetic emissions-
for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission	
The *INFANT RADIANT WARMER* is intended for use in the electromagnetic environment specified below. The customer of the user of the *INFANT RADIANT WARMER* should assure that it is used in such and environment.	
Emission test	**Compliance**
RF emissions CISPR 11	Group 1
RF emission CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Guidance and manufacturer's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity		
The *INFANT RADIANT WARMER* is intended for use in the electromagnetic environment specified below. The customer or the user of *INFANT RADIANT WARMER* should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	□8 kV contact □15 kV air	□8 kV contact □15 kV air
Electrical fast transient/burst IEC 61000-4-4	□2 kV for power supply lines	□2 kV for power supply lines
Surge IEC 61000-4-5	□1 kV differential mode □2 kV common mode	□1 kV differential mode □2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25 cycles Single phase: at 0° 0 % UT; 250cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25 cycles Single phase: at 0° 0 % UT; 250 cycle
Power frequency magnetic field（50/60HZ） IEC 61000-4-8	30A/m	30A/m
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity		
The *INFANT RADIANT WARMER*is intended for use in the electromagnetic environment specified below. The customer or the user of *INFANT RADIANT WARMER* should assure that it is used in such an environment.		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	$3V_{rms}$ 150 kHz to 80 MHz $6\ V_{rms}$ 150 kHz to 80 MHz in ISM bands	$3\ V_{rms}$ $6\ V_{rms}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10V/m
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
[a] The ISM(industrial, scientific and medical) bands between 150kHz and 80MHz are 6.765MHz to 6.795MHz; 13.553 MHz to 14.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. [b] The compliance levels in the ISM frequency bands between 150kHz and 80MHz and in the frequency range 80 MHz to 2.5GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges. [c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *INFANT RADIANT WARMER*is used exceeds the applicable RF compliance level above, the *INFANT RADIANT WARMER*should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Infant Incubator*. [d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.		

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

IMMUNITY to proximity fields from RF wireless communications equipment

The ENCLOSURE PORT of ME EQUIPMENT and ME SYSTEMS shall be tested as specified in Table 9 using the test methods specified in IEC 61000-4-3..

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHZ)	Band a) (MHZ)	Service a)	Modulation b)	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (v/m)
385	380-390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28
710	704-787	LTE Band13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9
5500						
5785						
NOTE If necessary to achieve the IMMUNITY TEST LEVEL , the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.						

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50 % duty cycle square wave signal.

c) As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

WARRANTY

The product being described in this manual is warranted against defects in materials or workmanship for one year from the date of shipment, with the following exceptions.

1. All consumable and disposable products are guaranteed to be free from defects upon shipment only.
2. Calibrations are considered normal maintenance and are not included in the 1-year warranty.

During the warranty period any defective parts other than those listed above will be replaced at no charge to the customer.

This warranty is rendered void and our company cannot be held liable for conditions resultant therefrom if:

1. Damage to the unit is incurred as a result of mishandling.
2. The customer fails to maintain the unit in a proper manner.
3. The customer uses any parts, accessories, or fittings not specified or sold by our company.
4. Sale or service is performed by the non-certified service/dealer agency.
5. For related technical instructions, please refer to the maintenance manual.

This warranty is in lieu of all other warranties, expressed or implied, and our company shall in no event be liable for incidental or consequential damages including loss of use, property damage, or personal injury resulting from breach of warranty.

The Accreditation Manual for Hospitals requires each piece of equipment to be tested prior to initial use and at least annually thereafter. To comply with this standard, we recommend that you participate in our accreditation Testing compliance Program during the warranty period. This service can be performed through our company and authorized dealers.

SERVICE

For optimal performance, product service should be performed only by authorized and qualified service personnel from our company. Please contact the local agency or the After-Sales of our company to get more technical information about maintenance.

OPERATING PRECAUTIONS

1. INFANT RADIANT WARMER (Radiant warmer) belongs to high risk medical device which can endanger infant's life. Therefore please use the device only in operation room, neonate nursing room, pediatric intensive care unit or similar sickroom in hospital. Operator for the device should be specially trained and operate the device under the instruction of medical practitioner.

2. The operator must keep observing the patient's condition while the device is working. Supervise and record baby's temperature regularly to check whether the temperature of the patient is over high/low or any other unusual conditions happen. Suggest monitoring the baby temperature at least 1 time every half an hour.

3. Please stop using the device when it fails or malfunction appears. Turn off the power and transfer the patient out from the device, then inform our company or our authorized agency for service. DO NOT ask for service from person who's not been authorized by our company.

4. To make sure to keep the body temperature of infant stable when the infant receives the phototherapy treatment, try to make the ambient environment suitable and stable where the INFANT RADIANT WARMER is located. If not, it will affect the infant. If the ambient temperature is much lower, it will decrease the body temperature of infant and make the infant catch cold; while If the ambient temperature is much higher, it will increase the body temperature of infant and make the infant overheat.

5. DO NOT store the drugs and infusion liquids in the radiation area of the INFANT RADIANT WARMER. 6. Direct radiation from sunlight or other infrared source could cause overheating of the infant without activating the Over Temperature Alarm. DO NOT leave the WARMER in direct sunlight or near other sources of radiant heat.

7. DO NOT leave the WARMER in the presence of flammable anesthetic gases or other flammable materials, such as some types of cleaning fluids.
8. DO NOT leave the WARMER in the presence of strong electromagnetic field. Portable and mobile RF communication devices may have an impact on this device.
9. Devices which are easily interfered by magnetic field should not be used near the WARMER because they may be interfered by the WARMER.
10. The fast air flow can affect the thermal balance of the infant. Therefore, the WARMER should be placed in the room where the air flow rate is less than 0.3m/s.
11. Please DO NOT use the WARMER under working environment not stipulated in table 1.1, or else, it may cause the failure or the WARMER can not meet the requirements.
12. Check the panels regularly to examine whether these panels are installed firmly to avoid the infant falling on the floor.
13. Please check the firm of panel regularly, DO NOT leave the infant alone to prevent the baby falling from the bassinet.

14. When operating the panel, pay attention not to touch any part of the infant to avoid the harm on the skin of infant.

15. If the infant wears the clothes or is covered with the blanket, and it can affect the infrared radiation of infant, so we suggest that the infant should be naked.
16. When the bassinet tilts, some part of the patient is near heater so as to absorb more radiant heat, therefore, these parts should be checked more than before.
17. Please DO NOT touch the heater or its protective parts to avoid the scald.
18. Please DO NOT put anything on the top of WARMER, or else, it will cause the damage and the hazard.
19. To avoid overturning, please DO NOT move the WARMER laterally .
20. One person of sufficient strength is required to move the WARMER. The shake hands handle which located in the front of warmer can be used as mobile handle (This handle can not carry the whole machine). Please disconnect all power cords before moving.
21. Casters should be locked tightly to prevent moving.
22. Please DO NOT keep the power switch on for a long time when the mains power is disconnected. Or else, it may waste the power of internal battery or damage the battery.
23. Only the authorized and qualified maintenance personnel can replace the fuse according to the specification. When replace the fuse, you should disconnect the power supply of the radiant warmer first, and can not touch the patients and metal parts at the same time.
24. Do not put the objects which are higher than the casters under the VHA stand. Or they will affect the operation of the VHA stand.
25. When operating the VHA stand, support the warmer with one hand on to prevent it from unbalance.
26. In nursing operation, the operator can not touch the other charged equipment at the same time, may bring shock hazard to patients.
27. The radiant warmer must be cleaned and sterilized for the first time for initial use, finish the operation for a baby or after used it for one week and there's dirt on the device. The detail clean/sterilize method please check the Section 6. The radiant warmer super load of continuous use may accelerate all the components aging or increase the failure frequency, therefore, please stop using the equipment when it continue work for one week.
28. Must use neutral cleaning/disinfectant to clean. Other disinfectant (like alcohol) will destroy some parts of the radiant warmer. Please follow the instruction for detergent usage to use.
29. After cleaning the radiant warmer by combustible cleaning solvent should airing the radiant warmer completely. The residual a handful of the flammable solvent (such as ethyl ether, ethanol or similar cleaning solvent) in the radiant warmer can cause a fire.

30. Please only use skin temperature sensor, rechargeable battery,power cord or other accessories provided by our company. Otherwise, it may reduce the safety and noise immunity of the equipment or increase the equipment launch.

31. Generally the life period of rechargeable battery inside the radiant warmer is 3 years. Before using the product each time, should inspect the rechargeable battery according to maintenance requirements of 6.3. If it isn't getting through the inspection or the battery has been used more than 3 years, the battery should be replaced. The replacement of the internal rechargeable battery required by authorized qualified service personnel.
32. Damages will be easily caused if using the warmer after it reached its lifetime. Guideline and requirement for original capability cannot be reached as well, which requirement for disabled.
33. The lifetime for the infant radiant warmer is 8 years. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. If you discard randomly, it will cause environment pollution. So please follow Local Ordinances or Regulations for disposal, or return to our company for disposal.
34. The device should not be close to or use with other device. If have to, please observed to verify that in its use of configuration can run normally or not.
35. Using additional heating function of bassinet of radiant heater or using the jaundice treating function during the Heater in the use of radiation, may lead to patients over heated. This factor should be fully considered under such situation and the operator need to set the correct radiant heating function.

ELECTRICAL PRECAUTIONS

1. In order to avoid the risk of electric shock, the equipment should only be connected with the protective grounding grid. Do not operate the equipment if you have any doubt about the ground connection.
2. Using auxiliary equipment that is not compatible with the safety requirements will reduce the safety. Please make sure that the auxiliary equipment has passed the safety testing according to adjusted national standards based on IEC60601-1 and got the safety certificate.
3. When equipped with the VHA stand, to protect the equipment damaged or disconnect of power by accident, do not connect the power supply of the warmer module to the network directly. The power supply should be provided by the VHA stand.
4. Considering the reason of the electric shock hazard, please refer to the authorized and qualified service personnel.
5. Make sure the power supply meets the requirements which are listed on the electrical nameplate.
6. When stop using the warmer or maintain the warmer, in order to ensure the safety, please disconnect all power line. If equipped with the VHA stand, please disconnect the power line of the stand.

7. Equipment provided an integral multiple socket-outlet, If connecting the auxiliary equipment on this interface, the maximum power of the auxiliary equipment shall not exceed the prescribed load limit, The assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of IEC60601-1, clause 16. Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.
8. For safety, this device adopts main plug or appliance coupler as isolated from the controller is mounted on stand. This device adopts mains plug or appliance coupler as isolation from the supply mains when the radiant warmer is mounted on VHA stand. Please always make mains plug or appliance coupler easy to operate.
9. General Power switch used as isolation device from the mains supply. When the operator wants to safely terminate operation of Me Equipment, please cut off the General Power switch. Equipment should be placed where it is easy to operate.
10. Any parts are not serviced or maintained while in use with the patient.
11. When selecting the ancillary equipment must insure that the equipment had tested according to the requirements in IEC60601-1 or other relevant standard, and acquire the safety certificate.

ILLUMININATION PRECAUTION

1. DO NOT store the drugs and infusion liquids in the radiation area of the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT.
2. During the use time, the equipment will cause a certain amount of radiation, the operator must operate in accordance with the provisions of section 5 operation.
3. The light source for generating the radiation is LED with wavelength 420~470nm, the emission limit of single phototherapy（AEL）≤6000μW.
4. To avoid hurting the retina of patient, please wear the eye mask for the patient during illumination.
5. To ensure phototherapy treatment effect, when the radiation source is over the expected useful lifetime, all should be replaced.
6. To ensure the safety and effectiveness of phototherapy equipment, the radiation resource only can be provided by our company.

SEASONAL SAFETY CHECK

1. Please clean the plug of power cord at least once a year. Too much dust on plug may cause the fire.
2. The skin temperature sensor should be calibrated every half year by authorized and qualified service personnel.
3. The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

○1. Inspect the equipment and accessories for mechanical and functional damage.

○2. Inspect the safety relevant labels for legibility.

○3. Inspect the fuse to verify compliance with rated current and breaking characteristics.

○4. Verify that the device functions properly as described in the instructions for use.

○5. Test the protection earth resistance according IEC 60601-1:2005+A1:2012: Limit 0.1Ω (including Power line: Limit 0.2Ω).

○6. Test the earth leakage current according IEC 60601-1:2005+A1:2012: Limit: NC less than 5mA, SFC less than 10mA.

○7. Test the enclosure leakage current according to IEC 60601-1:2005+A1:2012: Limit: NC less than 100μA, SFC less than 500μA.

○8. Test the patient leakage current according IEC 60601-1:2005+A1:2012: Limit: for AC less than 100μA, for DC less than 10μA.

○9. Test the patient leakage current under single fault condition according IEC 60601-1:2005+A1:2012: Limit: for AC less than 500μA, for DC less than 50μA.

⑩. Test the patient leakage current under single fault condition (with mains voltage on the applied part) according IEC 60601-1:2005+A1:2012 less than 5000μA.

○11. Test the patient auxiliary leakage current according IEC 60601-1:2005+A1:2012: Limit: NC for AC less than 100μA, for DC less than10μA. SFC for AC less than 500μA, for DC less than 50μA.

4. The essential performance should be verified at least once a year by qualified service personnel who gets trained and obtain written authorization of the company. The essential performance verification method shall meet the requirements of clause 201.12.1.104, 201.12.1.106, 201.15.4.2.1ee) and 201.15.4.2.1dd) of IEC60601-2-19:2016.

TABLE OF DEFINITIONS AND SYMBOLS

TECHNICAL DEFINITIONS

SKIN TEMPERATURE SENSOR: A sensing device including the link with the equipment intended to measure the infant's baby temperature.

CONTROL TEMPERATURE: The temperature which is set on the temperature controller.

PRE-WARM MODE: A warm mode which can keep the mattress at a properly temperature. The heater output will work automatically according to the set programmer in this mode.

MANUAL MODE: A operation mode of in which the heater output is either at a fixed level or a proportion of its maximum output set by the operator.

BABY MODE: A mode of operation in which the power output varies automatically in response to the temperature of the baby, to achieve a temperature close to a value set by the operator.

STEADY TEMPERATURE CONDITION: A condition which is reached when the temperature, measured at the center of the TEST DEVICE positioned on the mid point of the EQUIPMENT mattress, does not vary by more than 1℃ over a period of 1 hour.

TEMPERATURE ALARM CHECKOUT STATE: The difference between the indicated temperature and control temperature is within ±0.5℃ and such state lasts for over 5 minutes. When checkout the temperature alarm function, operation should be enter this state.

APGAR TIMER: It offers the functions of three periods alarming indication: 1min, 5min, and 10min for clinical treatment.

TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} : Irradiance equal to the evaluated irradiance in the range between 400 nm and 550nm.

UNIFORMITY G_2 OF THE TOTAL IRRADIANCE FOR BILIRUBIN: Ratio of the lowest TOTAL IRRADIANCE FOR BILIRUBIN $E_{bi\ min}$ to the highest TOTAL IRRADIANCE FOR BILIRUBIN $E_{bi\ max}$ on the EFFECTIVE SURFACE AREA in section 5.

LED'S LIFETIME : The total time of the light source has been in use continuously.

LED EFFECTIVE SERVICE TIME： Sum of the service time when the total bilirubin irradiance Ebi Is attenuated by 25% of the claimed value.

VHA STAND: Abbreviation of vertical height adjustment stand.

LIFETIME OF PRODUCT: The period from sell-by date to the date of discarding as useless.

NOTE, IMPORTANT, CAUTION AND WARNING

NOTE: A note is inserted in text to point out procedures or conditions, which may otherwise be misinterpreted or overlooked. A note may also be used to clarify apparently contradictory or confusing situations.

IMPORTANT: Similar to a Note but be used where greater emphasis is required.

CAUTION: A caution is inserted in text to call attention of a procedure which, It not followed exactly, can lead to damage or destruction of the equipment.

WARNING: A warning is inserted in text to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal Injury or death of the operator or patient.

SYMBOLS


General warning sign


Follow instructions for use

CLASS I Class I Equipment

On (Power: Connection to the mains)


On (only for a part of equipment)

Time Mode Select Key


Mode Select Key


Set Up Key / Height adjustment up key


Silence/Reset Key

Calibration Key


Warning; Hot surface


Warning; Non-ionizing radiation

Type BF Applied Part


Off (Power: Disconnection to the mains)

Off (only for a part of equipment)


Protect infant's eyes with opaque eye protection / Power switch of phototherapy unit


Heater Power Indicator


Set Down Key / Height adjustment down key


Keypad lock key

RS-232 Data communication interface

220-230V~/50Hz Input Power

220-230V~/50Hz
MAX:0.3A Auxiliary Mains Output, MAX:0.3A

F 5AH/250V Type F Fuse 5AH/250V

F 6.3AH/250V Type F Fuse 6.3AH/250V

No heavy load


Authorized representative in the European community

Date of Manufacture


Manufacturer

Serial Number

CE Marking

TABLE OF CONTENTS

SECTION PAGE

NOTE: THE PRODUCT'S APPEARANCES MAYBE DIFFER FROM THE ONE IN THIS MANUAL, BUT IT DOSE NOT AFFECT THE CAPABILITY OF PRODUCT. PLEASE UNDERSTAND IF IT BRINGS YOU TROUBLES.

SECTION 1 GENERAL INTRODUCTION

1.1 INTRODUCTION

This manual provides instructions for installation, debugging, operation, cleaning and maintenance of Infant Radiant Warmer (warmer for short in this manual). We are not responsible for the malfunction which is caused due to not following the instructions on our manual.

The operator should read and understand the content of this manual.

This manual should be put together with the device so the client can check at any moment. The VHA stand is the optional accessory for the product. We also provide the disposable skin temperature sensor for your choice. If you do not buy the accessory, you can give up this part.

1.2 INTENDED USE

The infant radiant warmer is a radiant warming; open type incubator intended to provide an optimum clinical environment for observation, examination, temperature regulation, and management of neonates.

1.3 PRODUCT CONTRAINDICATIONS

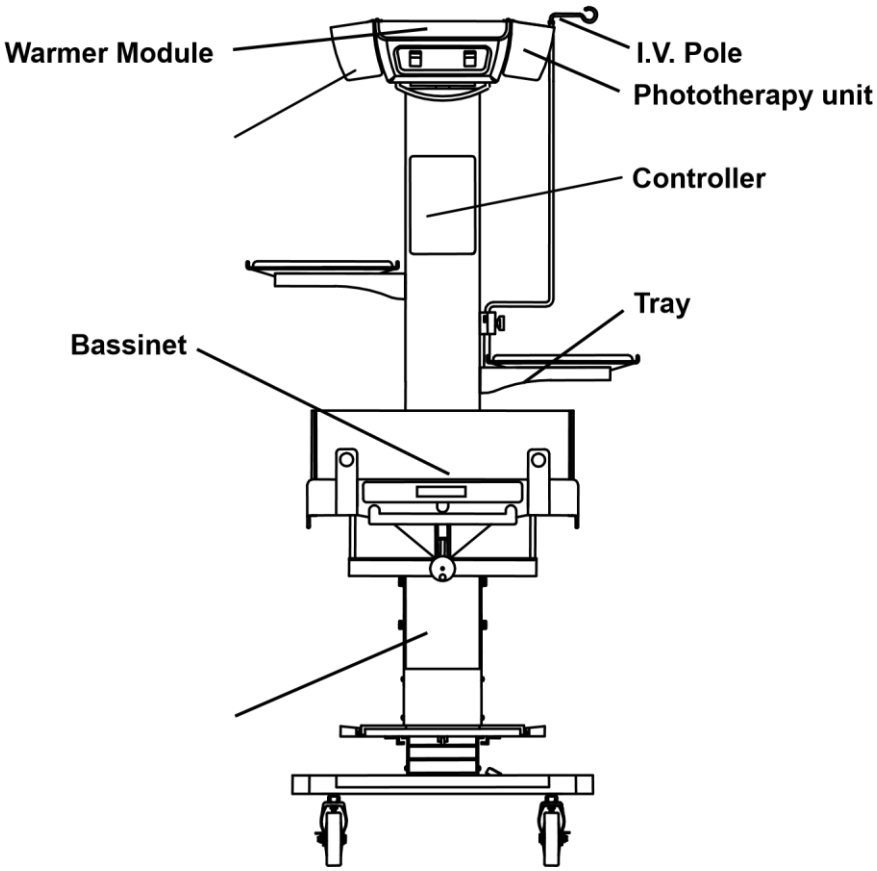
It is not clear now.

1.4 COMPOSITION OF PRODUCTS

The infant radiant warmer consists of five components: the warmer module, the bassinet, the main column, the mobile stand, and the controller.

1.5 DESCRIPTION

The following diagram shows the main parts of the infant radiant warmer:



DESCRIPTION OF PART	EXPLANATION
Warmer Module	This main part is composed of the Heater, Reflective Cover, a built-in illumination Light and so on, it is intended to provide the radiation for electromagnetic spectrum infrared range with weight of 16Kg, and its angle can be adjusted horizontally in two ways. The lifetime of heater is 2000hrs.
Phototherapy unit	It is intended for treating the bilirubin of patient. The light source of this device is LED, the effective service time of LEDs is 5000hrs, and lifetime of LEDs is 20000hrs. Please wear the eye mask for patient when this part works, as for the detail, please refer to section 5.
I.V. Pole	A kind of bearing part, which is used for hanging the infusion bottle. Max. Load: 2Kg
Controller	The core part with 3 temperature control mode: **Pre-warm Mode**, **Manual Mode**, **Baby Mode**, APGAR timer, timing function, and it is used for automatic controlling of infrared radiation heat output, please refer to section 4.
Tray	A kind of bearing part, which is used for putting some small objects. Max. Load: 2 Kg
Bassinet	It is used for placing the infant. The bassinet can be tilted. Max. Load: 10 Kg. This bassinet is equipped with 4pcs of panels to avoid the patient from falling off. Size of mattress: 760mm×595mm
Stand	Stand or VHA stand, stand is the conventional configuration. Stand(standard parts) : the height from the bassinet to the floor is 890mm; VHA stand(optional parts) : the height from the bassinet to the floor is 890mm~ 1030mm.

The maximum bearing weight of I.V. Pole and other accessories is described in the table. Please do not overload to avoid damages to accessories.

NOTE: Size of whole unit: L1100×W730×H1795mm（with stand）;

L1100×W730×H1795mm~ L1100×W730×H1935mm (with VHA Stand).

Weight of whole unit: 105Kg (with stand),

140Kg（with VHA Stand）

1.6 SPECIFICATION

This product's classification as follows:

By the electric shock protection type classification: Type I equipment.

By the degree of shock proof classification: Type BF application part

By the specified of IEC60529 for liquid protection degree classification: IPX0.

By the manufacturers recommended disinfection and sterilization method classification: Use neutral disinfection solvents or solution to clean.

By the air mixer of flammable gas or with oxygen or nitrous oxide mixture of flammable anaesthetic gas safety degree classification: It should not use in air mixer of flammable gas or with oxygen or nitrous oxide mixture of flammable anaesthetic gas.

By operational mode classification: Continuous operation.

Specifications for the Radiant Warmer are provided in table 1.1.

TABLE 1.1 SPECIFICATIONS

Power Requirements……AC220V-230V/50Hz, 750VA
Maximum Heater Power Output……580W/240V
Auxiliary Mains Power Output……AC220V-230V/50Hz, MAX. CURRENT 0.3A
Heater power display……0 to 100%, adjustable in 10% increments
Heater modes……Pre-warm mode
Manual mode
Baby mode
Baby mode Temperature Control range……34.5℃ ℃~37.5
Temperature sensor display range……5℃ ℃~65
Deviation between the measure baby temperature by the sensor and control temperature……≤0.5℃
Accuracy of skin temperature sensor……±0.2℃
Temperature uniformity of mattress……≤2℃
ENVIRONMENT TEMP (Not to use in the environment exceed specified)
Operating range……+18℃～+30℃ **Storage and transport range**……-40℃～+55℃
ENVIRONMENT HUMIDITY
Operating range……30%RH～75%RH
Storage and transport range……≤93%RH
ATMOSPHERE PRESSURE
Shipment and store atmospheric pressure range……500hPa~1060hPa
Working atmospheric pressure range……800hPa ~1060hPa

TABLE 1.1 SPECIFICATIONS (continued)

Application environment altitude……≤2000m

Over-voltage category……II

Pollution degree……2

AIR FLOW RATE

Ambient air movement rate……<0.3m/s

OTHER SPECIFICATION

Phototherapy unit working noise……Ambient noise≤40dB(A), working noise≤50dB(A)

APGAR Timer……Audible and visible alarm when the device runs to 50″～1′, 4′50″～5′, 9′50″～10′

The Maximum of total irradiance for bilirubin of effective range on the mattress……0.75mW/cm^2

Uniformity of the total irradiance for bilirubin of effective range on the mattress……>0.4

The average of total irradiance for bilirubin of effective range on the mattress……≥0.58mW/cm^2

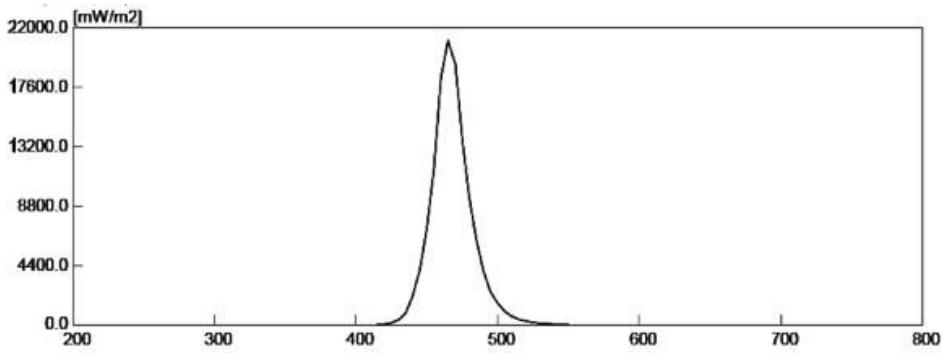
The total irradiance E_{bi} on the effective surface area……≥0.66mW/cm^2

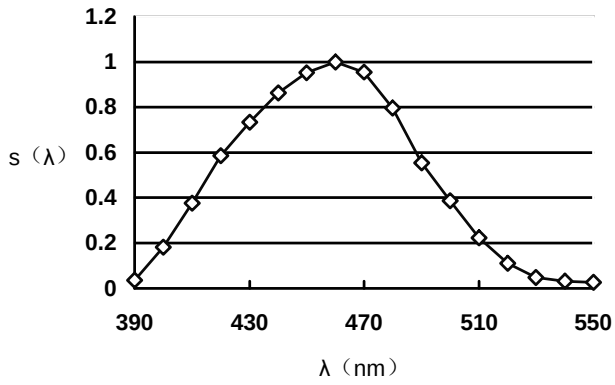
NOTE: Changing the inside room air flow rate or the angle of declination of bassinet, or using the heating device beside this mode, may affect the relations among temperature uniformity of mattress, indicated temperature or baby temperature.

TABLE 1.1 SPECIFICATIONS (continued)

Averaged of total spectral irradiance, Interval of 5nm for the wavelength rage between 320nm and 550nm

320	0.0000000000	440	2.0851640000
325	0.0000000000	445	4.0588730000
330	0.0000000000	450	7.1860800000
335	0.0000000000	455	11.5261200000
340	0.0000000000	460	18.2637400000
345	0.0000000000	465	21.0351500000
350	0.0000000000	470	19.3089700000
355	0.0000000000	475	13.6934800000
360	0.0000000000	480	9.3698260000
365	0.0000000000	485	6.3107570000
370	0.0000000000	490	3.9971590000
375	0.0000000000	495	2.4550760000
380	0.0000000000	500	1.5803700000
385	0.0000000000	505	0.9958963000
390	0.0000000000	510	0.6231434000
395	0.0000000000	515	0.3886996000
400	0.0000000000	520	0.2505039000
405	0.0000000000	525	0.1611249000
410	0.0000000000	530	0.1039433000
415	0.0014880750	535	0.0651738000
420	0.0412178700	540	0.0426970300
425	0.1388389000	545	0.0260784500
430	0.3533474000	550	0.0148105000
435	0.8143584000		





Calibration curve of the measurement device

SECTION 2
INSTALLATION

2.1 GENERAL

This section provides installing procedures about WARMER.

2.2 UNPACKING

Generally, the WARMER is usually packed into to one carton. When taking out the equipment from the cartons, take care not to damage the spare parts of the WARMER.

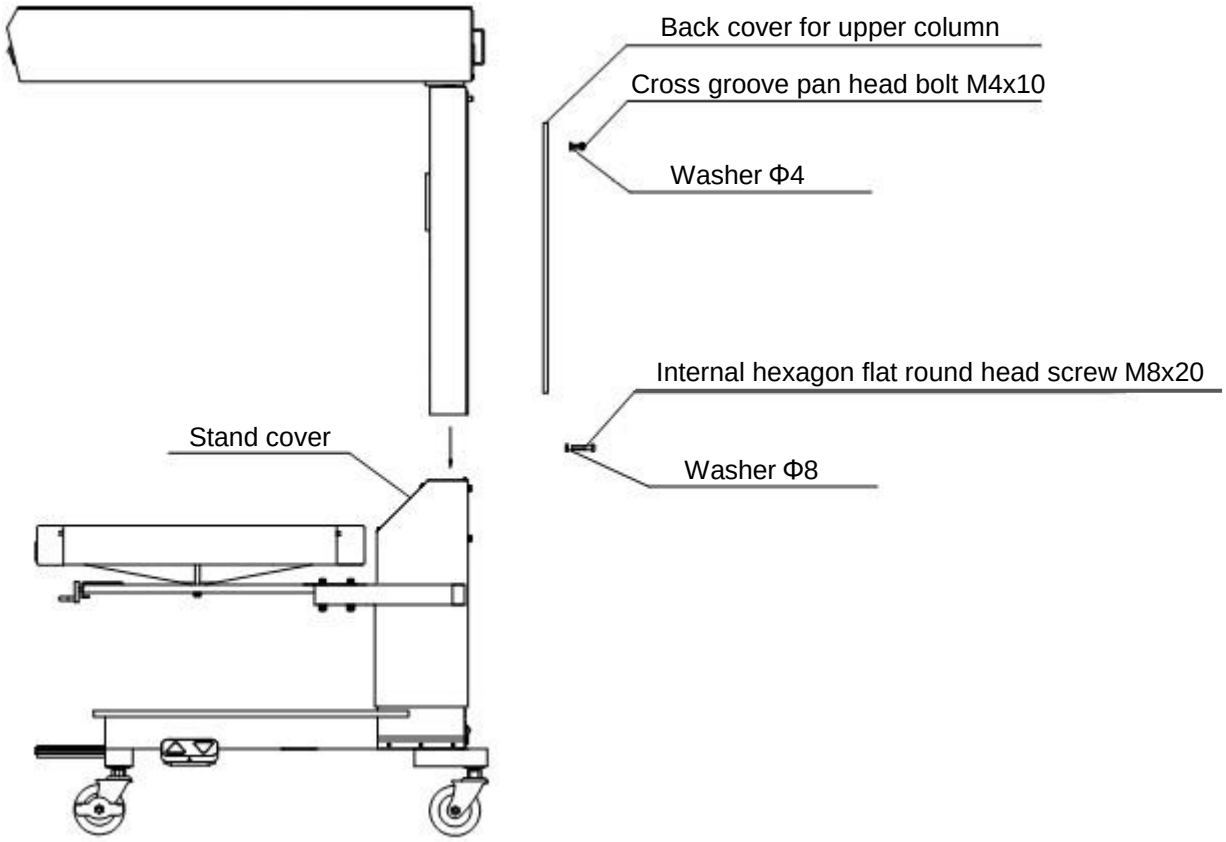


FIGURE 2. 1

2.3 INSTALLATION

Before installation, check if the surface of structure parts attached is adequate. At least two professionals are required to do the installation of the WARMER with spanners and screwdriver.

Installation step:

A. Install the upper column groupware (upper column + warmer module)

a. The installation of the warmer with VHA.

① Unscrew the fixing bolt on the stand cover with screwdriver and remove the cover, and pull out the power cord of warmer module.

② Unscrew the bolt M8X20 and washer Φ8 in figure 2.1 with spanner.

③ Unscrew the bolt M4X10 and washer Φ4 in figure 2.1 with screwdriver to disassemble the back cover of upper column.

④ Insert the upper column into the stand column, and tighten it with the previous unscrewed bolt M8X20 and washer Φ8; insert the power cord of warmer module into the socket in figure 2.2 long with the path inside the upper column. Then fix the clamp on the power connecting wire to the upper column with bolts as the following figure 4.2 shows.

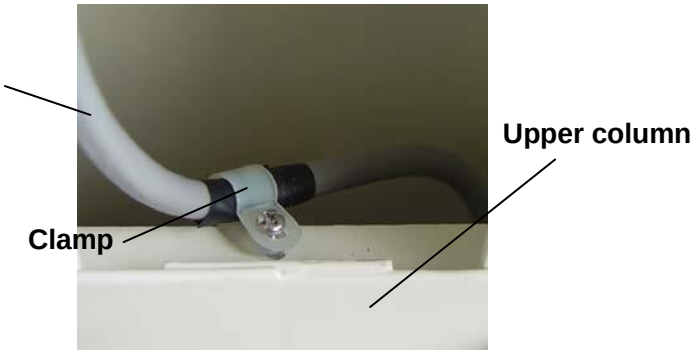


FIGURE 2.2

⑤ Assemble the stand cover into its original position with the unscrewed bolts and tighten the cover with the unscrewed bolt M4X10 and washer Φ4.

b. The installation of the warmer with fixed stand

① Unscrew the bolt M8X20 and washers Φ8 on the upper column.

② Insert the upper column groupware into the stand's column as figure 2.3 indicates, and tighten it with the previous unscrewed bolt M8X20 and washers Φ8.

FIGURE 2.3

IMPORTANT: Please make sure that the upper column and the stand are vertical, or else, it will affect the temperature uniformity on the mattress.

B. Install the panel

Insert the panel into the Fixed seat as the arrow indicates in figure 2.4.1, and turn it upward to make it vertical and press it as the figure 2.4.2 indicates.

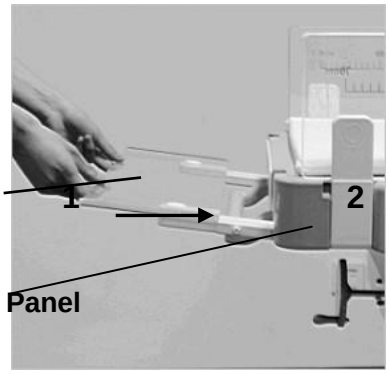


FIGURE 2.4.1

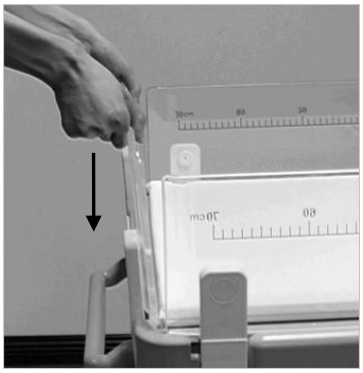


FIGURE 2.4.2

NOTE: 1. Total 4 pieces of panels, the panel with groove is the back panel.

2. Make the bassinet tilt when installing the back panel.

C. Install tray and I.V. Pole

① as the figure 2.5.1 shows, put the tray inside bottom of the fixed block as the direction of the arrow, then fix it with the fixing bolt as the figure 2.5.2 shows.

② See figure 2.5.3, install the I.V. Pole on the upper column, and tighten the bolt.

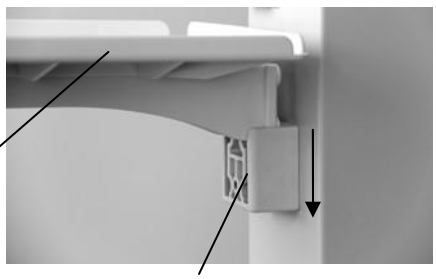


FIGURE 2.5.1

FIGURE 2.5.2

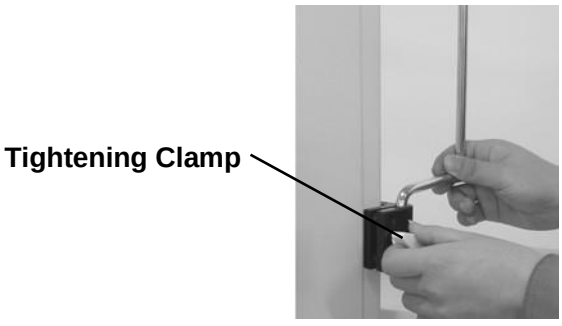
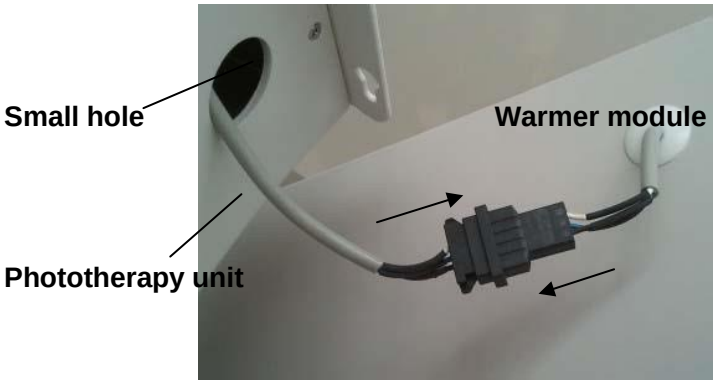


FIGURE 2.5.3

D. Install the phototherapy

① In figure 2.6.1, connect the plug from phototherapy unit and the one from the warmer module, and then insert the wires into the small hole on the Phototherapy unit.

② In figure 2.6.2, aim the three holes on the phototherapy unit at the three holes on the top of the warmer module and tighten the bolts with a screwdriver.



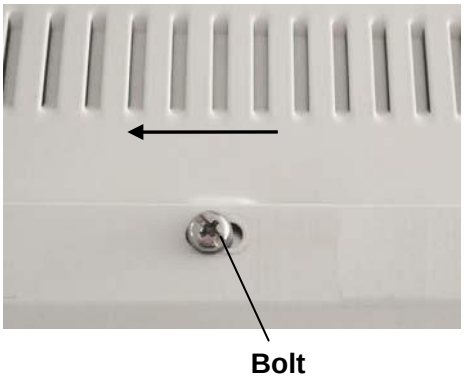


FIGURE 2.6.1 **FIGURE 2.6.2**

E. Insert the power cord

Insert the power cord into the socket of general power supply in figure 4.1. (for VHA stand); Insert the power cord into the socket of general power supply in figure 4.3. (for fixed stand).

Check the WARMER according to the instruction in section 4.4.

Attention: when with VHA stand configuration, the main power switch of the warmer is located on the base of VHA stand; when with stand configuration, the main power switch of the warmer is located on the back of the controller; do not place the equipment to where it is hard to operate the power switch.

SECTION 3
FUNCTION DESCRIPTION

3.1 OVERALL FUNCTION DESCRIPTION

The Infant Radiant Warmer adopts 3 kinds of control mode: **Pre-warm Mode**, **Manual Mode** and **Baby Mode**. Once the device starts working, it can enter into the **Pre-warm Mode** automatically without pressing any key.

The set temperature and baby temperature can be indicated separately.

Except for the listed parts in section 1.5, the warmer also has lamp and X-Ray tray for clinical use.

Heating output control under Pre-warm Mode : The output ratio of radiant module heater can work automatically according to the preconcerted procedure of warmer, please refer to the section 4.5.1.2;

Heating output control under Manual Mode : The output power of radiant module heater can work according to the settled heating ratio preconcerted set by operator, it isn't influenced of baby temperature, please refer to the section 4.5.2.1;

Heating output control under Baby Mode : Servo control the radiant module heater according to the baby temperature, please refer to the section 4.5.2.2;

3.2 TEMPERATURE CONTROL PRINCIPLE

See figure 3.1, the heat from the heater of the warmer module will be radiated to the surface of mattress through the reflective cover in shape of parabola with high reflectivity. Then the heat could reach the infant.

In **Manual Mode**, the radiant heater outputs in the way of fixed proportion to make the body temperature of patient resume; in **Baby Mode**, the device will adjust the heat output proportion automatically by comparing the baby temperature and the set temperature to keep the heat balance.

NOTE: During the process of getting the radiation and heat, the losing heat in convection, evaporation, radiation, conduction will affect the heat balance. Therefore, to decrease the dissipation on baby, it is necessary to use the device in the environment of no rapid air flowing ,and cover waterproof velum (polyethylene velum) the naked skin or to use the waterproof net to increase the humidity around the skin to decrease the water evaporation.

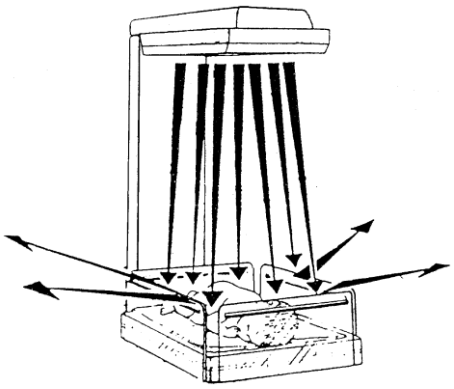


FIGURE 3.1 RADIATION PRINCIPLES

3.3 DATA COMMUNICATION CONNECTOR

This device is equipped with RS232 connector, which is used for data terminal output. The RS-232 communication connector is expected to connect with POS microprinter to achieve one-way data transmission and print temperature, alarm and other data stored in the chip of the device. The POS microprinter, when used in the infant radiant warmer, shall comply with IEC or ISO safety standards.

1. If connecting the auxiliary equipment on this interface, the establishment or modification of the medical system in its lifetime period should be evaluated according to requirements of the section 16 for IEC60601-1.

2. Everyone should be responsible for the safety of the whole system requirements. 3. Only the equipment provided by our company can be connected with RS232 data interface. When using, must ensure the reliable connection.

4. The service department should be responsible for the maintenance of data communication interface, and inspect the data communication every year.

5. The connection and usage of the data communication must be performed by special trained medical personnel, and the personnel should clear and definite the risk of data communication.

6. Do not touch the data communication interface and the patients at the same time. 7. If have any question, please contact with the agency or the service department of our company.

3.4 ALARMING AND SYSTEM INDICATION INFORMATION STATE

1. Alarm Information

High priority: The most urgent information, red alarm light flashing, alarm sounds more than 65dB(A). Five tones order alarm, ring twice, and every 2.5 seconds to repeat again

Note: The sound of power failure alarm whose sound source is a single buzzer which is different from other high priority alarms.

Medium priority: Medium priority information, yellow alarm light flashing, alarm sounds more than 65dB(A).

Three tones order alarm, and every 7.5 seconds to repeat again.

2. The alarm preference is arranged according to the alarm serial number, the bigger the serial number is, the lower level it is. When various failures appear, the alarm prompts according to the priority, the sound is different too.

Alarm introduction

Alarm No.	Alarm information	Alarm character	Alarm activate condition	Control mode	The state of heater	Alarm level	Alarm delay time
1	Power failure alarm	"Power" alarm light is on, red alarm light flashes, sound alarm start	Turn on the switch when no power supply	All	Off	High priority	<5s
2	Skin sensor failure alarm	"Sensor" alarm light is on, red alarm light flashes, set indicator shows "E01", sound alarm start	Short circuit, open circuit or bad connection occurs inside the skin temperature sensor	Baby mode	Off	High priority	<5s
3	Skin isolated sensor failure alarm	"Sensor" alarm light is on, red alarm light flashes, set indicator shows "E02", sound alarm start	Short circuit, open circuit or bad connection occurs inside the isolated temperature sensor	Baby mode	Off	High priority	<15s
4	Skin sensor difference failure alarm	"Sensor" alarm light is on, red alarm light flashes, set indicator shows "E03", sound alarm start	The difference between the main probe and isolated probe of skin sensor is over 0.8℃	Baby mode	Off	High priority	<1min
5	Over temp alarm	"Over" alarm light is on, red alarm light flashes, set indicator shows "E04", sound alarm start	The temperature measured by the skin temperature sensor is more than 38.5℃	Baby mode	Off	High priority	<10s
6	Alarm deviation	"H/L" alarm light is on, red alarm light flashes, set indicator shows "E05", sound alarm start	The displayed skin temperature is higher than set temperature 1℃	Baby mode	Off	High priority	<5s
		"H/L" alarm light is on, red alarm light flashes, set indicator shows "E06", sound alarm start	The displayed skin temperature is lower than set temperature 1℃	Baby mode	On	High priority	<5s
7	Set alarm	"SET" alarm light is on，red alarm light flashes, set indicator shows "E07", sound alarm start	The temperature measured by skin sensor is lower than set temperature 3.5℃ above, and this state was maintained for about 2 minutes.	Baby mode	Off	High priority	<2min
		"SET" alarm light is on，red alarm light flashes, set indicator shows "E08", sound alarm start	When temperature at stable state, due to accident or unreasonable action the skin temperature sensor measured over 0.4℃ from steady state and do not back to steady state in 3 minutes and also do not occur the deviation alarm	Baby mode	Off	High priority	<3min

8	Check alarm	"CHECK" alarm light is on，red alarm light flashes, set indicator shows "E09", sound alarm start	Heating ratio is over 30% and triggered after operating 15min	Manual mode	On	High priority	<15min

System failure alarm introduction

When system failure alarm occurs, the alarm light flashes, the set indicator shows the alarm code with the letter "H', and the alarm sound starts. The system failure alarm means the warmer can not work properly; the warmer should be stopped immediately, and should be repaired by the qualified maintenance personnel. The specific alarm delay time and the condition of alarm activation, please see the service manual.

NOTE：**1. All the above alarms except for the deviation alarm and skin over temperature alarm in baby mode belong to physiological alarm status, the power failure alarm belongs to other alarm status; the others are all technology alarm status.**

2. Except for the power failure alarm, the other alarms can all be silenced by pressing silence/reset key, the time for silence is 4mins. When the silence time is over, if the alarm condition is still not solved, the alarm will have to activate. If occur multiple alarm occurs at the same time, the device will give an alarm firstly for the higher grade. Pressing the twice of silence /reset key can cancel the alarm state then the equipment will be back to the set condition to monitor the alarm.

3. If checking alarm is activated, and the operator doesn't press the silence/reset key, the heater output will be limited to 30% automatically. This does not mean there is something wrong with the equipment, but for giving a hint that the operator should check and monitor the body temperature of patient.

4. The power failure alarm lasts at least 10 minutes, if the power supply recovers before the alarm, the device will be back to the alarm setting before the outage.

5. Alarm system will save all the alarm logs automatically. When the equipment is outage, the saved log contents did not change.

WARNING: When using the radiant warmer in any independent place, if using different alarm preset, there will be the potential risk.

SECTION 4
OPERATION

4.1 GENERAL

This section provides operating procedures for the infant radiant warmer.

4.2 POWER SUPPLY CONNECTION AND SWITCH CONTROL

See figure 4.1 and 4.2, for the infant radiant warmer with VHA, general power socket and the general power switch are located under the stand, the power socket for warmer module and main power supply socket are located at the back of radiant module; See figure 4.3, for the infant radiant warmer with fixed stand, general Power supply socket and general power switch of warmer are located on the back of warmer module.

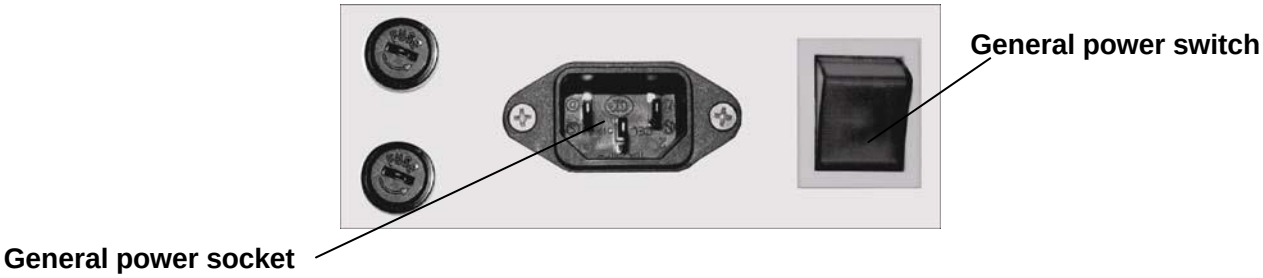


FIGURE 4.1

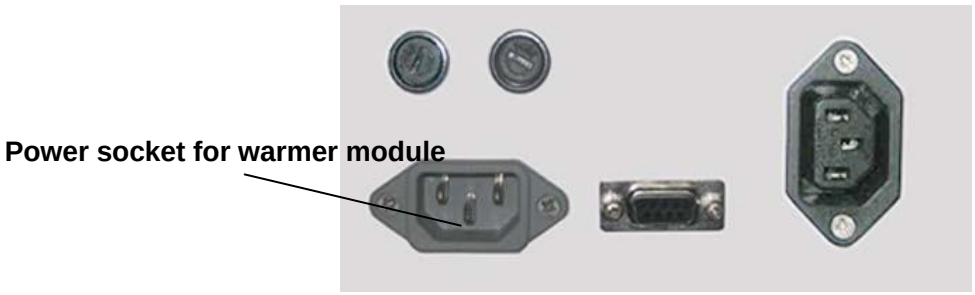


FIGURE 4.2

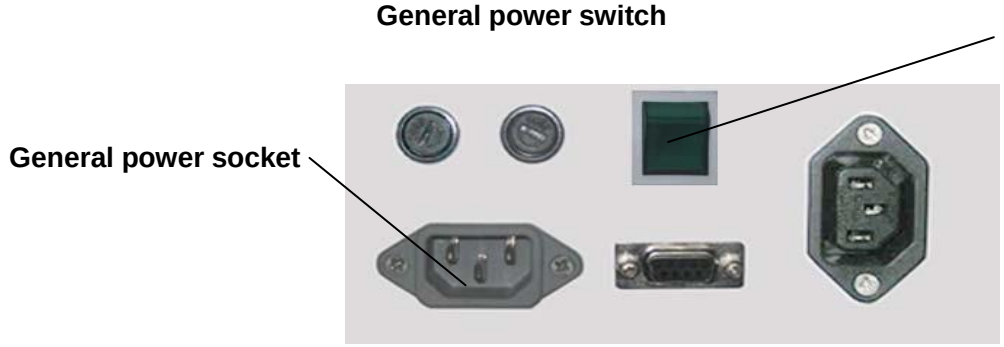


FIGURE 4.3

See figure 4.4, for the infant radiant warmer with VHA, the height adjustment foot button is on the bottom of stand.

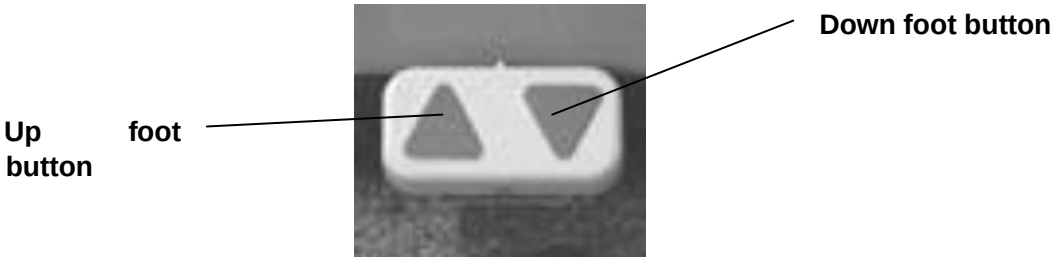


FIGURE 4.4

CATION: The VHA Stand is only for INTERMITTENT OPERATION with 30 seconds ON and 30 seconds OFF.

See figure 4.5, power switch of controller and power switch of illumination light are in the front of warmer module.

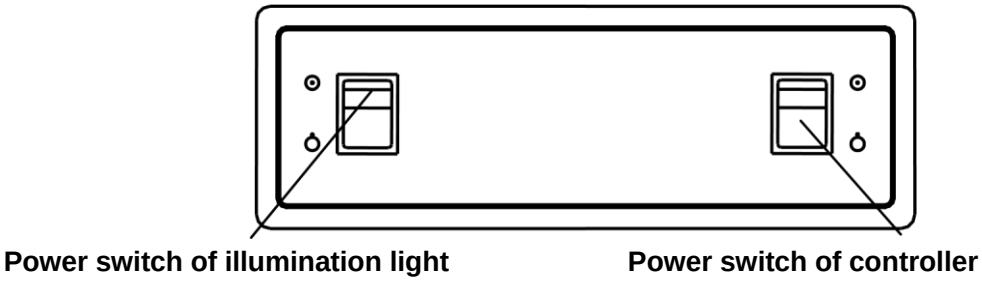


FIGURE 4.5

4.3 CONTROLLER AND INDICATORS

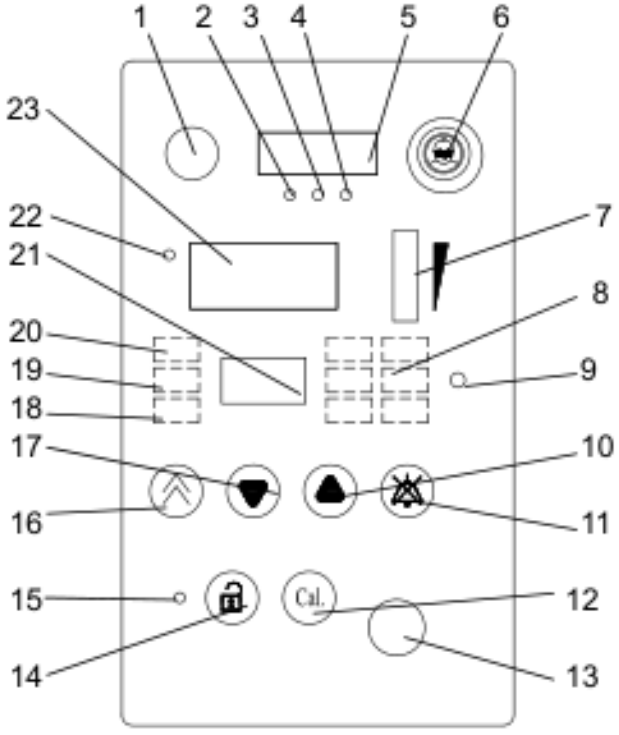


FIGURE 4.6

1
.

Press this key to choose the timer working mode, APGAR timer mode, and the running time for phototherapy.

2. Timer working mode indication light
During the timer working mode, the light is on.

3. APGAR Timer mode indication light
During the APGAR timer mode, the light is on.

4. Running time for phototherapy mode indication light
During the running time for phototherapy mode, the light is on.

5. Timer indicator
During the timer working mode and the running time for phototherapy mode, the unit is minute; while during the APGAR timer mode, the unit is second.

6. 

Press this key to turn on or turn off the switch for phototherapy unit.

7. Heater power indicator
Indicate the heater output proportion.

8. Alarm classification indication light
If the alarm activates, the relative light is on.

9. Alarm indication light

When device fails, the light is on.

hen the light is on, please stop using and consult the alarm information of section 3.4 and relevant content of system indication information of the operator's manual.

10. 

In the set state, press this key to increase the setting temperature to increase the heat power output ratio. Press this key constantly to speed the increasing temperature.

11. 

When it occurs alarm prompt, pressing this key can cancel the alarm, pressing twice can reset the alarm state then the equipment will be back to the set condition to monitor the alarm.

12. 

This key is only for the authorized and qualified service personnel to regularly check and calibrate the accuracy of skin temperature sensor, other people should not use this key.

CAUTION: Please do not press this key in normal operation.

13. Skin temperature sensor socket.

It is used for connecting the skin temperature sensor.

14. 

Pressing this key can activate and lock each function key.

15. Keypad lock indication light

If the light is on, that is to say the set state is opened, you can operate all keys; while if the light is off, that is to say the set state is closed, all settings are locked (Except for the time mode key and switch key of the phototherapy unit).

16. 

In the set state, press this key to select the Pre-warm mode, Manual mode and the Baby mode respectively.

17. 

In the set state, press this key to decrease the set temperature or output ratio of heating power. Press this key constantly to speed the decreasing temperature.

18. Baby mode indication light

This light is on when it is in the baby mode.

19. Manual mode indication light

This light is on when it is in the Manual mode.

20. Pre-warm mode indication light

This light is on when it is in the Pre-warm mode.

21. Set temperature indicator

Indicate the set temperature value in **Baby Mode**; while it can indicate"--.-" in the **Pre-warm Mode** and the **Manual Mode**; it can indicate the alarm code when alarm activates.

22. Battery condition indication light

It will show the condition of the electricity, and the yellow light means it is charging, while the green one means it is full. The temperature control will check the condition of the battery during warmer working and charge and discharge automatically.

23. Skin temperature indicator

Display the temperature where the skin temperature sensor is placed.

4.4 OPERATION CHECKOUT PROCEDURE

WARNING

1. **Once some functions of the device lost or the front panel or other parts fault, please stop using it and refer to qualified service personnel.**
2. **When equipped with VHA stand, in order to avoid the damage of VHA stand in the process of moving. Before moving you should take the VHA stand to the lowest position, to make the warmer get maximum stability.**
3. **Set temperature must be 3℃ higher than ambient temperature. And then you can proceed this checkout procedure.**

Radiant warmer should be only operated by trained personnel which are familiar with the general the general risk of operating the radiant warmer and under the instructions of medical practitioner.

Before using you should proceed the following checking procedure in each time.

The operator should operate the device within 20cm ahead，the specific distance depends on the comfort when operating.

4.4.1 CHECK THE INTEGRITY OF WARMER

- Make sure that the device has been sterilized;
- Make sure that the panels are locked firmly;
- Make sure that there is no crack or the sharp edge on the panels;
- Make sure that the tilt mechanism of bed can work properly ;
- Make sure that fasteners are installed firmly;
- Make sure that the needed accessories and other devices are available;
- Make sure that the power cord is connected and safe; putting it on the panel is forbidden.
- Make sure that the casters are installed well.

Check whether the caster can drop when lifting the radiant warmer 2cm above the ground. The drop of the caster will cause danger during transporting. Before replacing the loose casters, please do not use the radiant warmer.

4.4.2 CHECK TEMPERATURE CONTROLLER

WARNING

1. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

2. Make sure that the power supply is compatible with the electrical specifications attached on the radiant warmer. The equipment shall not use the extension power cord.

A. START-UP THE CONTROLLER

Turn on the switch of the main power supply and controller, the controller gives sound "Ding". All indicators are on, at this time, the device can do self-test automatically for 5s. After then, the **Set Temperature** indicator will display "--.-", at the same time, the **Skin Temperature** indicator displays the baby temperature (if the skin temperature sensor has been connected), and the timer indicates the current time, and the controller can enter into the **Pre-warm Mode** automatically, and the pre-warm light will be on. If self-check failed or no sound, please repair the radiant warmer.

B. CHECK "POWER" FAILURE ALARM

Pull off the power cord of whole unit, red alarm light flashes , the device gives continuous alarm sound, "POWER" alarm light is on.

This operation is used for checking if the power failure is normal or not. Insert the power cord again after finishing checking.

IMPORTANT: Make sure that the rechargeable battery is full before usage. If not full, it may cause the power failure without the alarming indication. If full, and there is no any indication after disconnecting the main power supply, please refer to the qualified service personnel.

C. CHECK HEATER

Control the environment temperature at 21℃ ~ 25℃, and set the setting value at 33.0℃, all the heat power indicators are on and indicator heater should power output completely.

NOTE: When the radiant warmer works under the set state, and continue the following operation procedure.

D. CHECK APGAR TIMER

When the controller is in the normal working state, press the **Timer Mode key**, choose the **APGAR Timer Mode**, the timer starts to indicate from 0s, when the timer indicates 50"～1', 4'50"～5', 9'50"～10', it sounds "du…", at the same time, the APGAR timer is flashing.

E. CHECK THE TIMER

In the normal working state, press the **Timer Mode key**, choose the **Timer Working Mode**. The **Timer** indicator displays the current running time, If the indicated time is not accurate, please reset, and the specific setting method is as follows:

Press the **Timer Mode key**, at the same time, turn on the controller for 3s, loosen the key when the indicated setting interface appears.

At this time, **Set Temperature** indicator shows the setting code, **Skin Temperature** indicator will indicate the relevant value (as for setting code, setting item and setting range, please refer to the following table), the **Timer** indicator will indicate P002(it means it has entered into the setting interface). Operator can choose the setting items by pressing the **Timer Mode key** or **The Switch Key For Phototherapy**, and press the **Set Up** and **Set Down key** to choose the data setting. After then, press the **Keypad lock key** to store the setting value, or you can press the **Silence/Reset key** to store and exit after finishing all setting procedure. If turn off the power supply without pressing the **Keypad lock key or**
Silence/Reset key, and this setting is invalid, and system will store the previous setting value.

TIME SET CODE

SETTING CODE	INDICATED ITEM	SET RANGE
001	The former two figure of year	19 ~20
002	The latter two figure of year	00 ~99
003	month	01 ~12
004	date	01 ~31
005	week	01~07（01means Sunday）
006	hour	00~23(24hrs)
007	minute	00~59
008	second	00~59

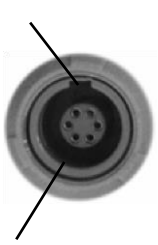
F. CHECK PHOTOTHERAPY UNIT AND TIMER

In normal working state, press the **Timer Mode key** and choose **The Running Time For Phototherapy Mode**, the light is on. Press **The Switch Key For Phototherapy** to activate the unit, and the **Timer** indicator will activate its timing from zero. Pressing **The Switch Key For Phototherapy** again to turn it off, and the **Timer** indicator remains the time recorded and stops timing, which will keep on timing according to the previous time recorded when restarting the phototherapy. If not, please refer to the qualified personnel to repair the phototherapy unit.

G. CHECK "SENSOR" FAILURE ALARM

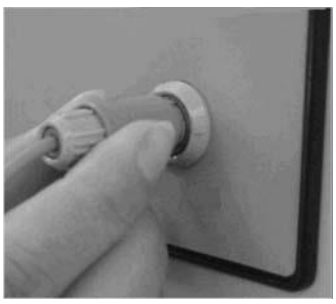
Pull off the skin temperature sensor in **Baby Mode**, the device should give a high priority alarm sound; the alarm character should be consistent with the description of section 3.4.

Opening



Sensor socket

Arrow



The arrow sign on the plug should aim to the opening on the sensor socket so that the sensor is inserted correctly.

1.Insert or pull out the skin sensor, you must hold the plug of skin sensor, pulling the leads is forbidden.
2.Please do not bend the connection of sensor.

H. CHECK "SET" ALARM

In **Baby Mode**, put the skin sensor into the water cup at temperature 3.5℃ lower than the set temperature for 2min, the device should give a high priority alarm sound; the Set temperature indicator shows "E07", and the alarm character should be consistent with the description of section 3.4.

Set the temperature at 36℃, after the device enters into the **TEMPERATURE ALARM CHECKOUT STATE**, put the skin sensor into the water cup at temperature 35.3℃±0.1℃ for 3min, the device should give a high priority alarm sound; the Set temperature indicator shows "E08", and the alarm character should be consistent with the description of section 3.4

I. CHECK "H/L" ALARM

In **Baby Mode**, set the temperature at 35.0 ºC. Enter **TEMPERATURE ALARM CHECKOUT STATE**, put the skin sensor into the water cup at 37 ºC. When the indicated temperature reaches 36.1 ºC, the device should give a high priority alarm sound; the Set temperature indicator shows "E05", and the alarm character should be consistent with the description of section 3.4; Set the temperature at 35.0℃, after the device enters into the **TEMPERATURE ALARM CHECKOUT STATE**, put the skin sensor into the water cup at temperature 33℃, when the indicated temperature decreases to 33.9 ºC, the device should give a high priority alarm sound; the Set temperature indicator shows "E06", and the alarm character should be consistent with the description of section 3.4

NOTE: If the system can not enter into the TEMPERATURE ALARM CHECKOUT STATE or the skin temperature does vary ±1℃ than the setting temperature, the deviation alarm can not occur.

J. CHECK "OVER" ALARM

In Baby Mode, put the skin sensor into the water cups at 39.5℃±0.5℃, the device should give a high priority alarm sound; the Set temperature indicator shows "E04", and the alarm character should be consistent with the description of section 3.4

K. CHECK "CHECK" ALARM

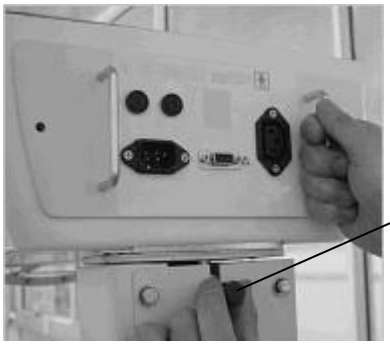
In **Manual Mode**, set the proportion of heating output at 50%, after 15mins, the device should give a high priority alarm sound; the Set Temperature indicator shows "E09", and the alarm characteristics s hould be consistent with the description in section 3.4.

4.4.3 CHECK OTHER FUNCTION

A.CHECK BASSINET TILT MACHANISM

The bassinet is the applied part of the device. Rotate the manual wheel as the figure indicates to adjust the bassinet tilt.

B. CHECK THE ADJUSTMENT FUNCTION OF ANGLE OF HEATER MODULE



Pull the handle for lock downward to rotate the heater module at horizon angle.

NOTE: Only 0°is stable for heater module, the heat of the bassinet's surface is also even.

C. CHECK ILLUMINATION LIGHT

Turn on the power switch of illumination lamp, and the light will be on.

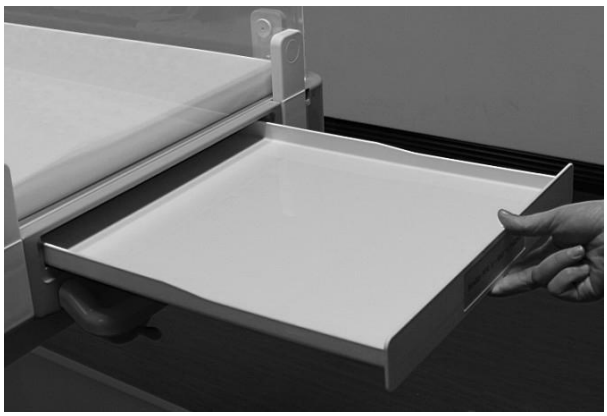
D. CHECK THE PANEL

Push and pull the panel and check if the panels are firm or not.

E. CHECK I.V. POLE AND TRAY

Check if the I.V. Pole and tray are tightened or not.

F. CHECK THE X-RAY TRAY



Push and pull the X-Ray tray and check if it is agile and handiness, or whether it is broken.

G. CHECK THE VERTICAL HEIGHT ADJUSTMENT

Tread the upper and down button in figure 4.4 to check it can work well or not.

4.5 GENERAL OPERATION PROCEDURE

WARNING

1. **Please read this operator's manual carefully before use.**
2. **You should not use the warmer without the checkout procedure, moreover, it needs to be lifted to the authorized and qualified service personnel to repair it.**
3. **The temperature display module of the controller is sensitive to the electromagnetic interference, so it can not be used in the high electromagnetic field intensity occasions. If the device which can send and receive small-signal is installed near this equipment, it may be affected by the electromagnetic wave sent by this equipment.**

Before using it, please check the devices around whether they are affected or not.

4.5.1 PREPARATION BEFORE OPERATION

4.5.1.1 Connect the power supply cord and skin temperature sensor correctly.

4.5.1.2 Pre-warm the warmer, put the patient on the bassinet after the temperature on the mattress's surface reaches the stable temperature to avoid the body temperature of the naked baby decreasing quickly. Transfer to manual mode or baby mode immediately when put the baby into the equipment.

This equipment has the **Pre-warm Mode**, after the device succeeds self-test, the device will enter into the following **Pre-warm Mode** without pressing any key:

The system will output the heat according to the set procedure, after a while, the system will output the heat at 30% (Radiation heating power output ≤10mW/cm^2) to keep the mattress temperature until the mode changes. During the process of pre-warm, the **Set Temperature** indicator shows "--.-", **skin temperature** indicator shows the real temperature.

We suggest the operator to keep the warmer work at least 30min in the **Pre-warm Mode**.

4.5.2 OPERATION

4.5.2.1 MANUAL MODE

In **Manual Mode**, infant radiant warmer will output a fixed heat according to the set heat proportion. This mode is intended for giving the patient the short treatment and the first aid or make the lower temperature patient resume the normal baby temperature.

NOTE: The operator should select and adjust the heating output percentage according to the environment temperature and the clinical operation requirement.

WARNING
1. Operator should not leave the baby alone.
2. Measure the body temperature of baby regularly.

The heat output proportion of system is 30% (the heating power is indicated inthree grades). In the set state, the operator can adjust the heat output within the range of 0%-100% via up or down key, when the heating ratio output proportion is 30%, the warmer can give audio and visual alarm every 15min with "CHECK"alarm light on, press the **Silence/Reset key** and the alarm will be stopped, the warmer can still operate according to the current working mode and the output power; When "**CHECK**" alarm activates, please do not press any key to ensure the safety of patient, after 1min, the system will limit the proportion of heating output to 30%.

NOTE: 1. In Manual Mode, the heating output proportion is fixed, but out of control by the baby temperature. Therefore, pay attention to the change of body temperature of patient.

2. It will activate audio and visual indication to remind the operator of the patient in danger. To ensure safety, patient should be monitored and body temperature should be measured.

4.5.2.2 BABY MODE

The **Baby Mode** is a kind of mode that the baby temperature can maintain under the setting temperature value. In this mode, the system can adjust the output of infrared radiation according to the differences between the baby temperature and the set temperature to maintain the heat balance of patient. This mode is intended for maintaining the body temperature of the patient. Skin temperature sensor is the applied part.

Considering that the **Manual Mode** can output the heat of infrared radiation according to the heat rate, it cannot be adjusted according to the real condition of patient, if it continues outputting the heat of infrared radiation in this mode, it will cause the patient over-heat, therefore to **make sure the safety of patient, please use Baby Mode**.

NOTE: The patient is in the state of shock or has a fever, please do not use this mode.

Please do not use the **Baby Mode** when the patient is in the state of shock, because the baby temperature is much lower than the normal temperature during shock, or else, the patient will be over-heat.

Please do not use the **Body Mode** when the patient has a fever, because the baby temperature is much higher than the normal temperature during fever, or else, it will cause the body temperature of the patient decrease.

For the patient's temperature, usually, the operators think it means the rectum temperature, which is measured by putting the thermometer into the rectum of patient. To measure the core temperature of patient accurately, the operator needs to insert the thermometer into the rectum at depth of 5cm, so it will be very dangerous (the struggle of patient will cause the crack of thermometer), if the insert depth is not enough or time is not long enough, the operator can not get the real body temperature of patient, therefore, it is improper to control the output of heater via rectum temperature.

CONNECT THE PROBE OF SKIN TEMPERATURE SENSOR TO THE PATIENT:

In **Baby Mode**, make sure that the probe of skin sensor is attached closely on the skin of patient. Put the probe on the right position of skin, and clean the position of skin where the skin sensor located and the metal surface of skin sensor probe with alcohol or the moderate water to wipe off the grease and dirt. If the patient lies on his/her back, please stick the metal surface of skin sensor probe between the xiphoid of the belly and the bellybutton, to avoid the liver; if the patient bends over, stick the metal surface of skin sensor probe on the back of patient, the best place is on the kidney. To make sure that the probe and the skin of patient is attached closely; please fix it with medical staple（the disposable skin sensor can be fixed by the gum itself）. If the patient lies on his/her side, as for the position of probe, please follow the instruction of doctor.

NOTE: 1.The skin temperature sensor only can be used after disinfection.

2. Please do not put the skin sensor under the patient.

3. Skin sensor probe can not be regarded as the rectum thermometer.

WARNING

1. **Make sure that the probe of skin sensor is attached closely on the skin of patient. If the probe falls off the patient, the measured temperature from sensor is not the real baby temperature, maybe the air temperature or the mattress temperature, and it may cause the patient to receive more heat or lose heat, even scald or death.**
2. **Please do not cover the blanket or diaper on the probe of skin sensor, because it will affect the accuracy of temperature.**
3. **The equipment cannot differentiate between an increase in core temperature with a cold skin (fever) and a low core and skin temperature (hypothermia). Skin sensor will measure the baby temperature of patient, not the real body temperature. Therefore, measure the body temperature regularly, and check whether the patient has a fever or not, whether the temperature of patient decreases.**

CHOICE OF BABY TEMPERATURE CONTROL VALUE:

In the set state, operator can adjust the baby temperature via pressing the **Set Up** and **Set Down key**.

NOTE: The operator should choose the baby temperature according to the clinical requirement.

WARNING

1. **In Baby Mode, it is servo-control baby temperature, the operator should not leave to avoid the patient is alone and cause the patient danger.**
2. **It is difficult for patient to feel the loss of water under the continuing heat radiation, so please add the water to patient to avoid the patient dehydration.**

4.5.3 OTHER OPERATION

A. Raise the head or foot of patient

Please raise the head or foot of patient according to the step A in section 4.4.3.

CAUTION: 1. Please do not add the over load on the mattress.

2. The mattress tilt will affect the temperature uniformity on the mattress, the horizontal position of mattress is best state.

WARNING：The handle on the bassinet should only be pulled and pushed, don't lift it.

B. X-ray tray

According to step B in section 4.4.3, move away the warmer module to process the x-ray tray for the patient.

NOTICE: Please try to shorten the time of moving the warmer module. The patient on the mattress will lose heat rapidly because there is no infrared radiation compensation when moving away the warmer module.

C. Phototherapy unit

See section 5.

4.5.4 SHUTDOWN

After finishing the operation, turn off the power switch of controller, lighting switch and general power switch, and disconnect the wire of power.

SECTION 5
PHOTOTHERAPY

5.1 GENERAL

The section provides operation, cleaning and maintenance instructions.

5.2 OPERATION

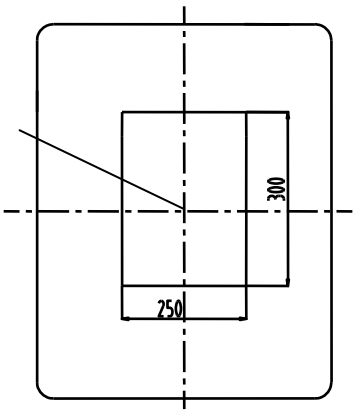
NOTE: 1. The varying ambient conditions (e.g., temperature, radiation source) around the PATIENT all can affect patient's temperature and the bilirubin value. Therefore, when the patient ambient conditions changes, should pay close attention to patients.

2. **It is not allowed to treat the PHOTOTHERAPY EQUIPMENT with flammable solutions (antiseptics, cleaning agents, etc).**
3. **The PHOTOTHERAPY EQUIPMENT shall not be used in the presence of gases which can support combustion (e.g. oxygen, nitrous oxide, anaesthetic agents).**
4. **Wear the eye mask for the patient during phototherapy treatment to avoid the keratitis or heat hurt of retina on the patient.**
5. **The patient's water balance may be disturbed during phototherapy treatment, the nurses should supply the water for the patient in time.**
6. **If you use the phototherapy on warmer, please choose the Baby Mode. Or else, the heat output ratio must be decreased according the body temperature of patient.**
7. **Please cover the genitalia of patient with diaper during treatment to avoid hurting the genitalia.**
8. **Please keep the patient naked during treatment so that the patients can get better treatment.**
9. **Please measure the bilirubin concentration of patient regularly during treatment.**
10. **Operation of the phototherapy equipment will affect the temperature uniformity on the bassinet and the skin temperature of infant. Therefore, it is necessary to measure the skin temperature of the patient.**
11. **If you use the phototherapy on warmer, it will affect the temperature uniformity on the surface of bassinet and the body temperature of patient although the heat from LED radiation is less, therefore, please monitor the body temperature of patient more than before.**
12. **Phototherapy sensitization isomer during treatment may cause the side effect, but no harm, and the nurse should monitor this. All the symptoms like diarrhea, short of riboflavin, hemolysis, anemia , skin rash, bronze disease, and so on will disappear after stopping treatment.**
13. **During Phototherapy, the nurse should not stare at the light source directly or through optical Equipment.**
14. **During Phototherapy, the nurse should not stay in the radiation area longer than 30 sec. to avoid being dizzy, nausea, or blurred vision. For long time nursing to patient, temporary turn off the Phototherapy is advised.**
15. **If using the reflection foil, can affect the radiation of the jaundice treating equipment, may cause the temperature changing in patients with risk.**
16. **Using the phototherapy equipment will affect the clinical observation of the patient's skin color, such as cyanosis, so we should turn off the phototherapy equipment when observing the color of the patients.**

WARNING: Please follow the below instruction, or else, the patient will be hurt by the laser radiation.

5.2.1 Please put the patient in the effective surface area, on the center of bassinet 300mm×250mm as the following figure indicates

Central point on the bassinet



IMPORTANT：To reach the best phototherapy treatment, make the patient lie on effective surface area. The dimension of effective surface area and the radiant source's distance will affect the average total irradiance value for bilirubin. The larger the effective surface area is, the smaller average total irradiance value becomes. The longer the radiant distance is, the smaller average total irradiance value becomes.

Conversely values are on the contrary.

5.2.2 Please wear the eye mask for the patient.

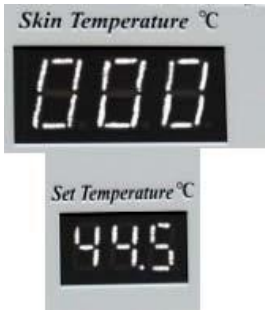
5.2.3 Turn on the phototherapy to give treatment to the patient.

5.2.4 The operator should exit the radiant area after finishing above procedure to avoid the long time LED radiation. Please do not stare at the light source when operate the unit again.

5.2.5 Current working time and the accumulative time of phototherapy unit.

How to get the current working time of phototherapy unit: when the controller is turned on, please press the **Time Mode key** to enter into the **Running Time For Phototherapy Mode**, at this time, the **Timer** indication will indicate the working time of phototherapy.

How to get the accumulative time of phototherapy unit: when the controller is turned on, please press the **Mode Select key**, and then press the **Switch Key For Phototherapy Mode**, and you can get the accumulative time of phototherapy on the **Skin Temperature** indicator and the **Set Temperature** indicator. You can read the accumulative time form left to right, it is total 6 figures. The last figure is decimal digits, if the working time is 0-30, it will indicate 0hr, if the working time is 30-59, it will indicate 0.5hr. E.g. if the read data is 00044.5, that is today the accumulative time for phototherapy is within range from 44hrs 30min to 44hrs 59min.



NOTE: When the controller is switched off, at the same time, press the Silence /Reset key and the switch key for phototherapy unit, and then turn on the switch for controller to make the accumulative time at zero.

5.3 CLEANING

A. Disassemble

Please take off the phototherapy from the heater head according the negative order for step D in section 2.3.

B. Use a neutral disinfectant-detergent (e.g. 84 disinfectant) to thoroughly clean all surfaces for phototherapy unit; then dry with a clean cloth or paper towel.

NOTE: The protective board is made of acrylic, to avoid the crack, please do not use alcohol or other organic detergent to clean; putting it under the direct ultraviolet radiation is forbidden.

C. Put the phototherapy unit back to its position after cleaning.

5.4 MAINTENANCE

When the lifetime for LED ends, please replace them to make sure the effectiveness due to the following reasons:

That the light radiation capacity will be reduced with the prolonging working time will make the average total bilirubin radiation decreased to 25% of the original value so that the equipment loses its preventative affect during phototherapy treatment.

Please ask the service man to repair the LED.

5.5 TROUBLESHOOTING

Troubleshooting of the infant radiant warmer is presented in the following table. If the fault cannot be localized from the table, the unit should be removed from service and servicing should be referred to our company or authorized and qualified service personnel.

SYMPTOM	POSSIBLE CAUSE	REMEDY
All LED do not work	Power cord of warmer module is unplugged	Plug it
	switch is not turned on	Turn on it.

SECTION 6
CLEANING AND MAINTENANCE

6.1 GENERAL

The section provides cleaning and maintenance instructions.

WARNING: Please cut off the main power connection and turn off all switches before cleaning and maintenance.

6.2 CLEANING

This device must be cleaned and sterilized for the first time after purchasing, or it is usage for one week.

6.2.1 DISASSEMBLY BEFORE CLEANING

A. Take out the skin temperature sensor from the temperature controller.

B. Take out the mattress from the bassinet.

C. Please disassemble the panel from the bassinet according to the contrary sequence as the step B of 2.3 in section 2.

D. Pull out the x-ray tray under the bassinet

6.2.2 CLEANING PROCEDURE

CAUTION: Some chemical cleaning agents may be conductive and/or leave a residue which may permit a build-up of dust or dirt which may be conductive. Do not permit cleaning agents to contact electrical components. Do not spray cleaning solutions onto any of those surfaces.

A. Clean the skin temperature sensor

Use neutral disinfectant-detergent to thoroughly clean all surfaces; then disinfect it with neutral disinfectant or ultraviolet.

CAUTION: 1. Do not put the sensor into the disinfectant-detergent. The disposable skin temperature sensor is only for the same patient's use, after using it, please discard.

2. Skin temperature sensor is suggested to be changed every two years, to avoid the damage of sensor surface and strong impact for long-time use and disinfection.

B. Clean the mattress

Use neutral disinfectant-detergent to thoroughly clean all surfaces of the mattress; then dry with a clean cloth or paper towel.

C. Clean the panel

NOTE: Alcohol can cause crazing of the clear panel. Do not use alcohol, acetone, or any organic solvents for cleaning. Do not expose the panel assembly to direct ultraviolet radiation.

Use neutral disinfectant-detergent to thoroughly clean all surfaces; then dry with a clean cloth or paper towel.

D. Clean the X-ray cassette

Use neutral disinfectant-detergent to thoroughly clean all surfaces; then dry with a clean cloth or paper towel.

E. Clean the bassinet, tray and I.V pole

Use neutral disinfectant-detergent to thoroughly clean all surfaces; then dry with a clean cloth or paper towel.

F. Clean the surface of the device.

Use neutral disinfectant-detergent to thoroughly clean all surfaces; then dry with a clean cloth or paper towel.

NOTE: You should wait for the heater head becoming cooling completely, then the surface of it can be cleaned.

CAUTION: 1. Please avoid the liquor flowed into the device during cleaning.

2. The reflect cover is an important parts which is used to reflect the infrared radiation heater to the mattress. It is easy to damage and you must be very careful to clean it to prevent damaging it, or change the shape of it.

G. Clean the phototherapy unit

Please refer to section 5.

6.2.3 ASSEMBLE AFTER CLEANING

NOTE: Before installing the parts onto the radiant warmer, please check each parts carefully and to see whether there is any broken. If there is any broken, it should be replaced immediately.

A. Insert the X-ray cassette under the bassinet

B. Please assemble the panel into the bassinet according to the step B of 2.3 in section 2.

C. Put the mattress back to the bassinet.

D. Put the skin temperature sensor into the sensor socket of Figure 4.6.

6.3 MAINTENANCE

Warning: To ensure the safety of using the equipment is not affected, the modification of infant radiant warmer is forbidden.

6.3.1 RECHARGEABLE BATTERY MAINTENANCE

Please check the condition of the build-in rechargeable battery before the first use of device or in the alternation of device using.

A. Operate the unit for a period of 12 to 24 hours.

B. Trigger a power failure alarm by disconnecting the AC power cord.

C. The power failure alarm should activate and continue to alarm for at least 10 minutes.

D. Reconnect the unit to the AC line and recharge the battery.

If the power failure alarm cannot last more than 10 minutes, please replace the rechargeable battery. For this battery, it should be replaced by authorized and qualified service personnel.

Note: The replaced rechargeable battery will affect the environment if being discarded, so it must be recycled according to the regulations.

6.3.2 HEATER'S REPLACE

In order to ensure the effect of the infrared radiant, when the heater passes the lifetime, it must be replaced although it can work normally. The reason is:

The electromagnetism spectrum infrared radiance of the heater will be reduced with the working time passing. Then the device will not achieve the standard as graph1.1 in this manual. Thereby it is lack of the effect when the doctor uses it to keep warm to the patient.

For the heater's replacing, it should be replaced by authorized and qualified service personnel.

6.4 TROUBLESHOOTING

Troubleshooting of the infant radiant warmer is presented in the following table. If the fault cannot be localized from the table, the unit should be removed from service and servicing should be referred to our company or authorized and qualified service personnel.

SYMPTOM	POSSIBLE CAUSE	REMEDY
No display on the screen	The switch is not turned on	Turn on the switch of power supply
Power failure alarm	Power switch is cut off	Turn off the switch of power supply
	Non-connection of power cord	Connect the power cord
Sensor failure alarm, **alarm code E01**	Skin sensor is not inserted	Insert the skin sensor
	Skin sensor is damaged	Replace the skin sensor
Sensor failure alarm, **alarm code E02**	Skin sensor is damaged	Replace the skin sensor
Sensor failure alarm, **alarm code E03**	Skin sensor is inaccurate	Replace the skin sensor

SYMPTOM	POSSIBLE CAUSE	REMEDY
Over-temp alarm, **alarm code E04**	The patient has a fever	Check the patient
Deviation alarm, **alarm code E05**	The ambient temperature changes a lot	Check the ambient
	The skin sensor is not put on the patient's body and fall down the bassinet	Check the place of skin sensor
	The baby temperature of the patient hoists a lot	Check the patient
Deviation alarm, **alarm code E06**	The ambient temperature changes a lot	Check the ambient
	The skin sensor is not put on the patient's body and fall out of the bassinet	Check the place of skin sensor
	The baby temperature of the patient reduced a lot	Check the patient
Setting alarm, **alarm code E07**	Skin temperature sensor is not on the patient, e.g. it is put out of the bassinet	Put the skin temperature sensor onto the patient
	Make the mistake of the temperature mode, e.g. use the baby mode to warmer the low- baby temperature patient	Choose the manual mode
Setting alarm, **alarm code E08**	Skin temperature sensor is fell down from the patient	Put the skin temperature sensor onto the patient
The height of whole unit is not adjusted if applicable.	The switch is not turned on	Turn on the switch of power supply
	Non-connection of power cord	Connect the power cord

SECTION 7

PARTS LIST

This section provides the lists of accessories and removable parts of the incubator. Users are only allowed to adopt the materials provided by our company, otherwise there is a chance to cause safety problems.

No.	Part Name	Replacement Period/Conditions
1	Skin temperature sensor	2 years
2	Rechargeable battery	3 years
3	Heater of warmer module	2000 hours
4	Mattress	If damaged
5	Power cable	

SPECIAL STATEMENT: All of the content in the manual is checked carefully, if there is any error or content of printing misunderstanding, our company retains finally explanation of this card-usage.

NOTE: The product's appearances maybe differ from the one in this manual, but it dose not affect the capability of product. Please understand if it brings you troubles.

DIXION

DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

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