DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

CE 0483

DIXION

BabyGuard W-1145

Infant radiant warmer

Operator´s Manual

Manual Ver: V1.6

Release Date: August 2024

Part Number: OM_BabyGuard W-1145_V1.6

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 intend 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.

4. Except for forced air devices, the average value of the contact surface temperature shall no differ from the value of the temperature indicated by the temperature control setting by more than ±1℃ but not exceeding 41℃.

5. Except for forced air devices, heating Devices with high heat transfer to the patient shall be equipped with an alarm system that includes at least a medium priority technical alarm condition if the average value of the contact surface temperature differs from the control setting by more than ±1 ℃ in the case of heating devices having high heat transfer both inwards toward and outwards from the patient

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 A
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies
NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.	

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 WARMERis used exceeds the applicable RF compliance level above, the INFANT RADIANT WARMERshould 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.		

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..

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

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 there from 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 accessories or consumables produced by other company.
4. The customer uses any parts, accessories, or fittings not specified or sold by our company when this product is changed, maintained or repaired.
5. For related technical instructions, please refer to the maintenance manual.

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 qualified service personnel who is authorized by manufacturer. Please contact the local agency or the After-Sales service department 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, and pediatric intensive care unit or similar sickroom in hospital. Operators for the device should be special 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 happen. Suggest monitoring the baby temperature at least 1 time every half an hour.
3. Please stop using the device when it failure or dysfunction. 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. Infant radiant warmer is only applied to the intended use specified in this manual.
5. Direct radiation from sunlight or other infrared source could cause overheating of the warmer mattress without activating the Over Temperature Alarm. DO NOT leave the RADIANT WARMER in direct sunlight or near other sources of radiant heat.
6. DO NOT leave the RADIANT WARMER in the presence of flammable anesthetic gases or other flammable materials, such as some types of cleaning fluids.
7. DO NOT leave the RADIANT WARMER in the presence of strong electromagnetic field. Portable and mobile RF communication devices may have an impact on this device.
8. Devices which are easily interfered by magnetic field should not be used near the RADIANT WARMER because they may interfered by the RADIANT WARMER.
9. The fast flow of air can affect the thermal balance of infant. So the Infant radiant warmer should be placed in the room where the air flow rate is less than 0.3m/s.
10. Please DO NOT use the RADIANT WARMER under working environment not stipulated in table

1.1, or else, it may cause the failure or the RADIANT WARMER can not reach the requirements.

11. Check the panels regularly to examine whether these panels are installed firmly to avoid the infant falling on the floor.
12. Please check the firm of panel regularly. Do not leave the infant uncared to prevent the baby falling from the bassinet.
13. When operating the panel, pay attention not to touch any part of the infant to avoid the harm on the skin of infant.
14. 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.
15. When the bassinet tilts or the warmer module is not in 0° position, some part of the patient is near heater so as to absorb more radiant heat. Therefore, these parts should be checked more than before.

16. Please DO NOT touch the heater or its protective parts to avoid the scald.

17. Please DO NOT put anything on the top of WARMER, or else, it will cause the damage and the hazard.

18. To avoid overturning, please DO NOT move the WARMER transverse.

19. One person of sufficient strength is required to move the radiant warmer. The handle located in front of the radiant warmer can be used as hands handle when moving. Please disconnect all power cords before moving.

20. Casters should be locked tightly to prevent moving.

21. 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.

22. In nursing operation, the operator can not touch the other charged equipment at the same time, may bring shock hazard to patients.

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. 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. If the warmer is overload continuously used, it may accelerate the components aging and increase failures more frequently. Therefore, when continuous use the warmer for a week, we recommend to suspend using.

25. 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.

26. After cleaning the 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 warmer can cause a fire.

27. 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 lauch.

28. Generally the life period of rechargeable battery inside the incubator 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.

29. Do not place any article higher than radiant warmer's caster under its VHA stand which may affect the stabilization of VHA stand.

30. When operating the VHA stand, the user should support the warmer with one hand on to prevent it from unbalance.

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.

31. The lifetime for the infant radiant warmer is 8 years. Damages will be easily caused if using the radiant warmer after it reached its lifetime. Previous capability guideline and requirement cannot be reached as well.

32. The device, accessories and the packaging have to be disposed of waste correctly at the end of

the usage. Please follow Local Ordinances or Regulations for disposal.

ELECTRICAL PRECAUTIONS

1. This equipment must only be connected to a supply mains with protective earth. If any doubt exists as to the grounding connection, do not operate the equipment.

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. Must ensure grounding reliability. If any doubt to the grounding connection, please stop using the equipment.

4. When maintenance the equipment, please call the qualified maintenance personnel.

5. Make sure the building power source is compatible with the electrical specifications shown on the radiant warmer.

6. For safety, and please pull off the power cord when stopping using the device or repair it.

7. Equipment provided an integral multiple socket-outlet, If connect 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. This device adopts mains plug or appliance coupler as isolation from the supply mains when the radiant warmer is mounted on VHA stand, for safety. 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 want 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 select 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. To avoid hurting the retina of patient, please wear the eye mask for the patient during illumination. 3. To ensure phototherapy treatment effect, when the radiation source is over the expected useful lifetime, all should be replaced.

4. 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.

○1 . Please according to the chapter 4.4 of this manual, inspect the mechanical structure and functional completeness of the equipment.

○2 . Inspect the safety relevant labels for legibility.

○3 . Check whether the value of fuse is same as its rated value or be damaged.

○4 . Verify that the device functions properly as Table 1.1 described in the instructions for use.

○5 . Test the protection ground impedance of the equipment according to IEC 60601-1:2005+A1:2012, it shall not be more than 0.2Ω.

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

○7 . Test the patient leakage current according to IEC 60601-1:2005+A1:2012, NC: ≤0.1mA, SFC: ≤0.5mA.

○8 . Test the patient leakage current (application part + net electric pressure) according to IEC 60601-1:2005+A1:2012, SFC: ≤5mA.

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 201.12.1.103 and 201.15.4.2.1 of IEC60601-2-21:2016.

TABLE OF DEFINITIONS AND SYMBOLS

TECHNICL DEFINITIONS

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

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 programme 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 value set by the operator.

BED TEMPERATURE : The temperature is equivalent to the temperature of the center touch point when the patient is in the mattress center.

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

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.

TEMPERATURE UNIFORMITY : In steady temperature condition, the different degree between the average temperature of the four test device and the average temperature of the midpoint device which is in the mattress center.

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

EFFECTIVE SURFACE : The surface that is irradiated by light and used for treatment. As its standard size, please see section 5.

TOTAL IRRADIANCE : Irradiance equal to the evaluated irradiance in the range between 320nm and 550nm.

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

UNIFORMITY OF THE TOTAL IRRADIANCE FOR BILIRUBIN：Ratio of the lowest TOTAL IRRADIANCE FOR BILIRUBIN Ebi min to the highest TOTAL IRRADIANCE FOR BILIRUBIN Ebi max on the effective surface area.

LIFETIME OF LIGHT SOURCE：Time after the average total irradiance for bilirubin Ebi is attenuated by 25%.

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

VHA STAND: Abbreviation of vertical height adjustment stand.

NOTE, IMPORTANT, CAUTION AND WARNING

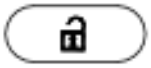
NOTE : A note is inserted in text to point out procedure or conditions, which may otherwise be misinterpreted or overlooked. A note may also be used to clarify apparently contradictory or confusing situations.

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 be happen, cleaning, and maintenance of the equipment which may result in personal injury or death of the operator or patient.

SYMBOLS

	General warning sign		Warning; Hot surface
	Follow instructions for use		No heavy load
	BF type applied part	**Class I**	Class I Equipment
RS-232	Data communication connector		Keypad lock key
	Main power on		Main power off
	Power on of the controller		Power off of controller
220-230V～50Hz	AC input	**220-230V～/50Hz MAX: 5A**	Auxiliary socket outlet of controller, MAX:5A
F 10AH/250V	F Type fuse10AH/250V	**220-230V～/50Hz MAX: 1A**	Auxiliary socket outlet of VHA, MAX:1A
	Set up key		Set down key
	Soft Key	**PART IPX2**	Partial spray proof mark
	Height adjustment down key		Height adjustment up key
	Socket for connection skin temperature sensor 1		Socket for connection skin temperature sensor 2
	Warning; Non-ionizing radiation		Silence/reset
T 3.15AL/250V	T Type fuse 3.15AL/250V		Date of manufacture
	Serial number		Manufacturer
	Authorized representative in the European community		CE Marking

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

TABLE OF CONTENTS

SECTION **PAGE**

NOTE : **The product's appearance maybe differs from the one in this manual, but it does 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. We are not responsible for the malfunction which is caused due to not following the instruction on our manual.

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

This manual should be put together with the device so as to the client to check at any moment.

Disposable skin temperature sensor is provided as option. You can ignore the relative contents if you haven't bought it.

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

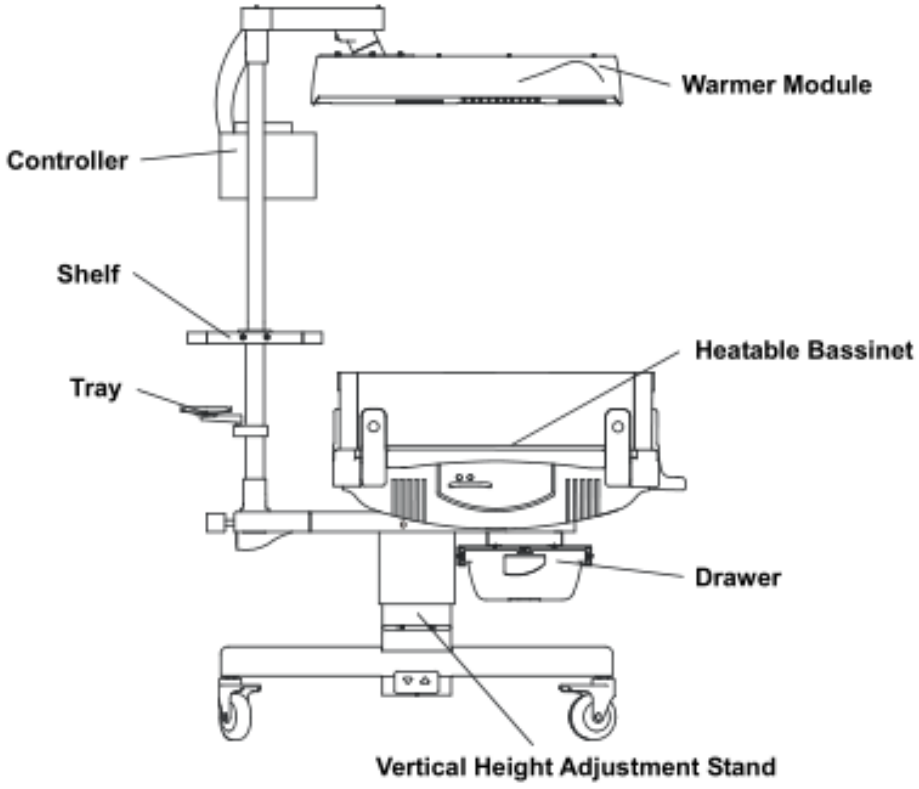
It is not clear now.

1.4 COMPOSITION OF PRODUCTS

The infant radiant warmer consists of five components: the warmer module, the bassinet with silicon mattress on it, the main column, the VHA 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 8Kg. It has the function that can move freely in the range of ±60°. The lifetime of the heater is 2000hrs. The warmer module contains phototherapy unit which is intended for treating the bilirubin of patient. Its light source is LED, and its lifetime is 5000hrs. Please wear the eye mask for patient when this part works, as for the detail, please refer to the section 5.
I.V. Pole	A kind of bearing part, which is used for hanging the infusing bottle. Max. Load: 2Kg
Controller	The core part of warmer has three temperature control modes: Pre-warm Mode, Manual Mode, and Baby Mode. It is used for automatic controlling of infrared radiation heat output. The controller also has APGAR timer and bassinet heat function, please refer to section 4.
Shelf	A kind of bearing part, which is expected to place some auxiliary devices or objects which are need to use in clinic. Max. Load: 8 Kg.
Tray	A kind of bearing part, which is used for putting some small objects. Max. Load: 2 Kg.
Heatable Bassinet	It is used for place the infant and with heating function. It is composed of silicon mattress, heating aluminum plate and control alarm system. The bassinet can be tilted (make the patient's head up or down) in clinical need. Max.Load:10 Kg. This bassinet is equipped with 4pcs panels and two inside flaps to avoid the patient dropping out from bassinet. Size of mattress: 830mm × 590mm.
VHA Stand	Includes drawers which are used for the users to storage. And they can be pulled-out from two sides. Max. Load of the Drawer: 5 Kg. The height from the bassinet to the floor is 800mm～970mm.

The max. Load of tray and the other accessories is the value in the list, not overloaded, so as not to damage to the accessories.

NOTE：**Size of whole unit**：L1353mm×W740×H1820 ~ L1353mm×W740×H1990.

Weight of whole unit：150Kg.

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: Heatable Bassinet is IPX2.

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 Infant Incubator are provided in table 1.1.

TABLE 1.1 SPECIFICATIONS

Power requirements	AC220-230V/50Hz, 900VA
Radiant heater	2X 330W±15W
Mattress heater	130W±20W
Blue light LED	10W
Working light	20W
Night light	8W
Auxiliary mains output of Controller	AC220-230V, 50Hz, MAX:5A
Auxiliary mains output of VHA	AC220-230V, 50Hz, MAX:1A
Temperature control mode*	Pre-warm mode Manual mode Baby mode
Baby mode Temperature Control range	34.5℃~37.5℃
Measuring Range	5℃～65℃
Deviation between the measure baby temperature by the sensor and control temperature	≤0.5℃
Accuracy of skin temperature sensor	within ±0.2℃
Temperature uniformity of mattress*	≤2℃
The total irradiance E_{bi} on the effective surface area *	≥1mW/cm^2
The average of total irradiance for bilirubin of effective range on the mattress	≥0.8mW/cm^2
Uniformity of the total irradiance for bilirubin of effective range on the mattress *	> 0.4
MATTRESS HEATING	
Mattress Temperature Control Range	25℃～38℃
Veracity of range	±0.7℃

TABLE 1.1 SPECIFICATIONS（continued）

ENVIRONMENT TEMP（Not to use in the environment exceed specified）

Operating range……18℃～30℃

Storage and transport range……-20℃～+55℃

ENVIRONMENT HUMIDITY

Operating range……30％～75％

Storage and transport range……≤93％

ATMOSPHERE PRESSURE

Storage and transport atmospheric pressure range……500hPa～1060hPa

Working atmosphere pressure range……800hPa～1060hPa

Application environment altitude……≤2000m

Overvoltage category……II

Pollution degree……2

AIR FLOW RATE

Ambient air movement rate……<0.3m/s

OTHER SPECIFICATION

APGAR Timer……Tones at 1, 5 and 10 minutes

* Please see the content of table of definitions and symbols.

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.**

SECTION 2
INSTALLATION

2.1 GENERAL

This section provides installing procedures about warmer.

2.2 UNPACKING

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

2.3 INSTALLATION

Before installation, please check whether the structural surface used to install the components is suitable or not. At least two professionals are required to do the installation of the warmer with inner hexagon spanner and wrench.

Installation step:

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

a. See figure 2.1, unscrew two clamp nuts according to the direction of arrow, and raise these two pieces of stainless pillars to the maximum height to make them on the same height.

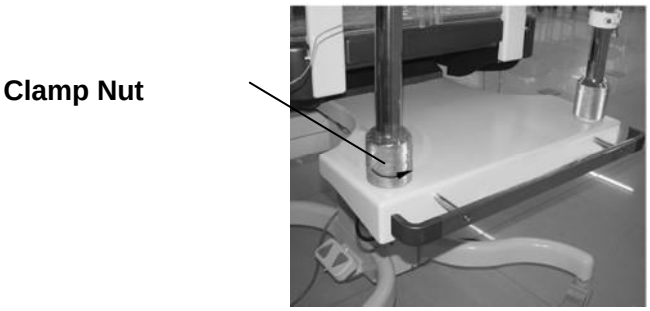


FIGURE 2.1 INSTALLATIONS THE PILLAR

IMPORTANT：**Must ensure that two columns at the same height, otherwise it will affect the temperature uniformity of the bed.**

b. See figure 2.2.1, figure 2.2.2, tighten the top cover as the arrow indicates, and insert the plug into the relevant sockets. See figure 2.2.3, tighten the cover on the side of the signal cable in the direction of arrow, and then loose two support poles to make it lower the setting position.See figure 2.2.4, tighten two bolts on the cover. At last, keeps the signal cable well-inserted.（**NOTE**：**After inserting the signal cable; you should screw the two sockets in place to prevent the interface loosen.**）

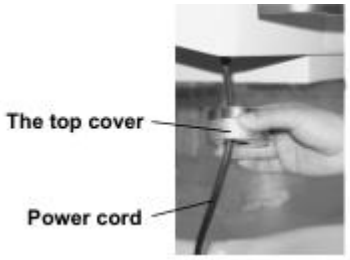


FIGURE 2.2.1

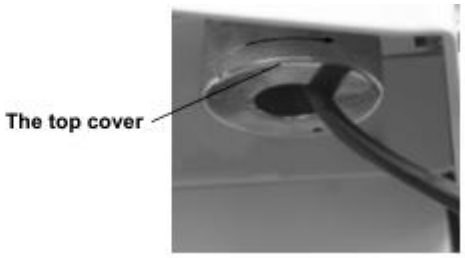


FIGURE 2.2.2

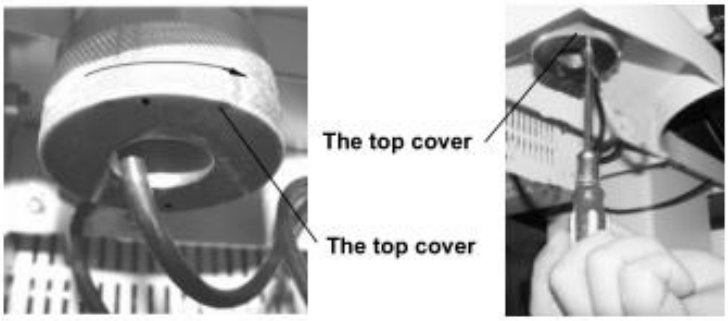


FIGURE 2.2.3 FIGURE 2.2.4

FIGURE 2.2 TIGHTEN THE TOP COVER

c. See figure 2.3, tighten these two clamp nuts as the arrow indicates.

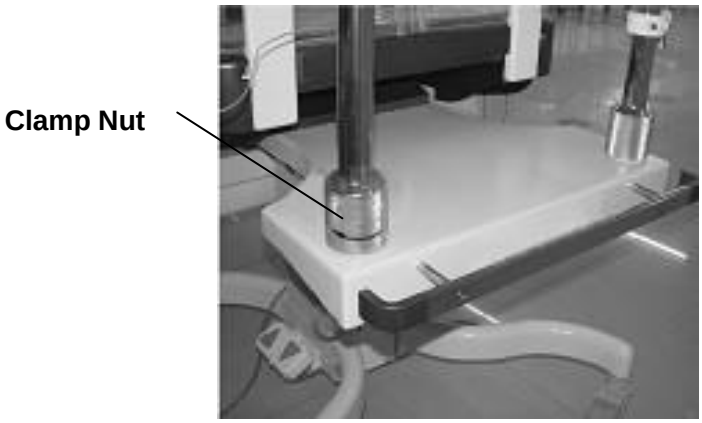


FIGURE 2.3 TIGHTEN THE CLAMP NUT

B. Install shelf

See figure 2.4, move the shelf to the relevant position to make its bottom and the marked line of pillar on the same level. Tighten the pillar stand with crossbeam and tighten the bolts on both sides of shelf with inner hexagon spanner to ensure the installation of the shelf firmly.

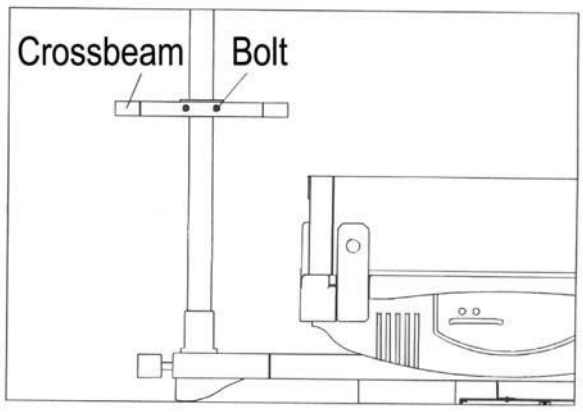


FIGURE 2.4 INSTALLATION OF SHELF

C. Install I.V.Pole

See figure 2.5, install four panels, the ones with I.V.Pole soft are the front and back panels, and all panels are installed with the same way.

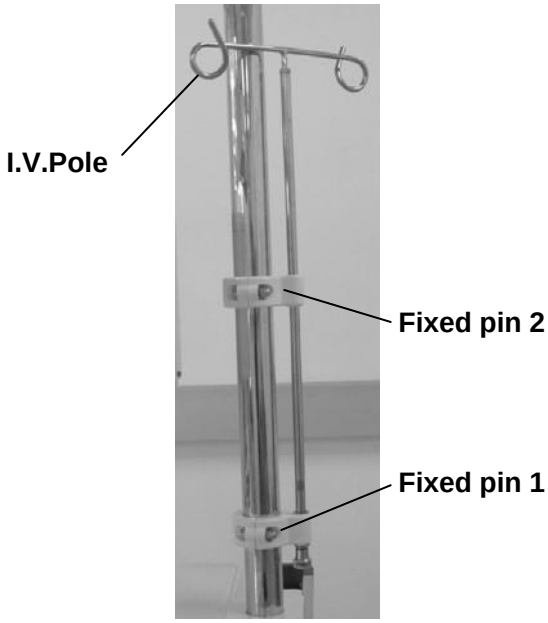


FIGURE 2.5.1

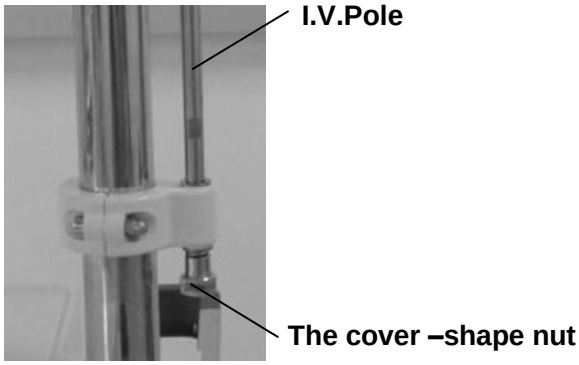


FIGURE 2.5.2

FIGURE 2.5 INSTALLATION OF I.V.POLE

D. Install tray

See figure 2.6, fix the pin on the pillar with spanner, insert the tray in to the hole of fixed pin and screw the cover-shape nut.

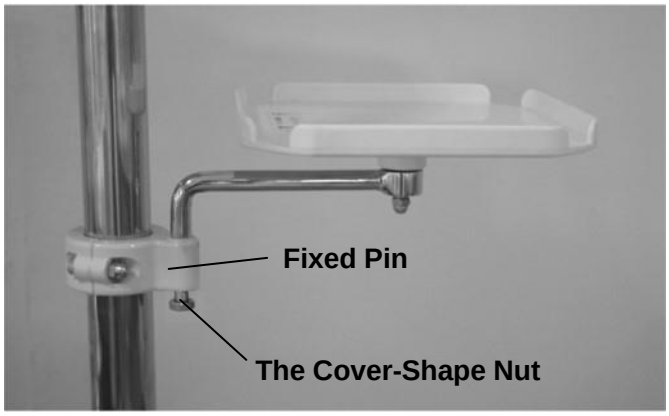


FIGURE 2.6 INSTALLATION OF THE TRAY

E. Insert the power cord

Insert the power cord into the socket of general power supply in figure 4.1.

Take the function examination in accordance with the SECTION 4.4.

NOTE: The main power switch of the incubator is located on the bottom of VHA cabinet. Do not place the incubator to a place where is difficult to operate the power switch.

SECTION 3
FUNCTION DESCRIPTION

3.1 OVERALL FUNCTION DESCRIPTION

The Infant Radiant Warmer has 3 temperature control modes: **Pre-warm Mode**, **Manual Mode** and **Baby Mode**. Once the device is started up, it can enter into the **Pre-warm Mode** automatically without pressing any key. In addition, the warmer has bassinet heating function. Infants can receive radiating heat as well as the heat from bassinet. The heat output of bassinet is independent heat supply, and it isn't influenced by heater of radiant module. When starting-up the warmer, the bassinet will work with default setting value (the default is the bed temperature setting value in last time). The LCD screen of the controller displays bed temperature、skin temperature and their setting values. Meanwhile, the LCD screen also shows skin temperature and bed temperature curvilinear trend.

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 4.5.2.2;

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 4.5.2.3;

Heating output control under Baby Mode : Servo control the radiant module heater according to the baby temperature, please refer to the section 4.5.2.4;

Heating output control of bassinet : Servo control the bassinet heater according to the bed temperature, please refer to the section 4.5.2.5.

In addition to the components listed in the 1.5 "component identify" of section 1, the warmer also has lamps (with work lamp and night lighting lamp) and phototherapy unit.

3.2 TEMPERATURE CONTROL PRINCIPLE

The heat from the warmer module will be radiated to the surface of mattress through the reflective cover in shape of parabola with high reflectively. Then the heat could reach the infant. Meanwhile, the mattress heater transfers the heat to patient who is at the bed surface by conduction.

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 make the baby decrease the dissipation, it is necessary to use the device in the environment of no rapid air flowing, and cover waterproof of velum(polyethylene velum) the naked skin or to use the waterproof net to increase the humidity around the skin to decrease the water evaporation.

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 realize 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 connect the auxiliary equipment on this interface, the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of IEC60601-1, clause 16.

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 communication connector. When using, must ensure the reliable connection.

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

5. The connection and using 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 RS232 data communication connector and patient simultaneously.

7. If have any question, please contact with the agency or the service department of our company.

3.4 ALARM MESSAGES AND SYSTEM INDICATION INFORMATION

STATE

1. Alarm information

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

NOTE: The sound of power failure alarm is different from the other high priority alarm which sound source is a single buzzle.

Medium priority: medium priority information, yellow alarm light flashing, alarm sounds more than 65dB; 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 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	Radiation heater state	Mattress heater state	Alarm level	Alarm delay time
1	Power off alarm	Power failure alarm light on, red alarm light flashes, alarm sound responses immediately	When no power supply, turn on the switch	All	Off	Off	High priority	<5s
2	Mattress temperature sensor faul	Red alarm indication light flashes, shows "Alarm: mattress temperature sensor Fault", alarm sound responses immediately	Failure occurs on the inner main probe of Mattress sensor	All	/	Off	High priority	<5s
3	Isolated Mattress temperature sensor fault	Red alarm indication light flashes, shows "Alarm: isolated Mattress temperature sensor Fault", alarm sound responses immediately	Failure occurs on the inner independent probe of Mattress sensor	All	/	Off	High priority	<5s
4	Mattress temperature sensor difference fault	Red alarm indication light flashes, shows "Alarm : mattress temperature Sensor difference Fault", alarm sound responses immediately	Difference between main probe and independent probe of mattress sensor is above 0.8℃	All	/	Off	High priority	<50s
5	Skin temperature sensor fault	Red alarm indication light flashes, shows "Alarm: skin temperature sensor Fault", alarm sound responses immediately	Failure occurs on the inner main probe of skin sensor	Baby	Off	/	High priority	<5s
6	Isolated Skin temperature sensor fault	Red alarm indication light flashes, shows "Alarm : isolated Skin temperature sensor Fault ", alarm sound responses immediately	Failure occurs on the inner independent probe of skin sensor	Baby	Off	/	High priority	<5s

ALARM INTRODUCTION （Continued）

Alarm no.	Alarm information	Alarm character	Alarm activate condition	Control mode	Radiation heater state	Mattress heater state	Alarm level	Alarm delay time
7	Skin temperature Sensor difference fault	Red alarm indication light flashes, shows "Alarm: skin temperature Sensor difference fault", alarm sound responses immediately	Difference between main probe and independent probe of skin sensor is above 0.8℃	Baby	Off	/	High priority	<70s
8	Mattress temperature over	Red alarm indication light flashes, shows "Alarm: mattress temperature Over", alarm sound responses immediately	The temperature measured by Mattress sensor is more than 39.5℃	All	30%	Off	High priority	<5s
9	Skin temperature over	Red alarm indication light flashes, shows "Alarm: skin temperature Over", alarm sound responses immediately	The temperature measured by Skin sensor is more than 38.5℃	Baby	Off	Off	High priority	<5s
10	Mattress temperature upper deviation	Red alarm indication light flashes, shows "Alarm : mattress temperature upper deviation", alarm sound responses immediately	If the mattress temperature indication 1.0℃ more than the set value	All	/	Off	High priority	<5s
11	Mattress temperature lower deviation	Red alarm indication light flashes, shows "Alarm : mattress temperature lower deviation", alarm sound responses immediately	If the mattress temperature indication 1.0℃ less than the set value	All	/	On	High priority	<5s
12	Skin temperature upper deviation	Red alarm indication light flashes, shows "Alarm: skin temperature upper deviation", alarm sound responses immediately	If the temperature of skin temperature sensor 1.0℃ more than the set value	Baby	Off	/	High priority	<5s
13	Skin temperature lower deviation	Red alarm indication light flashes, shows "Alarm: skin temperature lower deviation", alarm sound responses immediately	If the temperature of skin temperature sensor 1.0℃ less than the set value	Baby	On	/	High priority	<5s

ALARM INTRODUCTION （Continued）

Alarm no.	Alarm information	Alarm character	Alarm activate condition	Control mode	Radiation heater state	Mattress heater state	Alarm level	Alarm delay time
14	Check skin sensor	Red alarm indication light flashes, shows "Alarm : check Skin Sensor", alarm sound responses immediately	In baby mode, the measured value is lower than set value 0.4℃ or above, and no deviation alarm	Baby	Off	/	High priority	<3min
15	Check manual mode	Red alarm indication light flashes, shows "Alarm: check Manual Mode", alarm sound responses immediately	In Manual Mode, the alarm will happen every 15mins	Manual	On	/	High priority	<15min

System failure alarm introduction

When system failure alarm occurs, the alarm light flashes, the display screen shows the system alarm code, 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 alarm activate condition, please see the service manual.

NOTE: 1. All the above alarms except the deviation alarm and skin over temperature alarm in baby mode are 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 are all can silence 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 at the same time, the device will give an alarm firstly for the higher grade. Press the twice of silence /reset key can cancel the alarm state then the equipment back to the set condition to monitor the alarm.

3. If checking alarm active, 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 mins, if the power supply recover before the alarm, the device will back to the alarm setting before the outage.

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

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

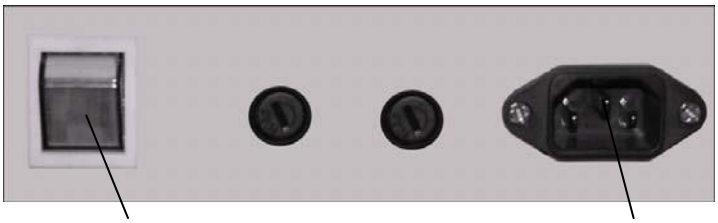
SECTION 4
OPERATION

4.1 GENERAL

This section provides operating procedures for the infant warmer.

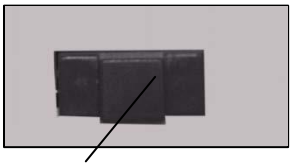
4.2 POWER SUPPLY CONNECTION AND SWITCH CONTROL

See figure 4.1 and 4.2, the general power socket and the general power switch of infant radiant warmer are located under the stand, the controller power switch located at the back of controller.



General power switch **General power socket**

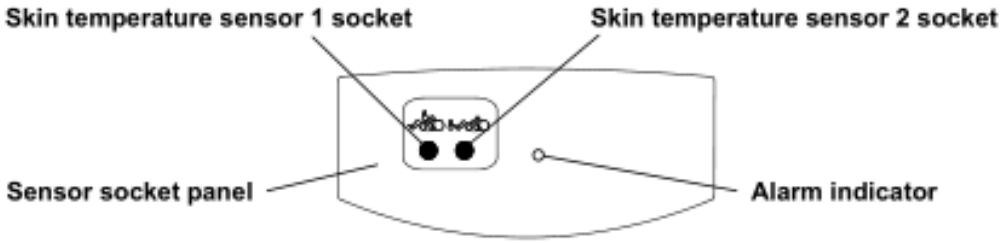
FIGURE 4.1



Controller power switch

FIGURE 4.2

4.3 CONTROLLER, INDICATE PANEL



Skin temperature sensor 1: Centre skin temperature sensor connect socket

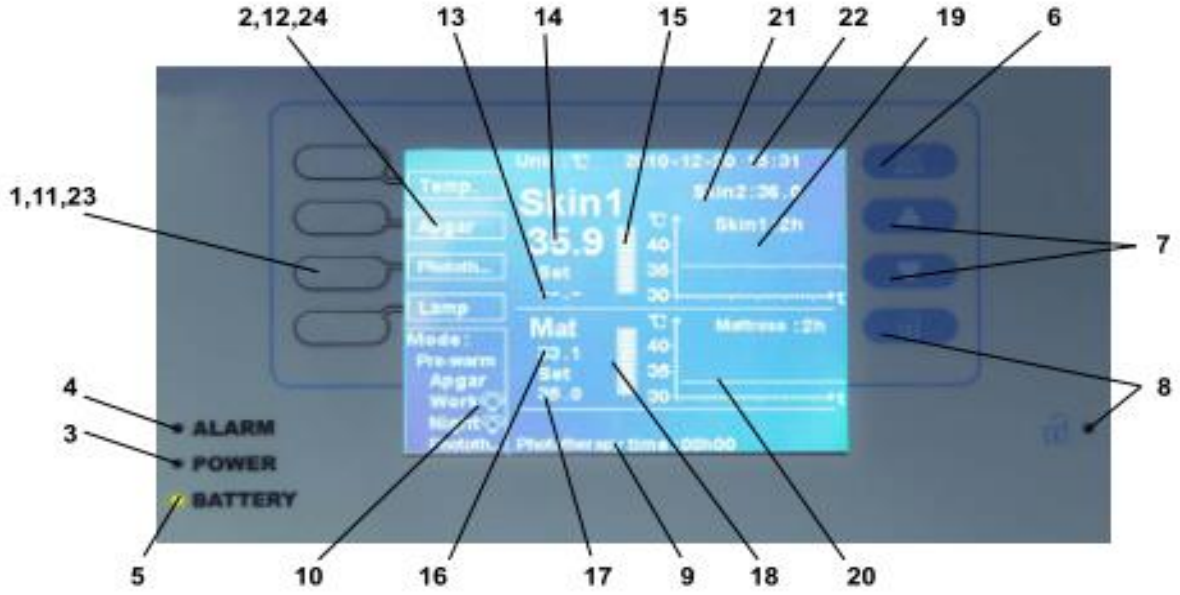
Skin temperature sensor 2: Peripheral skin temperature sensor connect socket

Alarm indicator: If one of the following conditions occurs, the alarm indicator will flash

- Inner Isolated probe of mattress-temp is failure;
- Mattress over-temp alarm;
- Inner isolated probe of skin-temp is failure;
- In baby mode, skin over-temp alarm;
- If relevant system failure alarm is activated on the device, please stop using it and hand it over to the qualified person for repair.

FIGURE 4.3

MAIN INTERFACE: TEMPERATURE, APGAR, PHOTOTHERAPY AND LAMP



1 Self-definite function key.
On Main interface, press to select one of the following parameter displays: temperature, Apgar, phototherapy and lamp. Press temperature, phototherapy and lamp keys to enter into the second indication interface. Press Apgar key, the equipment will enter into scoring and timing status, please refer to Apgar operation introduction. Other functions of functional key, please refer to independent parameters instructions.

2 Self-definite function key – indicate key
On Main interface, can appoint temperature, Apgar, phototherapy and lamp. Press "Temperature" key to enter into temperature operate interface of the second indication interface. Press "Phototherapy" key to enter into phototherapy operate interface of the second indication interface. Press "Lamp" key to enter into lamp operate interface of the second indication interface. Press "Apgar" key interface will not change, the time on the top right corner of screen will be changed into score and time. For other assigned functions, please refer to independent interface display instructions.

3 Power alarm indicator
When flashes, Illuminates along with audible alarm to indicate a power failure.

4. Alarm indication lamp

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

When the light is on, the equipment alarms to indicate that the equipment fails. Alarm messages substitute for Trend displays.

5 Battery status indicator
To be yellow indicates that it is recharging. To be green indicates that it has been full.

6 When it occurs alarm prompt, press this key can cancel the alarm, press twice can reset the alarm state then the equipment back to the set condition to monitor the alarm. Please Refer to the details for alarm descriptions.

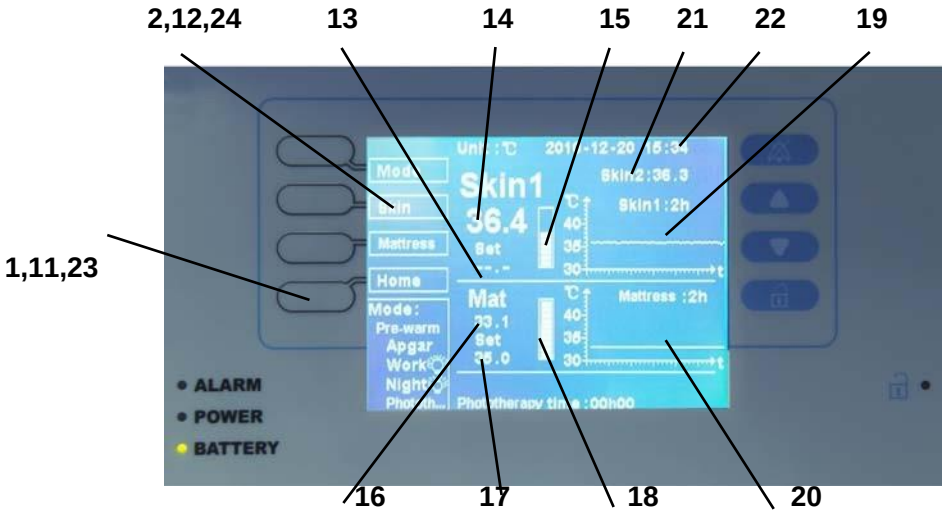
7 Up and down function key
Refer to individual parameter displays for function.

8 Keypad lock key and indicator
Press this key, the keypad lock indicator will flash, all operation keys are under the unlock status; press this key again, the indicator will extinguish and all operation keys are locked to avoid misoperation.
Note: In the alarming status, Silence/reset key is outside of control of keypad lock key.

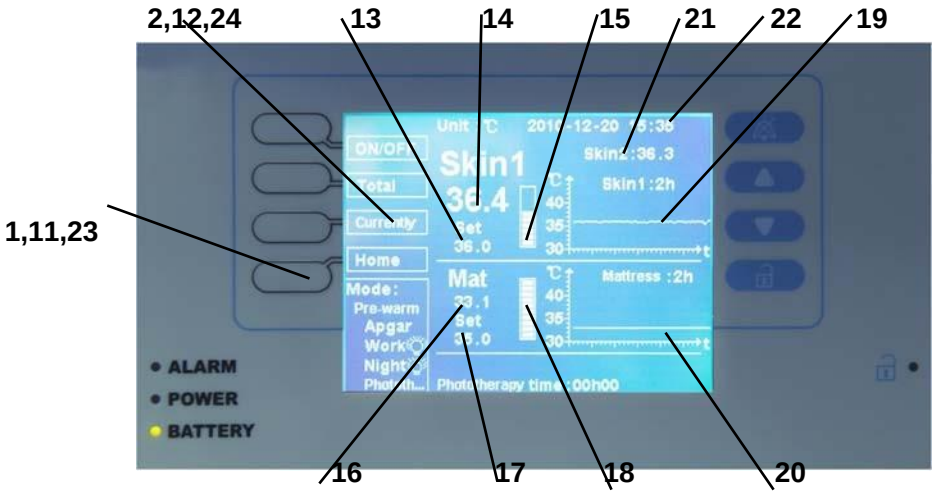
9 Message status bar
In normal working conditions, the status bar will display phototherapy accumulative time, or the current time for phototherapy care, or starting time for skin/mattress temperature curve. For the relevant display, please refer to independent interface display instructions. When the equipment occur alarms, the alarm fault message will replace the display it.

10 Work status bar
It will display running status of each function.
The current running mode of device displayed on the work status bar. For relevant display content, please refer to the relative mode select instructions. When the background of "Apgar", "Work lamp", Night lamp", "phototherapy" light which means the relative fuction is in working status, on the contrary, in the close status.

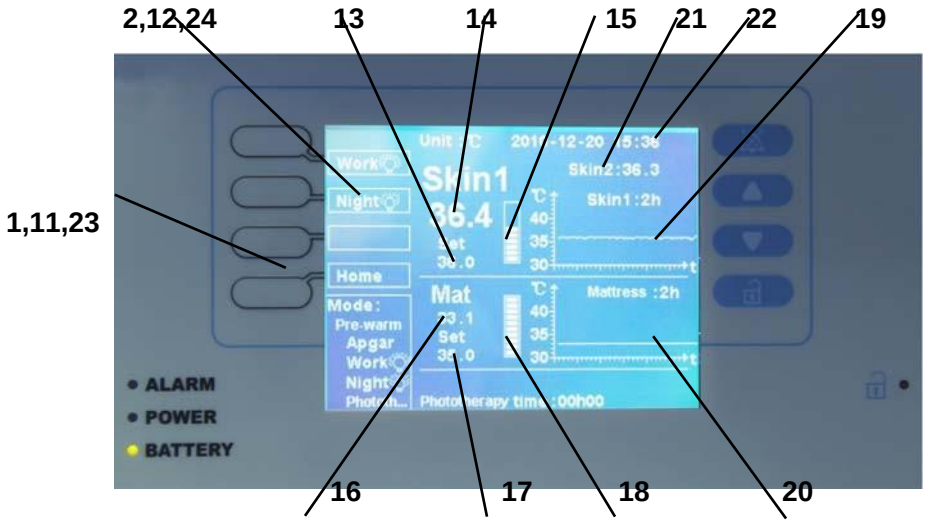
SECOND INTERFACE A：TEMPERATURE OPERATING INTERFACE



SECOND DISPLAY INTERFACE B：PHOTOTHERAPY OPERATING INTERFACE



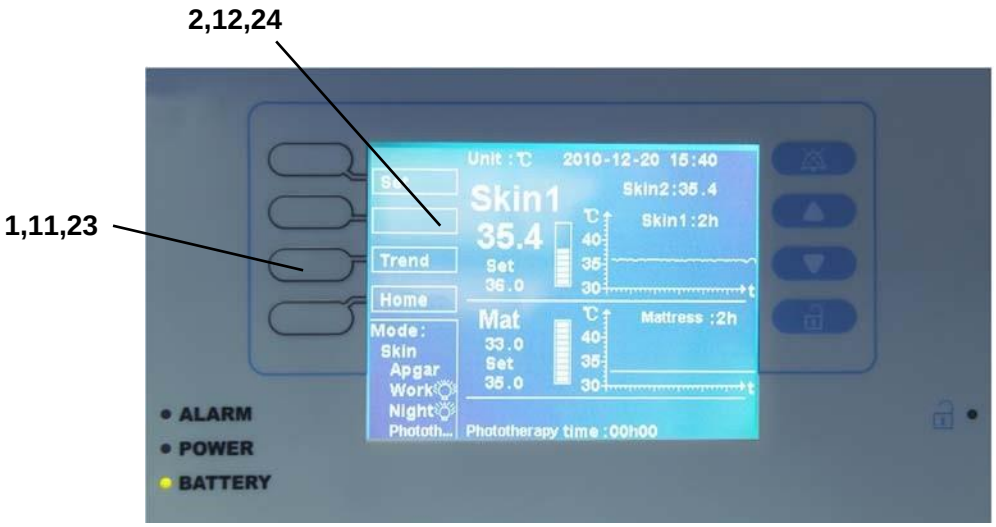
SECOND DISPLAY INTERFACE C：LAMP OPERATING INTERFACE



11 Self-definite function key. On second indication interface A,—Temperature operating interface, designates: mode, skin temperature, mattress temperature and home. Press mode, skin temperature and mattress temperature keys to enter into the relative third indication interface. On second indication interface B,—Phototherapy operating interface, designates: on/off, cumulative time, current time and home. On second indication interface C-lamp operation interface, designates: work lamp, night lamp and home. Relevant function operating, please refer to the separate display instructions.	12 Self-definite function key. – indicate key On second indication interface A,—Temperature operating interface, press "mode" key to enter into mode selection interface of third indication interface. Press "skin temperature" and "mattress temperature" key to enter into temperature setting interface of third indication interface. On second indication interface B,—Phototherapy operating interface, press "on/ off" key can open/close the phototherapy device, press "cumulative" or "current" key to select the display mode of phototherapy. On second indication interface C-lamp operation interface, press work lamp and night lamp to turn on /off the relevant lamp. For other defined functions, please refer to the separate interface.	13 Temperature Set Point Display 14 Displays skin temperature on socket 1. "--.-" will be displayed when Skin Probe is disconnected. 15 Indicate the power output percentages for radiant heating. 16 Displays mattress temperature.
17 Display mattress temperature set point of controller	18 Indicate the power-output percentage of heating mattress	19 Display temperature curve of skin temperature 1 within 2hrs
20 Display temperature curve of mattress temperature within 2hrs	21 Displays skin temperature on socket 2. "--.-" will be displayed when Skin Probe is disconnected.	22 Date/time indicator Display current date and time, user can reset time according to the local time, please refer to section4.4.2. When Apgar function is in open position, the "time/date indication" is replaced with the Apgar time.

THIRD DISPLAY INTERFACE A: MODE SELECTION INTERFACE

THIRD DISPLAY INTERFACE B: TEMPERATURE SET INTERFACE



23 self-definite function key

On the third display interface A-mode selection interface, press this key to choose pre-warm, manual, skin temperature and return to the last interface. On the third display interface B-temperature set interface, press this key to choose set, curve and return to the last interface. More relevant functions please refer to the relevant separate interface display.

24 self-definite function key- indication key

On the third display interface A-mode selection interface, press pre-warm, manual and skin temperature to choose temperature running mode. On the third interface B-temperature set interface, press set key to set skin control temperature or mat control temperature. For the specified operation, please refer to the section4.5.2; press "trend" to check detailed skin/mat temperature trend, please refer to section4.5.3 to check specified operation.

WARNING: To operate the Controller strictly as described in this Manual. Don't press any key optionally on the panel.

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. This checkout procedure related to temperature enable to use, only when set temperature must be higher 3℃ than ambient temperature.

3. Please do not damage the VHA stand during moving. And lower the stand to the lowest position before moving so that the radiant warmer is stable.

Radiant warmer should be only operated by trained personnel who is familiar with 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 equipment within 20cm in front of the device or on both sides of the device, and the specific distance between the device and the operator with the operation comfort level.

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 fasteners are installed firmly;
- Make sure that the gel mattress has been used correctly and its surface is kept well;
- Make sure that the tilt mechanism of bed can work properly ;
- 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.

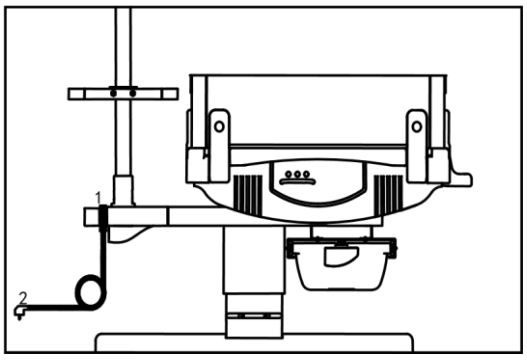
Check whether the caster can drop when lifting the radiant warmer 2cm above the ground. The drop of the caster will cause danger during transporting.

4.4.2 CHECK 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 labeled on the radiant warmer. The equipment can not use the extension power cord.



Connect the plug 1 with socket of general power. Connect plug 2 with socket of net power.

A. START-UP THE CONTROLLER

Open the power switch and the controller power switch when the power is supply, the device sounds like "di..." and company's label and the system edition will be displayed. Then self-check being carried for RAM, SRAM, REAL TIME CLOCK, EEPROM and communication system by the main body of the device. After passing self-check procedure, the device will enter operation and control interface, or else, the screen indicates the reason for not passing the self-check procedure and display the words of "**Please repair it by professional maintenance man**".

B. CHECK POWER FAILURE ALARM

Pull off the power cord of whole unit, the Power failure alarm should active. The power failure alarm light is on, red alarm indication light flashes; the device gives continuous alarm.

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.

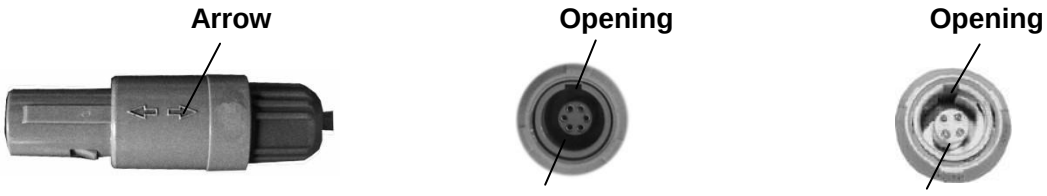
C. CHECK HEATER

Control the environment temperature at 21℃ ~ 25℃, and set the skin temperature and mattress temperature at 35.0℃, and all heat power indicator are on, and heater will output heat completely.

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

D. CHECK THE SKIN TEMPERATURE ALARM

Insert two skin temperature sensors into the socket of skin sensor 1 and skin sensor 2 separately as figure 4.3 indicates (Connecting socket of sensor is located on the left side of bed), the arrow sign on the plug should aim to the opening on the sensor socket so that the sensor is inserted correctly.



Socket of Skin Sensor 1 **Socket of Skin Sensor 2**

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.

In Baby Mode, pull off the skin temperature sensor1, the controller gives a high priority alarm sound, controller's Message Status Bar will show "**Alarm: skin temperature Sensor Fault**". The alarm character should be consistent with the description of section 3.4. Pull off skin temperature sensor 2, skin sensor 2 will display "--.-", the device is without alarm indication.

E. CHECK ACCURACY OF SKIN TEMPERATURE SENSOR

Put the skin temperature sensor 1 and skin temperature sensor 2 with the mercury thermograph for the accuracy with ±0.1℃ into the water cup with warm water. Make the probe of the skin temperature sensor and the mercury ball as closely as possible and stir enough, then read the value of mercury thermograph. Compare the value of the skin temperature sensor 1 and sensor 2 and the mercury thermograph, and the deviation must be within ±0.2℃.

NOTE: Please check again if the accuracy of the skin temperature sensor exceeds the permissibility deviation. Please let the professional maintenance man service machine if the accuracy the skin temperature sensor exceeds the permissibility of deviation again.

F. CHECK SKIN TEMPERATURE DEVIATION ALARM

In Baby Mode, set the skin temperature to 35.0℃, put the skin sensor 1 into the water cup at 37℃. When the temperature indication is more than 36.1℃, the device should give a high priority alarm. Message Status Bar will display " **Alarm: skin temperature upper deviation**". The alarm character should be consistent with the description of section 3.4. Set the skin temperature at 35.0℃, put the skin sensor 1 into the water cup at temperature 33℃, when the temperature indication is less than 33.9℃, the device should give a high priority alarm. Message Status Bar will display "**Alarm skin temperature lower deviation** ". The alarm character should be consistent with the description

of section 3.4.

G. CHECK OVER-TEMPERATURE ALARM

In Baby Mode, put the skin sensor into the water cups at 39.5℃±0.5℃, the device should give an alarm. The controller gives a high priority alarm sound, message Status Bar will display "**Alarm: skin temperature over**". The alarm character should be consistent with the description of section

3.4.

H. CHECK MATTRESS TEMPERATURE DEVIATION ALARM

Set the skin temperature to 35.0℃, the mat temperature raise up, when mat temperature reaches 36.1℃, the device should give a high priority alarm sound. Message Status Bar will display "**Alarm: mattress temperature upper deviation**". The alarm character should be consistent with the description of section 3.4. Set the skin temperature to 35.0℃, when mat temperature lowers to 33.9℃, the device should give a high priority alarm sound. Message Status Bar will display "**Alarm: mattress temperature lower deviation**." The alarm character should be consistent with the description of section 3.4.

I. CHECK MATTRESS-TEMPERATURE OVER ALARM

Keypad is locked. Press set down key and the third self-definite function key together, at this time, all heating indicators are on, if the set temperature is no indication, it means that the controller has entered into the mat over-temp test state. When the mat display temperature is not over 39.5℃, the controller gives a high priority alarm sound, message Status Bar will display "**Alarm: mattress temperature over** ". The alarm character should be consistent with the description of section 3.4.

J. CHECK MANUAL MODE ALARM FUNCTION

In Manual Mode, set the heater output proportion at 50%, after 15min, the device should give a high priority alarm sound. Message Status Bar will display "**Alarm: check Manual Mode**". The alarm character should be consistent with the description of section 3.4.

K. CHECK SKIN TEMPERATURE SETTING ALARM FUNCTION

In Baby Mode, put the skin sensor 1 into the water cup at temperature lower 3.5℃ than the set temperature for 2min, the device should give a high priority alarm sound. Message Status Bar will display "**Alarm: check Skin Sensor**". 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 1 into the water cup at temperature 35.3℃±0.1℃ for 3min, the device should give a high priority alarm sound. Message Status Bar will display "**Alarm: check Skin Sensor**". The alarm character should be consistent with the description of section 3.4.

L. CHECK APGAR TIMER

On the main interface, the keypad is unlocked, press the APGAR, the timer can indicate from 0s, when the time indicates 50"～1', 4'50"～5', 9'50"～10', it can sound "du…", at the same time, the time for APGAR is flashing.

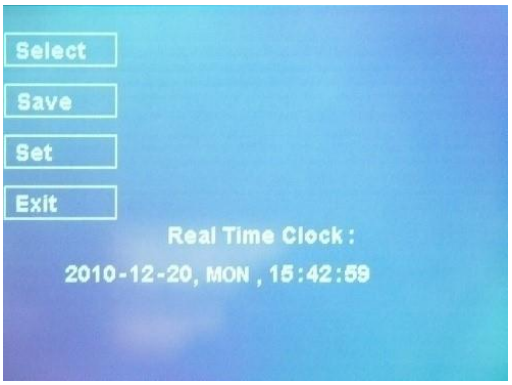
M. CHECK PHOTOTHERAPY INSTALLATION AND TIMING

On the phototherapy operating interface, the keypad is unlocked, start up phototherapy by pressing ON/OFF self-defined function key, accumulative time self-defined key, Message Status Bar will display phototherapy accumulative time; press current self-defined key, Message Status Bar will display the current phototherapy time. Press ON/OFF self-defined function key again, the phototherapy installation will be turned off.

N. CHECK CLOCK

The screen will display the current real time. If the displayed time is not correct, please reset the time. The setting method is as following:

The time can be indicated year (four figures, the former two are the century, the rest are the year), month, data, week, hour, minute, second. Press the first self-definite function key, and switch on the controller, and the controller can enter into the interface in follow figure to set the recording time of controller.



Press set self-definite function key, the underlined century can indicate, and then press the select self-definite function key, the underline can move with the time indication, press the increasing key or the decreasing key can change the underlined information, after correction, press the store key to change the time and record the time, press Exit key, the controller can enter into the first

interface.

O. CHECK ILLUMINATING LAMP

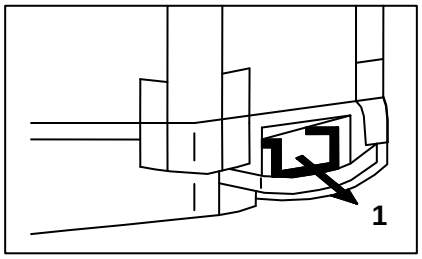
On the lamp operating interface with keypad unlocked, turn on / off the work lamp by pressing work lamp self-defined key, and turn on / off the night lamp by pressing night lamp key.

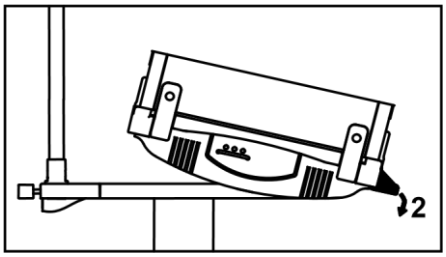
NOTE: During operation, no matter which status the device in, if not pressing any key, after 50s, the controller will return to main interface, and keypad lock key will light out as well as all keys in locking status.

4.4.3 MECHANICAL EXAMINATION

A. CHECK BASSINET TILT MACHANISM

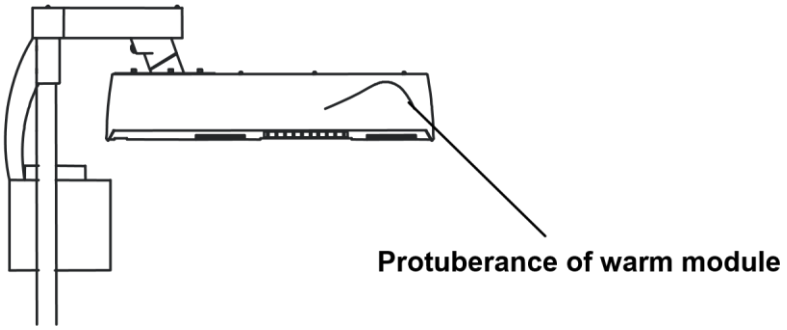
Pull the handle of the locking handle 1 forward, press handle 2 down or press handle 2 up, then release the handle to let the bed automatically locks into the selected position. The bed can be tilted in finely graduated steps. In the normal working position, when the mattress in horizontal or be tilt ±10°, positioning installation will help fixing position.





NOTE: The mattress may slip at maximum tilt.

B. CHECK THE ANGLE ADJUSTMENT FUNCTION OF RADIANT HEAD



Hold protuberance on two sides of warm module, can rotate the heater head toward left or right **NOTE: But only the 0°handle for lock is stable, the heat of the bed is also even.**

C. CHECK THE PANEL

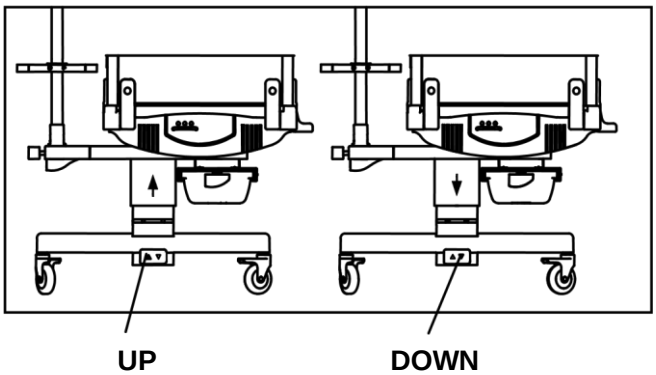
Push and pull the panel and check if the panels are firm or not.

D. CHECK I.V. POLE AND TRAY

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

E. CHECK HEIGHT ADJUSTMENT SYSTEM

To adjust the hight of whole unit by stepping on the pedal as figure shown.



NOTE: 1. The maximum load for height adjustment is 10 kg.

2. Hoses and cables should be long enough to ensure a secure connection even in the top or bottom height adjustment position.

3. Don't place any objects during the process of adjustment.

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

5. In order to keep warmer on maximum stability, stand wheel should be lowered to minimum height before being moved.

4.5 GENERAL OPERATING PROCEDURE

WARNING

1. Please read this operator's manual carefully before use.

2. You should not use the incubator without the checkout procedure, and please refer to the qualified person.

3. For the incubator's normal function, the setting temperature must 3℃ higher than environment temperature.

4. The display module of the controller is susceptible to electromagnetic interference, so can not use the controller under the high electromagnetic field. If a device which sends or receive weak signal installed in the equipment nearby, it may be affected by the electromagnetic wave sent by this equipment. Before using, please check if the device has been affected.

4.5.1 PREPARATION

CAUTION: Before switching on, the gel mattress should be put into the bed board, warmer should be warmed up for 1 hour and don't place infant in the warmer until the mattress' display temperature above 35 ℃ keep steady and the gel mattress has became warm. The skin-temperature sensor 1 should be put into the central position during preheating.

4.5.1.1 Connect the power supply cord, sensor modular and skin temperature sensor 1 correctly.

4.5.1.2 Pre-warm the warmer, put the patient on the bassinet after the mattress temperature 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.

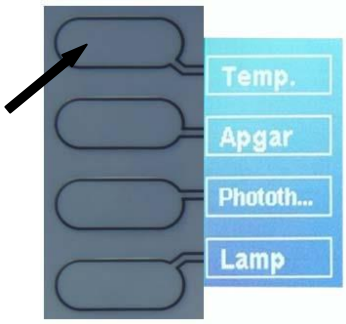
This equipment has the Pre-warm Mode, after the start-up system works, the device will enter into the following Pre-warm Mode without pressing any key:

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 pre-warm, skin temperature 1, skin temperature 2 and mattress temperature display the temperatures measured by skin temperature sensor 1, skin temperature sensor 2 and mattress temperature sensor. The set point of skin temperature and mattress temperature display the set point of last shutdown.

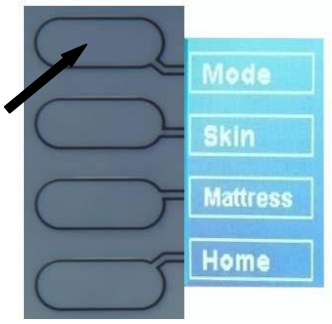
4.5.2 OPERATION

4.5.2.1 MODE SELECTION

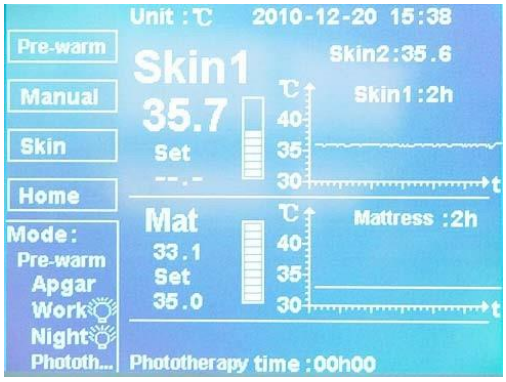
On first indication interface, the keypad is unlocked; press the temperature self-definite function key to enter into the second interface A, press mode self-defined function key again to choose pre-warm mode, manual mode or skin mode. The selected mode will display on the mode status bar.



Main interface



Temperature setting interface



Mode select interface

NOTE: 1. All setting should be operating under the Indicator lights.

2. If no keys are pressed within 50 seconds of selecting this Display, it will automatically revert to first indication interface and store the last operation result.

1. 

Press this key to enter into Pre-warm Mode.

2. 

Press this key to enter into Manual Mode.

3. 

Press this key to enter into Skin Mode.

4. 

Press to acknowledge Set Temperature setting and return to first indication interface.

4.5.2.2 PRE-WARM MODE

The device will enter into pre-warm mode when it startup. In other modes, please choose pre-warm mode according to 4.5.2.1

4.5.2.3 MANUAL MODE

In **Manual Mode**, infant radiant warmer will output a fixed heating radiant quantity according to the set heat rate. This mode is just for giving the patient the short treatment and the fist aid or makes the lower temperature patient under 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 non-care.
2. Measure the body temperature of baby regularly.

The heat output of system is 30% (the heating state indication is displayed with three grades). Under manual mode, the operator can adjust the heat output setting in the range of 0%-100% via upper or lower key, when the heating ratio output is ＞30%, the warmer can give alarming every 15min with alarming light flashing, Message Status Bar prompts "**Alarm check Manual Mode**", press the Silence/Reset key, and then the alarming will be stopped, the warmer can also operate according to the current working mode and the output power; When alarm actived, if the operator doesn't press Silence/Reset key, to ensure the safety of patient, after 1min, the system will limit the heating output to 30%.

NOTE: 1. In Manual Mode, the heating output power is fixed, without the control by the baby temperature. Therefore, pay attention to the change of body temperature of patient.

2. It will alarm every 15mins to draw the attention of operator that the patient is in the dangerous environment, to ensure the safety, the operator must monitor the body temperature of patient.

MANUAL MODE AND TEMPERATURE SETTING
Select manual mode as 4.5.2.1 indicates, press UP and DOWN to adjust the heating ratio to the required ratio. In manual mode, skin 1 will display real temperature measured by skin temperature sensor1, skin 2 will display real time temperature measured by skin temperature sensor2, Mattress temperature will display real time temperature measured by mat temperature sensor (--. – will be displayed when failure of the link between skin temperature sensor1/skin temperature sensor 2 and equipment have occurred) Skin temperature setting and mattress temperature setting will display last setting value before last shutdown.

4.5.2.4 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 setting temperature to maintain the hear balance of patient. This mode is intended to use for maintaining the body temperature of the patient. The skin temperature sensor is applied part.

Considering that the **Manual Mode** can output the heat of infrared radiation according to the heat rate, cannot be adjusted of the real condition of patient, if continue to output 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 Body Mode.**

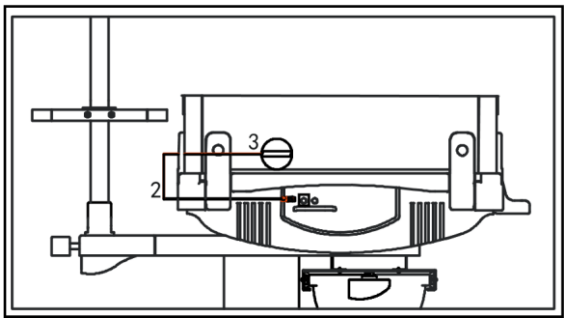
NOTE: The patient is in the state of shock or has a fever; please do not use this mode.

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 **Baby 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 dangerous (the struggle of patient will cause the crack of thermometer), if the insert depth is not enough or time is not long, 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:



Plug the skin temperature sensor1into socket 1. Feed the sensor cable 2 through the flexible pad for transfusion in the cot, and attach the sensor probe 3 to the appropriate area of the patient's skin. In the **Baby Mode**, make sure that the probe of skin sensor1 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. 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 must be disinfected completely before use.

2. Please do not put the skin sensor 1under the patient. 3. Skin sensor probe can not be regarded as the rectum thermometer.

WARNING

1. Make sure that the probe of skin sensor1 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 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.

SELECT BABY MODE AND SET POINT

Select baby mode as operation in 4.5.2.1. Press return self-defined function key to go back to the last interface: temperature operation interface. On this interface, press skin self-defined function to enter into temperature setting interface. Press setting self-defined function key to adjust the control temperature by pressing UP and DOWN key. In baby mode, skin 1 will display real temperature measured by skin temperature sensor1, skin 2 will display real time temperature measured by skin temperature sensor2, Mattress temperature will display real time temperature measured by mat temperature sensor(--. - will be displayed when failure of the link between skin temperature sensor 2 and equipment have occurred).

Temperature Operation Interface **Temperature Setting Interface**

NOTE: 1. All setting should be operating under the Indicator lights.

2. If no keys are pressed within 50 seconds of selecting this Display, it will automatically revert to first indication interface and restore the last operation results.

1. 

Press this key to enter the Skin Temperature Setting, the Indicator "Set" flashes.

2. 

Press to enter skin temperature curve trend interface.

3. 

Press this key and return to first indication interface.

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

WARNING

1. In Baby Mode, it is servo-control baby temperature, the operator should not leave to avoid the patient is non-cared and cause the patient danger.

2. The patient maybe not feel the loss of water under the continuing heat radiation, so please add the water to patient to avoid the patient dehydration.

4.5.2.5 USE OF HEATING GEL MATTRESS

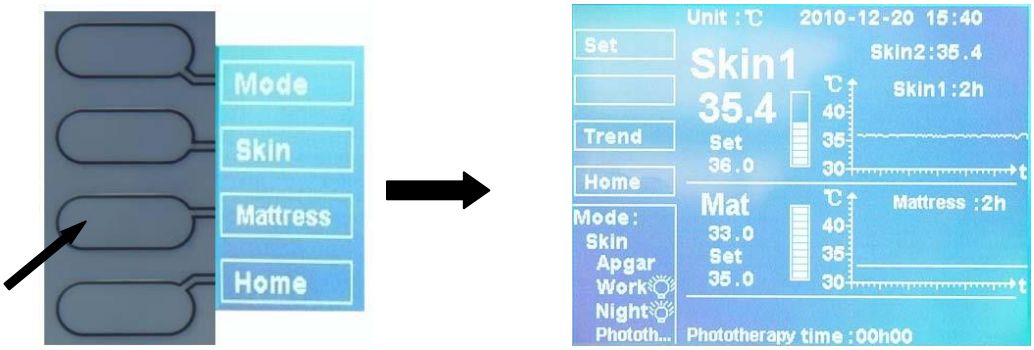
WARNING

1. **Place the gel mattress before using, and then put the patient in the center of the mattress.**
2. **The surface of mattress must be checked before each use.**
3. **You should prevent sharp objects to touch the mattress so as to avoid damaging the gel mattress. Besides, you should not fold or wring the gel mattress; you should roll it during moving.**
4. **Avoid put the things on the mattress, like pillow or bed sheet and so on. Because the partial covering mattress may cause danger.**
5. **When use the heating function of the bassinet, the use of the HF surgical instruments or endocardial catheters may cause harm, such as the RISK of electrical shock.**
6. **When use the heating function of the bassinet, warm transdermal drug (patches) can increase drug deliver, resulting in possible HARM to the PATIENT.**
7. **When the heating function of bassinet, radiant heater and the jaundice treating function work at the same time may lead to patients over heated, at this moment, we should give full consideration to the factor when set the heating system, the operation personnel should set the radiant heating function and bassinet heating function correctly alone or combined operation.**
8. **Gel mattress has the good heating conductivity, when using it with heating mattress, if mattress setting value is over low, it may decrease the body temperature of patient.**

The mattress of the bassinet is the applied part. Starting to heat the mattress will not affect the temperature uniformity of bed surface on the warmer. In order to shorten the time of warm-up for radiant warmer, or let the contacting surface between patient and mattress reach the desired temperature, whatever the controlling state is, and the heating function of mattress can be turned on. The mattress temperature is merely referred to the temperature that can be reached in the range of contacting region. That is to say, only when the patient lies on the bed, in the state of constant temperature, what the mattress temperature display is the real time contacting-region temperature between patient and mattress.Without radiating heat; it will take about 90mins to heat mat temperature from 23℃ ℃ to 37 .

SET MATTRESS TEMPERATURE

As 4.5.2.1 indicates, press mattress self-defined function key to enter into temperature setting interface, then press set key till the setting value flash, then adjust the mat temperature control value by pressing UP and DOWN key. Skin 1 will display realtime temperature measured by skin temperature sensor1,skin 2 will display realtime temperature measured by skin temperature sensor2,Mattress temperature will display real time temperature measured by mat temperature sensor (--. - will be displayed if skin temperature sensor 2 is not connect).



Temperature Operation Interface **Temperature Setting Interface**

NOTE: 1. All setting should be operating under the Indicator lights.

2. If no keys are pressed within 50 seconds of selecting this Display, it will automatically revert to first indication interface and restore the last operation results.

1. 

Press this key to enter into mattress temperature setting status.

2. 

Press this key to enter into mat temperature curve interface.

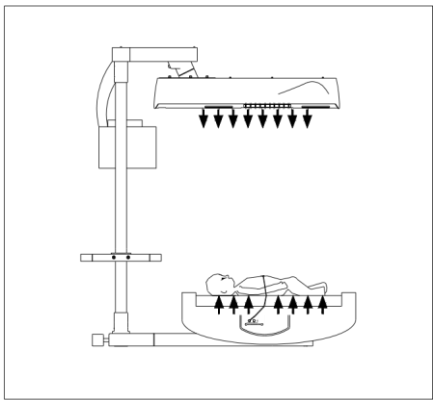
3. 

Press this key to return to the last interface.

The recommended skin control temperature should be close to the patient's skin temperature, mattress control temperature should be close to the patient's body temperature.

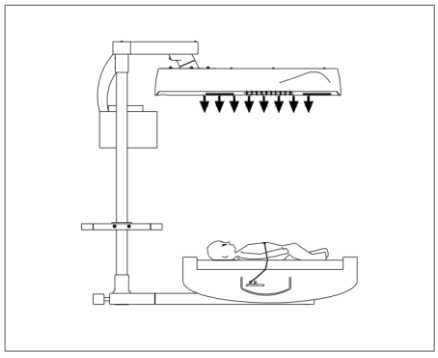
Increase patient's body temperature:

Set mattress temperature to desired body temperature. If necessary, set skin temperature to a slightly higher value. For a very hypothermic patient, set mattress temperature and skin control temperature to achieve a patient temperature increase rate of approximately 1℃ per hour.



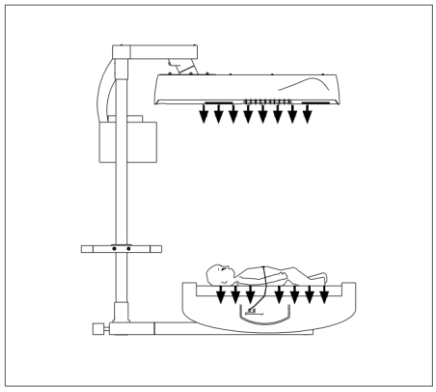
To stabilize or maintain patient temperature

Set the mattress temperature and skin temperature to the current body and skin temperature, respectively.



To decrease patient temperature

Set mattress temperature to the desired body temperature. If necessary, set skin control temperature to a slightly lower value.



4.5.3 Other operations

A. Operation of skin curve or mat curve

On the skin temperature/mattress temperature setting interface, press curve self-defined function key to enter into the curve display interface as the following figure shown. Time interval is two hours, users can query the restored temperature curve by pressing "Front 2h" or "Back 2h".

1. 

On skin temperature interface, press this key, a skin trend diagram will be turned 2hrs ago from the start time of skin temperature shown along the bottom of screen; on mat temperature interface, press this key, a mattress trend diagram will be turned 2hrs ago from the start time of mat temperature shown along the bottom of screen.

2. 

On skin temperature interface, press this key, a skin trend diagram will be turned 2hrs later from the start time of skin temperature shown along the bottom of screen; On mat temperature interface, press this key, a mat trend diagram will be turned 2hrs later from the start time of mat temperature shown along the bottom of screen.

3. 

Press this key to restore from the current state, meanwhile,the former start time will be cancelled.

4. 

Press this key to return to the last interface.

B. Use of skin temperature sensor 2

Skin temperature sensor 2 is recommended to work for mastering completely patient's heating status, display of periphery skin temperature.

Connect skin temperature sensor 2

Insert skin temperature sensor2 into socket 2, then pass through the soft port and fix the probe on the four limbs (it's better to fix on the foot) to ensure that the sensor is fixed reliable.

Periphery skin temperature display

Connect skin temperature sensor2, skin 2 on the screen will display the real temperature measured by skin temperature sensor 2. If display "---", please consult the qualified personnel to repair. Measured value of skin 2 has no effect on the output of radiant quantity, only for reference of temperature display.

C. 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.

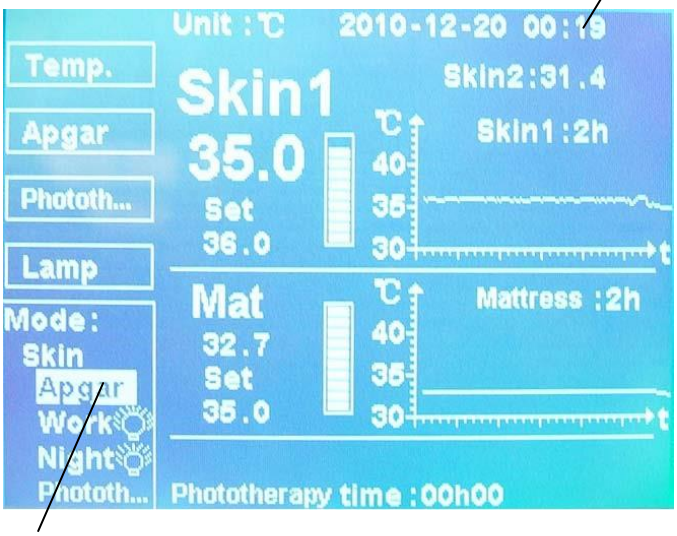
2. The mattress tilt will affect the temperature uniformity on the mattress, the horizontal position of mattress is best state.

The handle of the infant bed can only be used for pulling or pushing, not for lifting up.

D. APGAR TIMER

On the main interface, the keypad is unlocked, press APGAR, interface will not change, but the time on the top right corner will change into grade and time.

APGAR display



In APGAR status

E. LAMP

On the main interface, the keypad is unlocked, press lamp key to enter into the second interface,

then press work lamp or Night lamp to turn on/off the relevant lamps.

Work lamp is on

F. PHOTOTHERAPY INSTALLATION

Refer to section 5.

4.5.4 SHUTDOWN

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

OPERATOR'S MANUAL FOR INFA NT RADIANT WARMER

SECTION 5
PHOTOTHERAPY

5.1 GENERAL

This section provides operation and maintenance procedures for the PHOTOTHERAPY EQUIPMENT.

When the phototherapy unit is working in the ambient that the noise is lower than 45dB(A), the work noise of the unit will not exceed 55dB(A). The total irradiance of maximum bilirubin is 1.3mW/cm^2 on effective surface of the bed surface. Wavelength chart is illustrated in Figure 1.

The total spectral irradiance Ebi over a wavelength interval of 5 nm for the wavelength range 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		

Unit: W/m^2

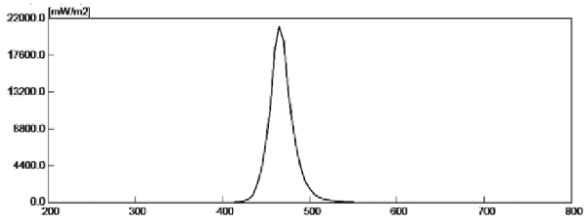
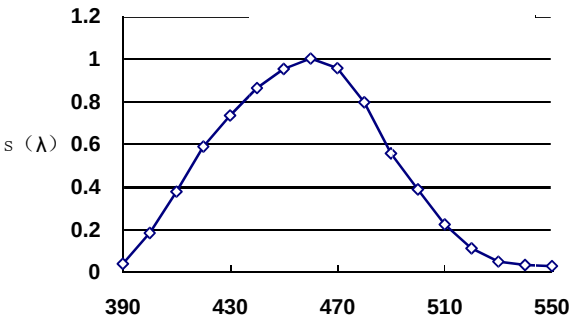


FIGURE 1



λ（nm）

FIGURE 2

NOTE: Figure 2 shows the calibration curve of measuring equipment, abscissa of the figure represents radiation wavelength, vertical axis represents the sensitivity of measuring equipment and the cuves represents the sensitivity of measurig equipment relative to the different wavelengths of light radiation.

5.2 OPERATION

NOTE：**1. The varying ambient cinditions (e.g., temperature, radiation source) around the patient all can affect patients' temperature and the bilirubin value. Therefore, when the patient ambient cinditions 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. Please cover the genitalia of patient with diaper during treatment to avoid hurting the genitalia.

6. The patients' water balance may be disturbed during phototherapy treatment, the nurses should supply the water for the patient in time.

7. If the warmer is on when use the phototherapy equipment, please switch to baby mode, or the heating output of the warmer will reduce.

8. Photoisomers of the bilirubin may cause toxic effects. For example, the patient maybe has diarrhea, kernicterus shortage, hemolysis, anemia , skin rash, bronze disease, and so on, so the nurse should give more wardship.

9. Measure the bilirubin concentration of patient regularly.

10. During Phototherapy, the nurse should not stare at the light source directly or through optical Equopment.

11. 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.

12. During the phototherapy period, heat produced by radiant of the illumination will influence Temperature Uniformity of the bed and infant's temperature. Please monitor the body temperature of patient more than before.

13. 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.

14. If use the reflection foil, can affect the radiation of the jaundice treating equipment, may cause the temperature changes in patients with risk.

15. Use 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 observe the color of the patients.

WARNING: If do not use or adjust the apparatus, or operate each step according to the following rules, it will cause LED radiating damage.

5.2.1 PREPARATION BEFORE OPERATION

5.2.1.1 Make sure to clean and sterilize the PHOTOTHERAPY UNIT according to the instruction in 5.3 of this manual.

5.2.1.2 Make sure that the PHOTOTHERAPY installation can work. For example, all light sources can work can work too.

5.2.2 OPERATION

5.2.2.1 Location of radiation window as figure 3 shown:

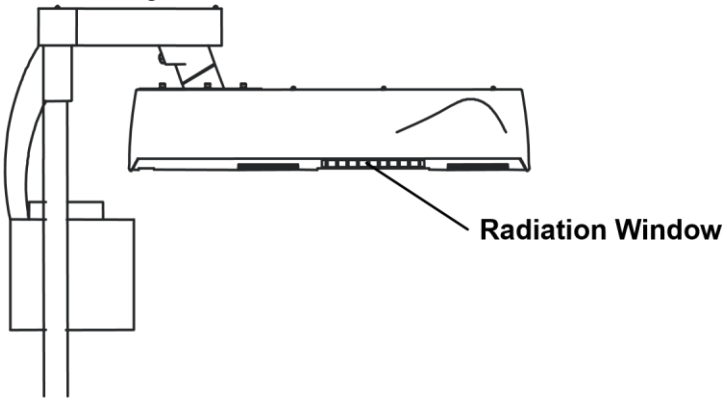


FIGURE 3

5.2.2.2 The phototherapy installation is fixed on the radiant warmer, so that the space between the effective surface and phototherapy installation is 78cm (see figure 4). Place naked patient on the effective surface 300mm×250mm as figure 5 indicates.

NOTE: Paramedics can adjust infant bed as clinical requirements, but any changes in the angle of inclination will have an effect on the total irradiance. Thus, during phototherapy period, it's necessary to ensure that the bed is at horizontal position.

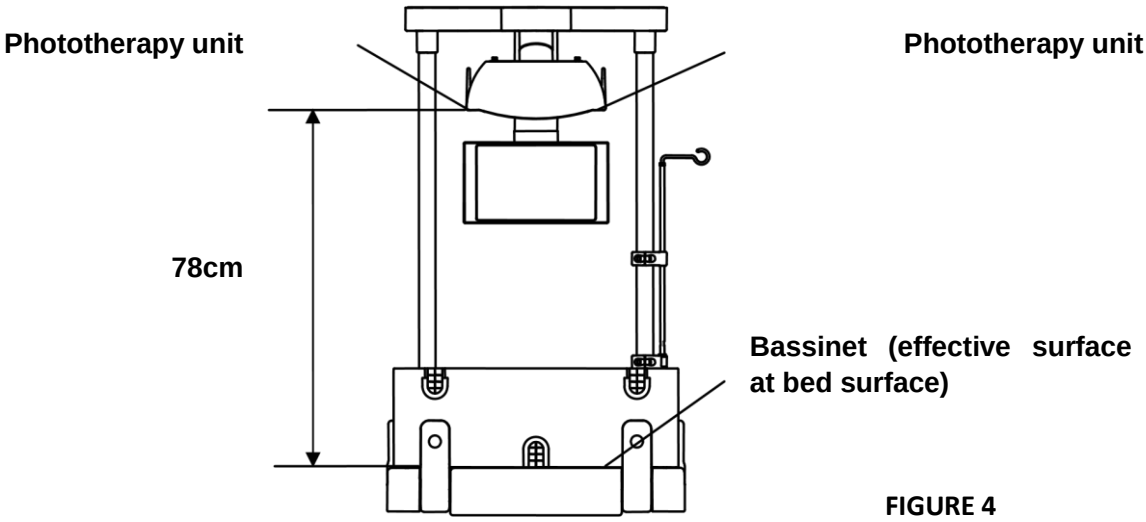


FIGURE 4

OPERATOR'S MANUAL FOR INFANT RADIANT WARMER

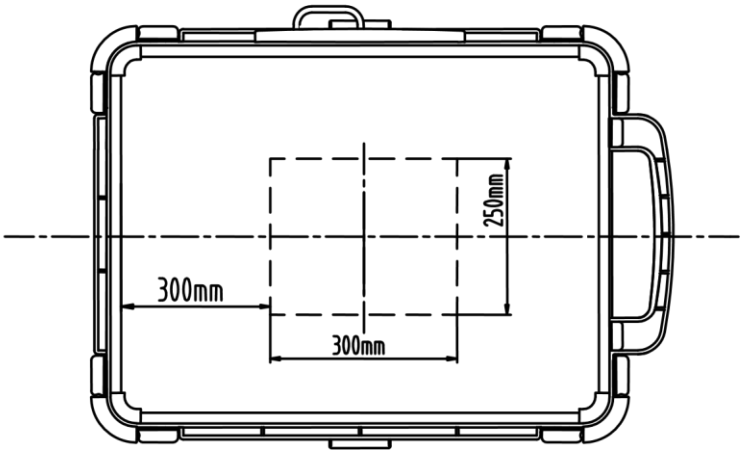


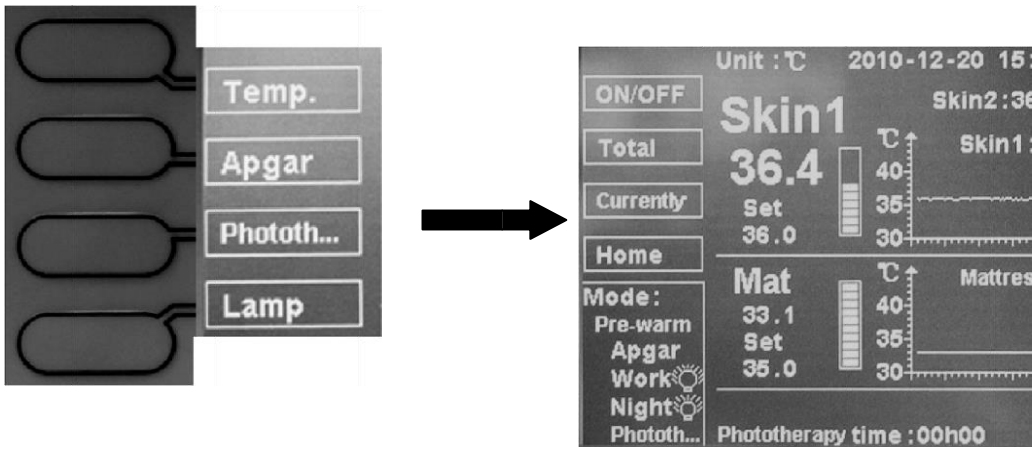
FIGURE 5

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. Larger the effective surface area is, the smaller average total irradiance value becomes. Longer the radiant distance is, the smaller average total irradiance value becomes. Conversely values are on the contrary.**

5.2.2.3 Please Wear the eye mask for the patient or cover the genitalia with diaper or its likes.

5.2.2.4 Operation of phototherapy unit

On main interface with keypad unlocked, press phototherapy self-defined function key, the controller enters into the second display interface B, then operate phototherapy installation as the following figure indicates.



NOTE: 1. All setting should be operating when the keypad lock Indicator lights.

2. If no keys are pressed within 15 seconds of selecting this Display, it will automatically revert to first indication interface and restore the last operation results.

1. 

Press this key to turn on/off phototherapy installation

2. 

Press this key, phototherapy accumulative time will be displayed on the bottom of screen.

3. 

Press this key, the current phototherapy time will be displayed on the bottom of screen.

4. 

Press this key, the device return to the first display interface.

NOTE: 1. As for the time of phototherapy treatment, please follow the instruction of doctors.

2. When the controller is off, press the third self-defined function key, then turn on the power switch of controller, the accumulative of phototherapy installation will return to zero.

5.2.2.5 When all the above operations completed, the operator must be away from the effective radiating area to avoid radiation for a long time.

5.3 CLEANING

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

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.**

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

5.4 MAINTENANCE

The total bilirubin radiation for the phototherapy equipment must be quarterly measured by the trained and experienced personnel.

Draw the effective surface on the infant bed as the description of section 5.2, firstly mark off rectangle subregion which distance is 100mm×50mm (The sensitivity of irradiatometer requires to meet "**The calibration curve of the measurement device**" shown), then measure total bilirubin radiation for each subregion and find out the maximum value, when the maximum total irradiance of measured bilirubin deviates from the specified value in the manual by 25%, please replace light resource. Measurement must be done by the professional and ensure that the indentification certification of irradiatometer is effective.

In order to ensure the good effect of phototherapy treatment, when the lifetime of lamp ends, it must be replaced although it can work normally. The reason is:

That the light radiation capacity will be reduced with the prolonging working time and make the total bilirubin radiation decreased, so that the equipment lost it preventative affect during phototherapy treatment.

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

SECTION 6
CLEANING AND MAINTENANCE

6.1 GENERAL

This section provides cleaning and maintenance instructions.

6.2 CLEANING

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

This device must be cleaned and sterilized for the first time after purchasing, or it is used 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 and the transfusion soft mat from the bassinet.

C. Please disassemble the panel from the bassinet.

See figure 6.1.1, pull the panel as the direction of the arrow and then turn it out to the vertical position. According to the figure 6.1.2 indicates; carry the panel away as the direction of the arrow, and then you can remove the panel.

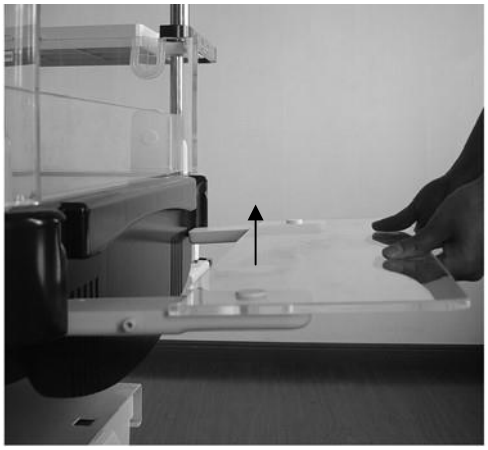


FIGURE 6.1.1 **FIGURE 6.1.2**

NOTE: 4 pieces panels totally. Make the bassinet tilt when installing the back panel.

6.2.2 CLEANING PROCEDURE

A. Clean the skin temperature sensor

Use a disinfectant-detergent to thoroughly clean all surfaces (including probe), then sterilize with neutral disinfectants or ultraviolet disinfection.

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 suggest 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 panel

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

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.

C. Clean soft port

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

D. Clean the bassinet, shelf and I.V.Pole

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

E. Clean the surface of the device

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

NOTE：**You should wait for the heater head became 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 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.

6.2.3 ASSEMBLE AFTER CLEANING

NOTE：**Before install 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. Put the mattress on the bassinet.

B. Install the panel back to bassinet and install the transfusion soft mat back to panel in the reversen steps according to the step C of section 6.2.1.

C. Put the skin temperature sensor into the sensor socket.

6.3 MAINTENANCE

WARNING: To ensure the safety of using the equipment is not affected, the modified 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 discard, so need to be recover 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 graph 1.1 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.

6.3.3 GEL MATTRESS REPLACEMENT

The lifetime of gel mattress is 2 years. Patch over small cuts or other damage in the covering film with adhesive tape.

If mattress has brittleness or big crack, it should be replaced immediately.

6.3.4 SOFT PORT

When the material appears brittleness and stickiness, it should be replaced immediately.

6.3.5 WORK LAMP AND NIGHT LAMP

If damaged, please consult the qualified personnel to replace it.

6.4 TROUBLESHOOTING

Troubleshooting of the infant radiant warmer is presenter 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
“Alarm skin temperature Sensor Fault” will display on the screen	Skin temperature sensor 1 is not inserted	Insert skin temperature sensor 1
	Skin temperature sensor1 is damaged	Replace the skin sensor1
“Alarm isolated skin temperature Sensor Fault” will display on the screen	Skin temperature sensor1 is damaged	Replace the skin sensor1
“Alarm skin temperature Sensor difference Fault” will display on the screen	Skin temperature sensor 1 is inaccuracy	Replace skin temperature sensor 1
“Alarm skin temperature over” will display on the screen	The temperature patient skin is over high	Check patient
“Alarm skin temperature upper deviation” will display on the screen	Excessive fluctuations in ambient temperature	Check environment
	The skin temperature sensor 1 is fallen off from patient.	Fix skin temperature sensor 1 again on the patient's body
	Skin temperature of patient raise obviously.	Check patient
“Alarm skin temperature lower deviation” will display on the screen	Excessive fluctuations in ambient temperature	Check environment
	The skin temperature sensor1 is fallen off from patient.	Fix skin temperature sensor 1 again on the patient's body
	Skin temperature of patient reduced obviously.	Check patient
“Alarm check skin sensor” will display on the screen	Skin temperature sensor 1 does not fix on the patient's body, for example:placed outside the bed	Fix skin temperature sensor 1 again on the patient's body
	Incorrect temperature control mode, for example: recover temperature for the patient with low body temperature.	Select manual mode
Height of whole unit can not be adjusted	Power switch is off	Turn on the power switch
	Power cord of whole unit is disconnected	Connect power cord of whole unit

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	Gel mattress	2 years
5	Soft port for I.V. Pole	If damaged
6	Soft port for I.V. Pole	

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

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