DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

CE 0483

DIXION

BabyGuard I-1107

Infant incubator

Operator´s Manual

Manual Ver: V1.10
Release Date: August 2024
Part Number: OM_BabyGuard I-1107_V1.10

EMC INFORMATION

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

ELECTROMAGNETIC COMPATIBILITY PRECAUTIONS

1. The equipment intends to use in the professional healthcare facility environment.

2. Equipment cannot be operated or exposed in RFID, X-RAY, MRI environments.

3. Pay attention to the electromagnetic environment at the scene, because the equipment may be affected by the electromagnetic environment at the scene.

4. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

5. Equipment should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.

6. If the essential performance is lost or degraded due to EM disturbances, the user might need to take mitigation measures, such as relocating or re-orienting the equipment.

7. Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

CABLES SUPPLIED BY THE MANUFACTURER

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

ESSENTIAL PERFORMANCE

1. With an INFANT INCUBATOR working in the BABY CONTROLLED INCUBATOR mode with horizontal MATTRESS orientation ， the temperature as measured by the SKIN TEMPERATURE SENSON shall not differ from the CONTROL TEMPERATURE by more than 0.7 ℃ in STEADY TEMPERATURE CONDITICN.

2. With an INFANT INCUBATOR or operating as an AIR CONTROLLED INCUBATOR, the AVERAGE INCUBATOR TEMPERATURE shall not differ from the CONTROL INCUBATOR by more than±1.5℃.

3. After STEADY TEMPERATURE CONDITIONS of an AIR CONTROLLED INCUBATOR have been achieved, any sensed temperature deviation of the displayed air temperature exceeding ±3℃ compared with the CONTROL TEMPERATURE shall cause an auditory and visual alarm to operate.

4. After STEADY TEMPERATURE CONDITIONS of a BABY CONTROLLED INCUBATOR have been achieved, any deviation of the displayed SKIN TEMAPERATURE exceeding ±1℃ compared with the CONTROL TEMPERATURE shall cause an auditory and visual alarm to operate.

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

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

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

Guidance and manufacturer's declaration – electromagnetic immunity		
The *Infant Incubator* is intended for use in the electromagnetic environment specified below. The customer or the user of *Infant Incubator* 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 Incubator* is intended for use in the electromagnetic environment specified below. The customer or the user of *Infant Incubator* 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 Incubator* is used exceeds the applicable RF compliance level above, the *Infant Incubator* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *Infant Incubator*.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Guidance and manufacturer's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS
IMMUNITY to proximity fields from RF wireless communications equipment

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

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

Test frequency (MHZ)	Band [a] (MHZ)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (v/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1 kHz sine	2	0,3	28
710	704-787	LTE Band13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b]) 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5500						
5785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL , the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

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

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

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

WARRANTY

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

1. All consumable and disposable products are guaranteed to be free from defects upon shipment only.

2. Calibrations are considered normal maintenance and are not included in the 1-year warranty.

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

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

1. Damage to the unit is incurred as a result of mishandling.

2. The customer fails to maintain the unit in a proper manner.

3. The customer uses any parts, accessories, or fittings not specified or sold by our company.

4. Sale or service is performed by the non-certified service/dealer agency.

5. For related technical instructions, please refer to the maintenance manual.

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

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

SERVICE

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

OPERATING PRECAUTIONS

1. INFANT INCUBATOR (incubator) belongs to high risk medical device which can endanger infant's life. Therefore please use the device only in neonate nursing room, children nursing room, pediatric intensive care unit or similar sickroom in hospital. Operator 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 conditions happen. Suggest motoring the baby temperature at least 1 time every half hour.

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

4. Direct radiation from sunlight or other infrared source could cause overheating of the infant without activating the Over Temperature Alarm. DO NOT leave the INCUBATOR in direct sunlight or near other sources of radiant heat.

5. DO NOT leave the INCUBATOR in the presence of flammable anaesthetic gases or other flammable materials, such as some types of cleaning fluids.

6. DO NOT leave the INCUBATOR in the presence of strong electromagnetic field. The equipment may be effected by portable and mobile radio frequency communication facilities.

7. Devices which are easily interfered by magnetic field should not be used near the INCUBATOR because they may interfered by the INCUBATOR.

8. The incubator does not equip the air cleaner, to make sure the good air quality inside hood, the incubator should be used in the environment with clean air.

9. Please DO NOT use the INCUBATOR under working environment not stipulated in table 1.1, or else, it may cause the failure or the INCUBATOR can not reach the requirements.

10. To prevent harm to the infant, the hood should not be raised while leads are connected to the infant or if the mattress tilted.

11. There should be no need to raise the hood at any time while the infant is cared for in the incubator. All necessary access to the infant can be achieved by means of the Access Panel and Access Doors.

12. When the Access Panel is open, the temperature from the air temperature indicator maybe not the real temperature inside incubator. Therefore, do not leave the Access Panel open much longer.

13. All access panel's latch should be firmly plugged, in case accidental open.

14. For infant safety, DO NOT leave the infant unattended when the Access Panel is open.

15. Other accessories within the incubator which can alter the air flow pattern may affect temperature uniformity and temperature variability.

16. Using phototherapy equipment may affect hood wall temperature, incubator temperature or infant skin temperature, so you have to measure the baby body temperature. In addition, we suggest the incubator use skin temperature mode, otherwise, according to the measured baby body temperature result you have to reduce the incubator setting temperature.

17. Patient safety and incubator performance may be compromised if air flow passages are not kept clear from obstructions (blankets, stuffed animals, etc.) during clinical usage.

18. Do not place surgical covers or blankets over the infant and warm air curtain or side vents simultaneously. This may cause heat that induces injury and burns.

19. The incubator should be moved by at least two personnel who have certain strength, the handle located on the left of the incubator can be used as hands handle when moving. Please pull out all power cords before moving.

20. To prevent the harm on patient for accidental movement, please lock the casters during usage.

21. To prevent accidental disconnection, secure all patient leads, infusion lines and ventilator tubing to the mattress with sufficient excess length to allow for the full range of mattress height adjustment.

22. To avoid water over flow from water chamber, and keeping the most stable position of infant incubator, before moving all of accessories should be fixed to the right position and let out all of the water.

23. Do not switch on for longer time than essential, when the machine is not connected to the power supply, otherwise, power supply failure alarm will be activated and the internal battery current waste.

24. When using X-Ray tray via incubator hood, the shadow of hood will reflect on the X-ray negative. That may influence the doctor's diagnose.

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

26. When operating the VHA stand, support the incubator with one hand on to prevent it from imbalance.

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

28. Only the authorized and qualified maintenance personnel can replace the fuse according to the specification. When replacing the fuse, you should disconnect the power supply of the incubator first, and can not touch the patients and metal parts at the same time.

29. The device must be fully cleaned and sterilized for the first time for initial use, after nursing for one baby, after used it for one week or there's dirt in the incubator. Cleaning and sterilizing methods please refer to Section 5.

30. Must use neutral cleaning/disinfectant to clean. Other disinfectant (like alcohol) will destroy some parts of the incubator. Please follow the instruction for detergent usage.

31. After cleaning the incubator by combustible cleaning solvent should airing the incubator completely. The residual a handful of the flammable solvent (such as ethyl ether, ethanol or similar cleaning solvent) in the incubator can cause a fire.

32. Please only use skin temperature sensor,rechargeable battery and other accessories provided by our company, otherwise it will reduce the safety of the equipment ,increase the equipment lanch or reduce the noise immunity.

33. 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 5.4. If it is not 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.

34. The equipment can not be close to or stacked with other equipment, if have to put together, please observe to be sure it can good running with other configurations.

35. Damages will be easily caused if using the incubator after it reached its lifetime. Previous capability guideline and requirement cannot be reached as well. Please stop using.

36. The life period of incubator is 8 years. 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. An electric shock hazard exists within the Controller and VHA stand when the cover is removed. Servicing should be performed only by qualified personnel with appropriate service documentation.

3. To prevent equipment damage or accidental power disconnection, Do NOT connect an Incubator power cord directly to an ac wall socket when the Incubator is mounted on a VHA stand. Always provide power to the Incubator using the power cord coming directly form the VHA stand.

4. Make sure the building power source is compatible with the electrical specifications shown on the rear center column of the VHA stand or on the Incubator.

5. This device adopts mains plug or appliance coupler as isolation form the supply mains when the Incubator is mounted on a VHA stand, for safety, and please pull off the power cord when stopping using the device or repair it.

6. Improbably using of the assistant device will cause the decrease of our device's safety. The safety of auxiliary devices shall comply with the general requirements for safety according to IEC60601-1, and have acquired the certificate by relative institution.

7. Equipment provided an integral multiple socket-outlet, If connecting the auxiliary equipment on this interface, the maximum power of the auxiliary equipment shall not exceed the prescribed load limit, The assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of IEC60601-1, clause 16. Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

8. For safety, this device adopts main plug or appliance coupler as isolated from the controller is mounted on cabinet. This device adopts mains plug or appliance coupler as isolation from the supply mains when the Incubator is mounted on VHA stand. Please always make mains plug or appliance coupler easy to operate.

9. General Power switch used as isolation device from the mains supply. When the operator wants to safely terminate operation of Me Equipment, please cut off the General Power switch. Equipment should be placed where it is easy to operate.

10. Any parts are not serviced or maintained while in use with the patient.

11. When selecting the ancillary equipment must insure that the equipment had tested according to the requirements in IEC60601-1 or other relevant standard, and acquire the safety certificate.

HUMIDITY PRECAUTIONS

1. The incubator is with the humidity controller, it can increase the Humidity of incubator according to the clinical demands.

2. Higher relative humidity will, at any given time, decrease an infant's evaporative water loss and may cause an increase in infant temperature. Monitor the infant's temperature as required.
3. Use only distilled water to fill or refill the Reservoir. Tap water may contain organisms that may flourish in the heated water of the humidifier.
4. Make sure all hood access door gaskets and tubing ports are properly installed. Any open gaps in the incubator hood will reduce the incubator's internal relative humidity.
5. Fill the humidity chamber to the bottom of the MAXIUM LIMIT line. DO NOT OVERFILL. Or else water spillage may result.
6. Following the doctor's advice when setting the relative humidity.

OXYGEN PRECAUTIONS

1. This incubator is with oxygen control system, please use iatric oxygen when feeding oxygen.
2. Abusing of supplemental oxygen may result in serious aftereffects which include blindness, brain damage, even death. Therefore, keeping to the main doctor's direction strictly and monitoring the oxygen supplement condition for the patient in a regularly time.
3. If it is necessary to administer Oxygen in an emergency, notify the attending physician immediately.
4. When supplementing the oxygen, calibrated oxygen analyzer must be turned on for monitoring the oxygen concentration.
5. Oxygen feeding may increase the noise level inside the hood.
6. As Oxygen use increases the danger of fire. To ensure the device safety, make all flammable material far away from incubator, and auxiliary equipment producing sparks should not be placed near incubator.
7. When the oil, grease, other fat substance and the compressed oxygen meet, it will self-ignite seriously, therefore, try to avoid the oxygen pressure reducing valve/adjustment valve, valve for oxygen cylinder, pipe, connector containing these substance.
8. Do not use combustible material like aether, alcohol etc. because once even a little aether, alcohol, or other combustible material mixed with oxygen in the incubator, it'll cause fire.
9. When modulating the oxygen flux every time, please leave 30min. at least for the incubator regaining the new oxygen concentration.
10. There's a pressurize device filling with potassium hydroxide electrolyte installed inside the oxygen sensor. If the sensor leaks, please stop using and chuck it. If the leaking electrolyte touches skin or clothes, please wash with clean water immediately. If the leaking electrolyte touches eyes, please wash eyes with clean water for 15 min. and keep them open, notify the doctor immediately.

11. Seasonal check the gas and the oxygen transporting parts to see if they are eroded or broken.

12. Seasonal check the battery of oxygen sensor to if they are leaking or aging. Replace them if it is necessary.

13. To operate the auxiliary oxygen equipment together with incubator,please refer to the corresponding instruction manual.

14. Under 100% oxygen concentration the oxygen sensor service life is up to 10000 hours.

WEIGHING PRECAUTIONS

1. The electrical scale installed in the bassinet must work after 30 minutes' warm-up in the incubator, that is to say the electrical scale can't work until being put in the incubator which is set the using temperature and begins working for at least 30min. Or else, the number read on the scale will surpass the regulated value.

2. Please keep the patient aclinic and in the middle of the bassinet while weighing.

3. The maximum weighing weight of Infant scale is 8 kg, please don't over loading, or else the scale will be damaged.

4. Lay the bassinet with infant scale gently when loading or unloading, don't press surface of the bassinet to avoid damage the weight sensor inside the bassinet.

5. The displayed weighing value is just for reference.

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 air sensor should be calibrated every half year, and only the authorized qualified service personnel can do that.

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

②. Inspect the safety relevant labels for legibility.

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

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

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

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

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

⑧. Test the patient leakage current according IEC 60601-1:2005+A1:2012: Limit: for a.c.: 100μA (BF), for d.c.: 10μA (BF).

⑨. Test the patient leakage current under single fault condition with mains voltage on the applied part according IEC 60601-1:2005+A1:2012: Limit: for a.c.:500μA (BF), for d.c.: 50μA (BF).

⑩. According to the test methods of IEC 60601-1:2005+A1:2012, the patient leakage current (net voltage should be added on the applied part) of the testing device must less than 5000μA.

⑪. Test the patient auxiliary leakage current according IEC 60601-1:2005+A1:2012: Limit: NC for a.c.: 100μA (BF), for d.c.: 10μA (BF).SFC for a.c.: 500μA (BF), for d.c.: 50μA (BF).

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

TABLE OF DEFINITIONS AND SYMBOLS

TECHNICAL DEFINITIONS

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

INCUBATOR TEMPERATURE: Air temperature at a point 10cm above and centered over the mattress surface.

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

AVERAGE INCUBATOR TEMPERATURE: The average of the maximum and minimum Incubator temperatures achieved during Temperature Condition.

STEADY TEMPERATURE CONDITION: A condition which is reached when the temperature does not vary by more than 1℃ over a period of 1 hour.

TEMPERATURE ALARM CHECKOUT STATE: The difference between real temperature and control temperature is within ±0.5℃. The equipment must stay in such state when checking up the alarm about temperature.

TEMPERATURE UNIFORMITY: The difference between the average temperature measured at the four points 10cm above the surface of the mattress and the stable average temperature.

TEMPERATURE VARIABILITY: The variability of the Incubator Temperature that will be observed over a one hour period after Incubator Temperature Equilibrium has been reached.

TEMPERATURE RISING TIME: The time required for the Incubator Temperature to rise 11℃, when the Air Control Temperature is at least 12℃ above ambient.

STEADY HUMIDITY CONDITION: A condition that the disparity between the indicated humidity value and control value is less than ±5%RH, and maintains over 2 min.

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

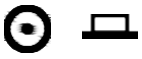
NOTE: A note is inserted in text to point out procedures or conditions, which may otherwise be misinterpreted or overlooked. A note may also be used to clarify apparently contradictory or confusing situations.

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

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

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

SYMBOLS

	General warning sign		Manufacturer
	Follow instructions for use		Protective Earth (Ground)
CLASS I	Class I Equipment		Type BF Applied part
	Main power on		Main power off
	Branch power on		Branch power off
	Branch power on(when equipped with VHA stand)		Branch power off(when equipped with VHA stand)
F 6.3AH/250V	Fuse Type F 6.3AH/250V	**220-230V~50Hz**	Input power
	No heavy load		High pressure, dangerous
RS-232	RS-232 Connector		Mattress Tilt Direction
	Socket for skin temperature 1		Socket for skin temperature 2
	Do not touch		Heating Power Indicator
	Oxygen supplement indication mark		Humidifying indication mark
	Indicator ON/OFF		Switch indicator key
	Silence / Reset Key		Keypad Key
	Set up key		Set down key
	Air Mode Key		Baby Mode Key
	＞37℃ setting key		Reset zero key
	Calibration key		CE Marking
	Water high-level mark		Water low-level mark
	Raise device's height		Lower device's height
	Forbidden cover the draught mark		Authorized representative in the European community
	Serial Number		Date of manufacture

220-230V~50Hz MAX:1.6A Assistant net power outlet, MAX：1.6A

CONTENTS

NOTE: The product composition maybe different from this manual, but it does not affect product function. Please understand.

SECTION 1
GENERAL INFORMATION

1.1INTRODUCTION

This manual provides instructions for installation, debugging, operation, cleaning and maintenance of Infant Incubator (incubator). 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 the content of this manual.

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

Vertical height adjustment stand (VHA stand), weighing system and Panel damping system are optional. We also provide disposable skin temperature sensor for your choice. You can ignore the relative contents if you do not purchase them. Neonate bilirubin phototherapy equipment is optional accessory, if you buy it with the incubator, please refer to the operation manual of Neonate bilirubin phototherapy equipment to see the relative operation.

1.2 INTENDED USE

The Infant Incubator is intended to provide a controlled thermal environment and isolation from ambient air for premature and neonatal infants. The infant incubator is not intended for the transport of infants.

1.3 PRODUCT CONTRAINDICATIONS

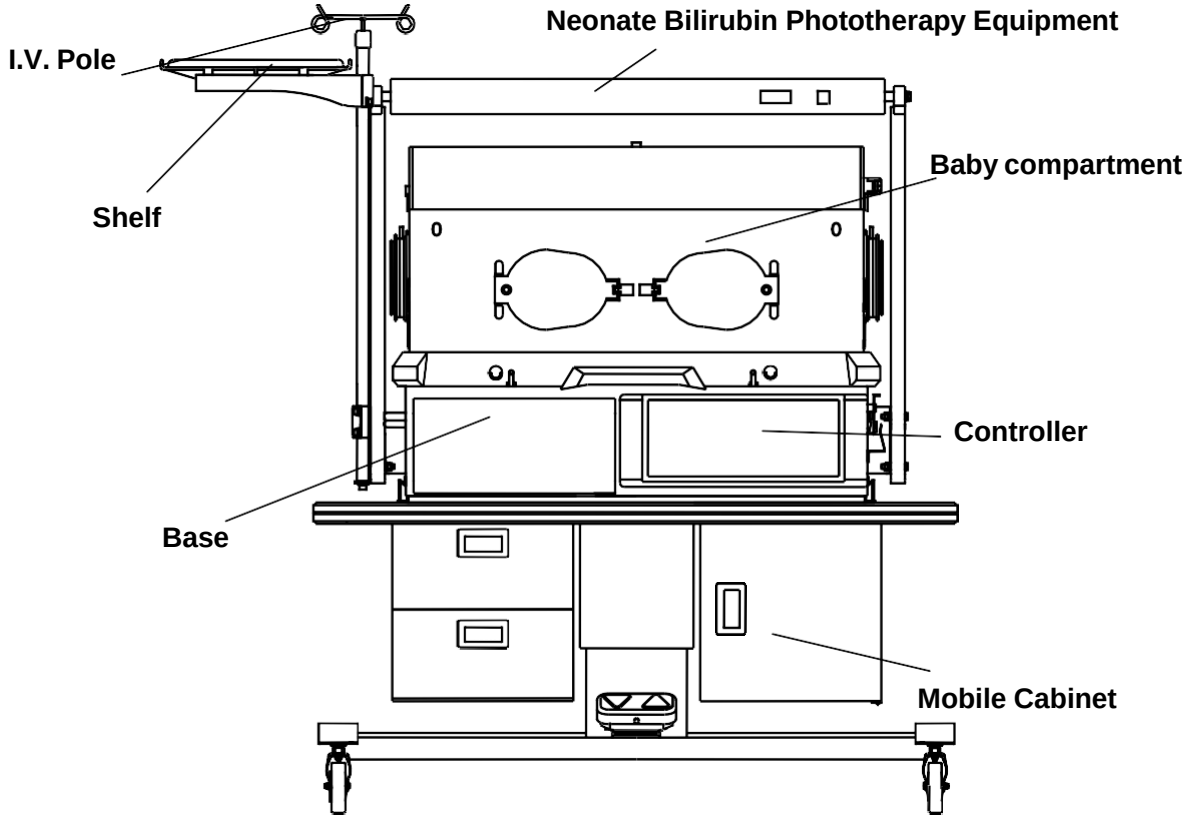
It is not clear now.

1.4 COMPOSITION OF PRODUCTS

The infant incubator consists of four components: the double wall hood, the base, the mobile cabinet, and the controller. The sponge is based on central mattress positions within the confines of the hood.

1.5 DESCRIPTION

The following diagram shows the main parts of the Infant Incubator.



I4

DESCRIPTION OF PART	EXPLANATION
I.V. pole	A kind of bearing part, which is used for hanging the infusion bottle. Max. Load: 2Kg
Controller	The core part with two kinds of temperature control modes: air mode, baby mode, moreover, it also has the functions of weighing, humidity control and oxygen concentration controlling system which are used for auto-controlling the heat output and the humidity and oxygen concentration in the incubator. The detail operation to temperature please refer to the section 4, to oxygen concentration please refer to the section 6, to humidity please refer to the section 7, to weighing please refers to the section 8.
Shelf	A kind of bearing part, which is used for putting some small objects. Max. Load: 3.5Kg
Baby compartment	It is used for placing the infant inside, including the Acrylic hood, bassinet, and so on. Panel damping system is optional for the access Panel. The bassinet can be tilted at the request of clinical needs. The baby scale is optional part, and the Max. Load of bassinet is 10 Kg. Max load of bassinet with weighting system is 8Kg. Size of mattress: 630mm × 355mm
Base	An important part of Infant Incubator, and it is mainly composed of the Aluminium tank, humidity chamber, air filter, and so on.
Mobile Cabinet	A part which can support the main body of Infant Incubator. We have two kinds of cabinet: fixed type and vertical height adjustment type. Usually we equip the former one, and the second one is optional part. The Max. Load of the drawer is 2 Kg. The Max. Load of the toolbox is 4 Kg.
Neonate bilirubin phototherapy equipment	It is intended for treating the bilirubin of patient. This part is mounted on top of Infant Incubator, and its light source has two kinds: fluorescent lamp and LED lamp, the user can choose either. For the Neonate Bilirubin Phototherapy Equipment with fluorescent lamp, please refer to the user's manual BABYGUARD U-1131, while for the Neonate Bilirubin Phototherapy Equipment with LED lamp, please refer to the user's manual BABYGUARD U-1133.

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

NOTE: Size of Infant Incubator:

L1170mm× W620 × H1620

(for Infant Incubator with fixed cabinet);

L1170mm × W620 × H1550~ L1170mm × W620 × H1700

(for Infant Incubator with vertical height adjustment cabinet).

Distance from the bassinet to the floor:

980mm (for Infant Incubator with fixed cabinet);

950mm ~ 1100mm (for Infant Incubator with vertical height adjustment cabinet).

Weight of Infant Incubator with fixed cabinet: 103Kg;

Weight of Infant Incubator with vertical height adjustment cabinet: 125 Kg.

1.6 SPECIFICATIONS

This product's classification as follows:

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

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

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

By the manufacturers recommended disinfection and sterilization method classification: Use neutral disinfection solvents or solution to clean. The tank can use steam sterilization.

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…..AC220V-230V/50Hz, 1000VA

Maximum Heater Power Output… W/240V

Auxiliary Mains Power Output….....AC220V-230V/50Hz, MAX. CURRENT 1.6A

Heater power display……0 to 100%, adjustable in 10% increments

Temperature control modes……Air mode

Baby mode

Air Temperature Control range….....25℃~37℃

override mode: 37℃~39℃

Baby Temperature Control range… ..... 34℃~37℃

override mode: 37℃~38℃

Temperature sensor display range….....5℃~65℃

Temperature rise Time* (environment temperature is +22℃)..... ... ≤30min

Temperature Variation*…..... ≤0.5℃

Temperature Uniformity* (level mattress) ..... ≤0.8℃

Temperature Uniformity* (Tilt mattress)..... ≤1.0℃

The difference between average incubator temperature with the control temperature ……≤1.0℃

Deviation between the indicated air temperature and the real temperature……≤0.8℃

Accuracy of skin temperature sensor……±0.2℃

HUMIDITY CONTROLLING

Running time after the Reservoir filled with distilled water…Humidity<60%RH, 24h at least

Reservoir's capacity 1600ml

Humidity display range… .....0%RH～99%RH

Humidity Control range… ..... 0%～90%（adjustable in 1% each time）

Humidity control precision….....±5%RH

Humidity display precision (ENVI TEM. 25℃, ENVI humidity 45% RH±**5%** RH **)** .....±5%RH

NOTE: In the surrounding of high humidity, it may not control the humidity to a relatively low level.

OXYGEN CONCENTRATION CONTROLLING

Oxygen concentration display range… ..... 0%O_2～99%O_2

Oxygen concentration display resolution.....1%

Oxygen concentration display precision……

±2%O_2（Oxygen concentration set value is below 25%）

±3%O_2（Oxygen concentration set value is above 25%）

I4

TABLE 1.1 SPECIFICATIONS (continued)

Oxygen concentration control precision…..±4%（Volume concentration）
Oxygen concentration setting range…..20%O_2～60%O_2（adjustable in 1% O_2 each time）
Life time of oxygen sensor…..10000h MAX. with 100% oxygen

WEIGHING DISPLAY
Weight range…..100～8000g
Resolving power of weight display.....1g
Accuracy of weight display.....±1%

ENVIRONMENT TEMP (Not to use in the environment exceed specified)
Operating range…..+20～+30℃
Transport and storage range…..…-20～+55℃

ENVIRONMENT HUMIDITY
Operating range…..30%～75%RH
Transport and storage range…..≤93%RH

ATMOSPHERIC PRESSUR
Transport and Store atmospheric pressure range…..500hPa～1060hPa
Operating atmospheric 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
Noise inside hood..... Under the steady temperature condition ≤45dB(A)
under other conditions ≤50dB(A)
[Ambient noise: ≤35dB(A)]
Carbon dioxide(CO_2) concentration within the hood…..Less than 0.5% when a mixture CO_2 is delivered at 750ml/min at a point 10cm above the center of the mattress.
Air Flow rate above Mattress…..≤0.35m/s

*Refer to Table of Definitions and Symbols

NOTE: If opening the front Access Panel or Access door or using infant bed, supplies or other equipment within incubator can alter the air flow pattern so as to affect the temperature uniformity, temperature variability, the correlation of the incubator temperature reading to center mattress temperature and skin temperature.

I4

SECTION 2
INSTALLATION

2.1 GENERAL

This section provides installing procedures about Infant Incubator.

2.2 UNPACKING

Generally, the Infant Incubator is usually packed to two cartons: main body and fixed cabinet or Vertical Height Adjustment stand (VHA stand). When taking out the equipment from the cartons, take care not to damage the spare parts of the Infant Incubator.

2.3 INSTALLATION

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

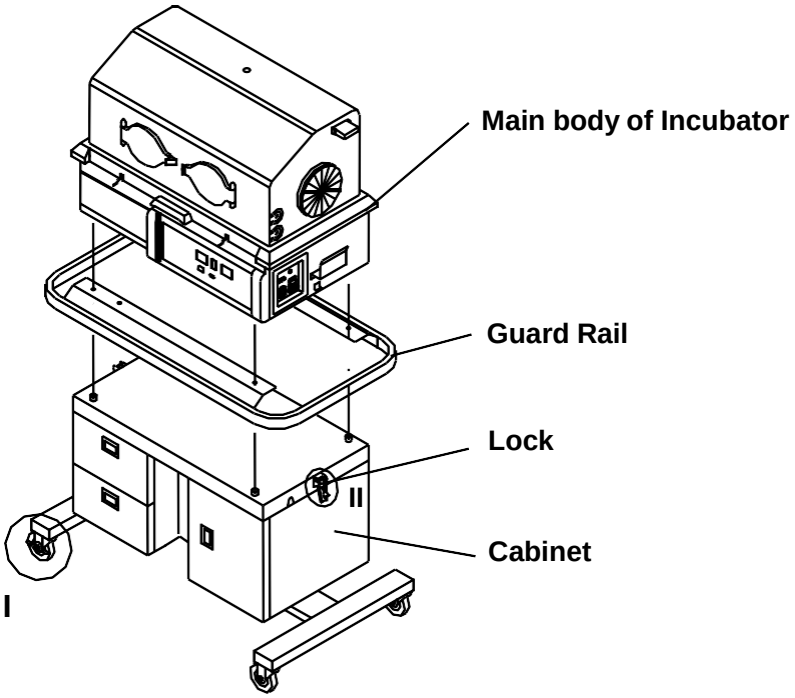
1. Install the main body onto the fixed cabinet or VHA stand

A. The installation of main body onto the fixed cabinet

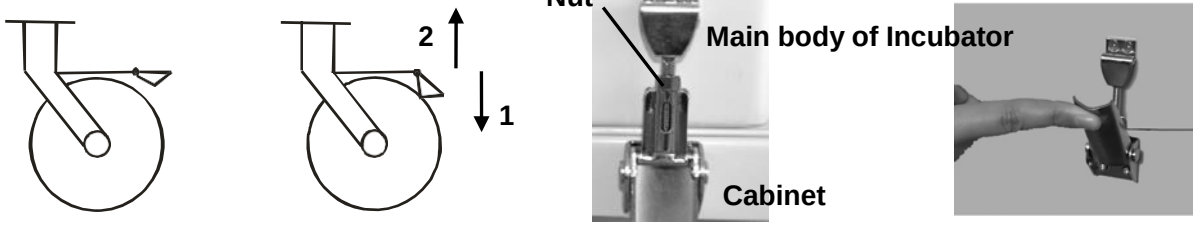
a. As figure 2.1 indicates, put on the spring washer, flat washer on the casters, and then connect with cabinet firmly. Note: The caster with brake must be installed in front of the cabinet.

FIGURE 2.1

b. As figure 2.2 indicates, lock the casters with brake, and put the guard rail and main body on the cabinet, and then fix them with the lock mechanism on two sides of cabinet.



(Enlarged figure I) **(Enlarged figure II)**



wheel unlocked wheel locked hang the lock buckle fasten the lock

NOTE: As shown in the figure I, lock the casters as the arrow 1 indicates, and unlock the casters as the arrow 2 indicates.

As shown in the figure II, loosen the nut and adjust the lock position at appropriate height. Then hang the lock buckle, and screw the nut tightly. Finally fasten the lock.

IMPORTANT: Be careful not to install the guard rail in wrong direction, or else, the controller can not be taken out. The front access panel and the cabinet door should be in the same direction.

The guard rail ensures grounding through bolt，therefore, fix the guard rail on the cabinet with bolts.

FIGURE 2.2

B. Install the main body onto the VHA stand

a. The method of installation casters is same as part A.

b. The method of installation main body, guard rail on the VHA stand same as part A.

c. After installation, insert the power cord on the right side of Vertical Height Adjustment cabinet into the power socket in figure 4.2.

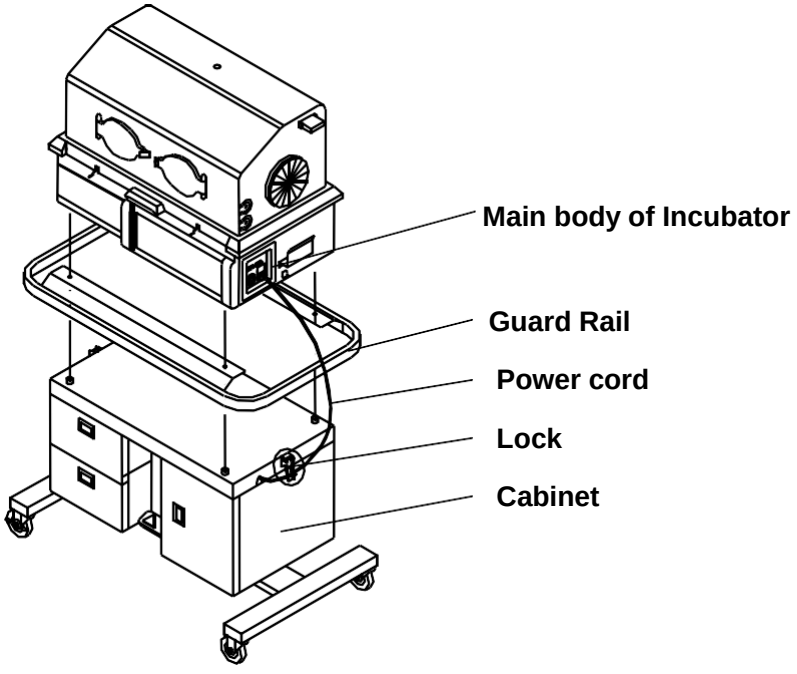


FIGURE 2.3

WARNING: Firm the main body onto the fixed cabinet or VHA stand with lock mechanism. If not, it will cause the main body to deviate from the fixed cabinet or VHA stand when the cabinet tilts, especially when the hood is open.

In order to prevent incubator which stops on the slope from sliding, the front locked wheel for mobile cabinet or VHA stand must be locked down along the slope line.

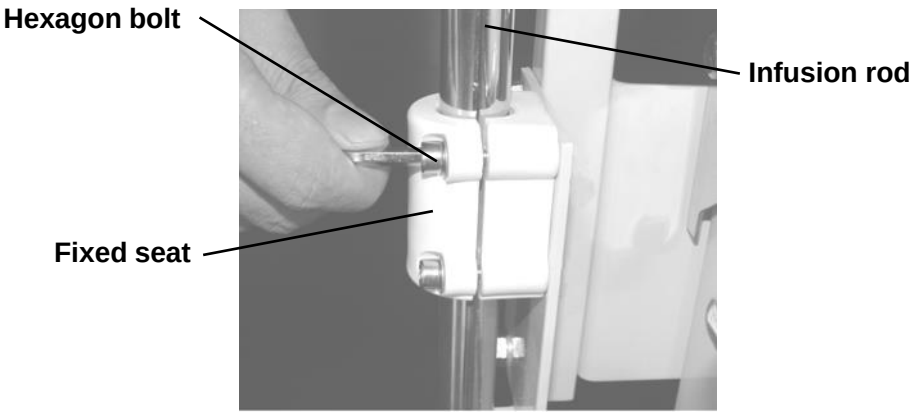
2. Install the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT (If applicable), I.V.Pole and shelf

A. Install the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT

Please refer to the method of installation for incubator mounted PHOTOTHERAPY unit BABYGUARD U-1131 and BABYGUARD U-1133 in the accompanying documents.

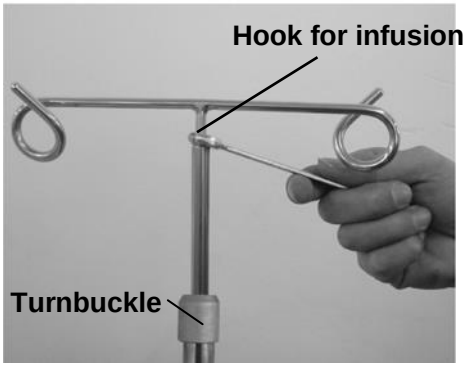
B. Install I.V. Pole and shelf

① Install the I.V. Pole beside the incubator as figure 2.4 indicates, and then adjust the hook to a proper height, fix it with the turnbuckle.



Step 1: Loosen the hexagon bolts on the fixed seat with spanner, insert the I.V. Pole to the bottom, and fix the bolt to fasten the infusion rod.

Step 2: Tighten the hexagon bolts on the bottom of infusion rod to fix the rod.



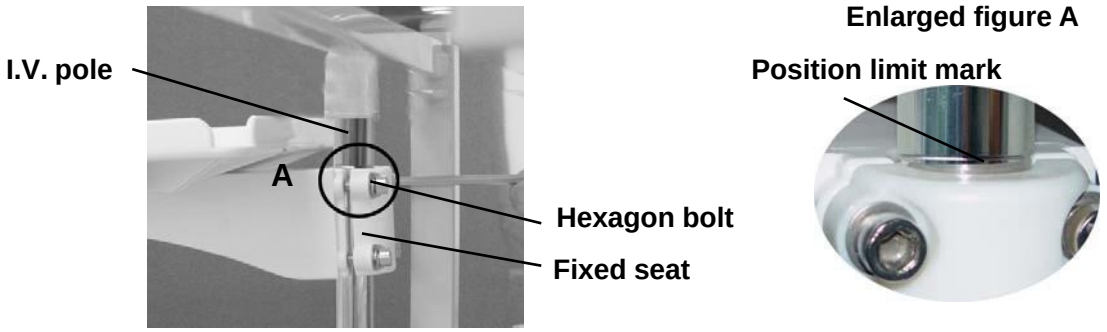
Step 3: Rotate the hook into the I.V. Pole, and then tighten the hexagon bolts.

FIGURE 2.4

I4

② Install shelf

Loosen the hexagon bolts on the fixed seat as figure 2.5 indicates，insert the fixed seat to the I.V. pole. As Enlarged figure A shows, make sure the top of fixed seat and the position limit marked on the rod is on the same level. And then screw the hexagon bolt of the fixed seat back.



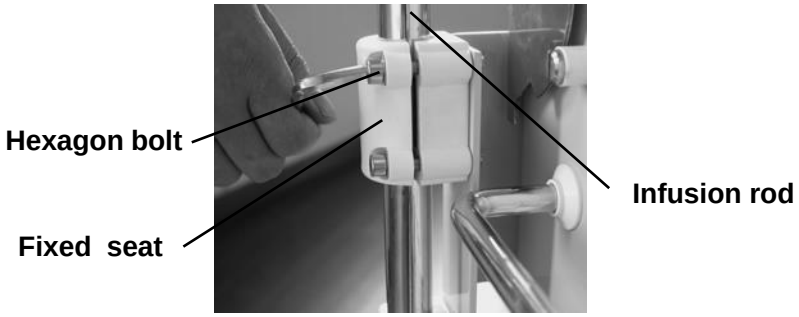
When installing the tray, the side with note label should be placed in the front of incubator.

FIGURE 2.5

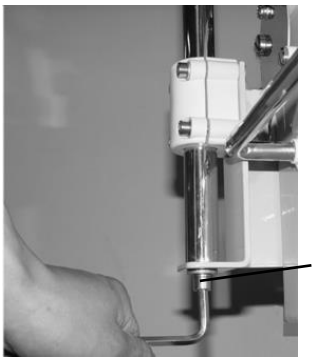
C. Install I.V. Pole and shelf without NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT equipped.

① Install the I.V. Pole

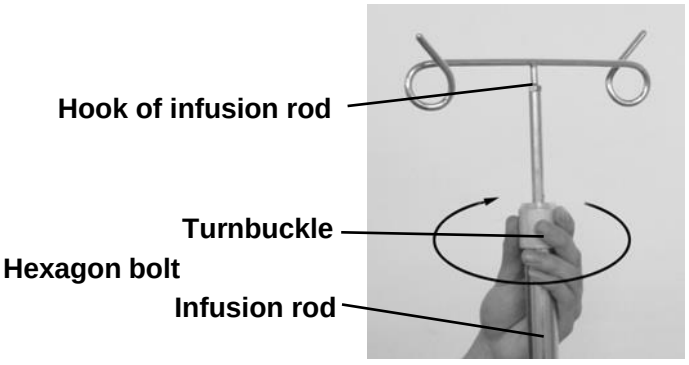
Install the I.V. Pole beside the incubator as figure 2.6 indicates, and then adjust the I.V. Pole to a proper height, fix it with the turnbuckle.



Step 1: Loosen the hexagon bolts on the fixed seat with spanner, insert the I.V. Pole to the bottom, and fix the bolt to fasten the infusion rod.



Step 2: Tighten the hexagon bolts on the bottom of infusion rod to fix the rod.

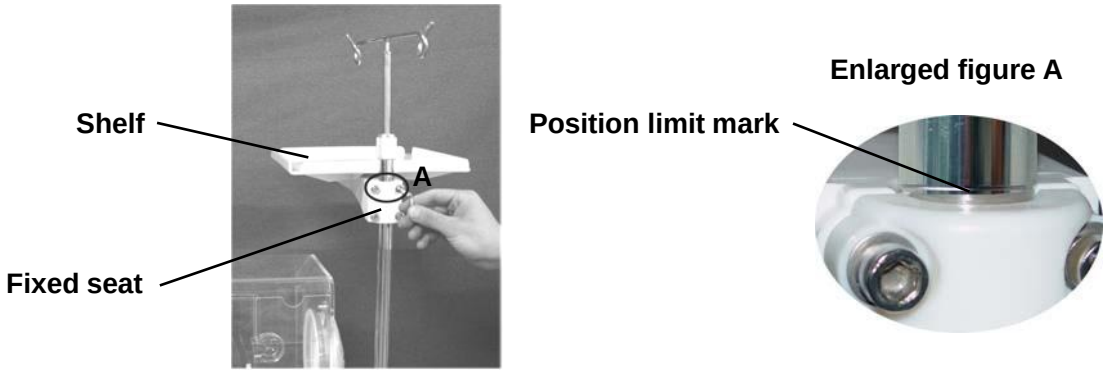


Step 3: Insert the hook of infusion rod into the infusion rod, then tighten the turnbuckle according to the direct as the arrow shows.

FIGURE 2.6

② Install Shelf

Loosen the hexagon bolts on the fixed seat as figure 2.7 indicates，insert the fixed seat to the I.V. pole. As Enlarged figure A shows, make sure the top of fixed seat and the position limit marked on the rod is on the same level. And then screw the hexagon bolt of the fixed seat back.



When installing the tray, the side with note label should be placed in the front of incubator.

FIGURE 2.7

3. Connect the sensor

Connect the sensor connector with sensor socket which is on the side of the incubator's main body as figure 2.8 directs. Then tighten the bolt in the connector.

NOTE: Connection between the sensor connector and socket should be in the right orientation for these two parts have their own direction.

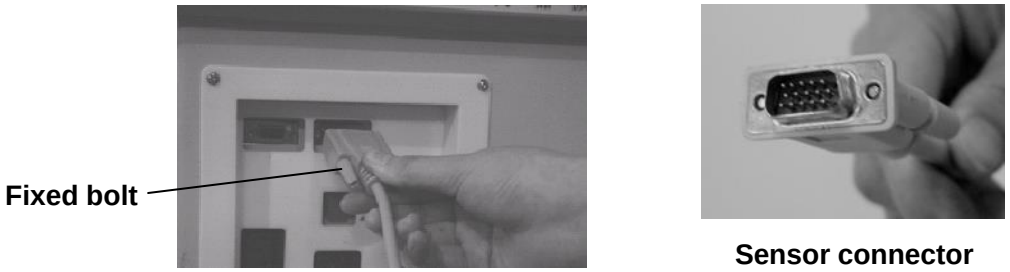


FIGURE 2.8

4. Install oxygen sensor

Refer to the section 6 to see the detail.

5. Install weighing system

Refer to the section 8 to see the detail.

6. Insert the power cord

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

Insert the power cord into the socket of general power supply in figure 4.2 (for fixed cabinet).

Check the INCUBATOR according to the instruction in section 4.4.

NOTE: Do place the equipment to the position where it is easy to operate the power switch.

SECTION 3
FUNCTIONAL DESCRIPTION

3.1 OVERALL FUNCTION DESCRIPTION

The Infant Incubator adopts temperature control system (**Air Mode** and **Baby Mode**), humidity controlling system, oxygen concentration controlling system and weighing system (if it is applicable).

Heat output control in Air Mode: it will control the heater's output automatically according to the Air temperature sensor, see instruction in section 4.5.2.1;

Heat output control in Baby Mode: it will control the heater's output automatically according to the Skin temperature sensor, see instruction in section 4.5.2.2;

Oxygen input control: Auto-control the valve according to the oxygen concentration in the incubator which is detected by the oxygen concentration sensor. Please refer the section 6 to see the details;

Reservoir humidifying output control: Auto-control the humidifier according to the humidity in the incubator which is detected by the humidity sensor. Please refer the section 7 to see the details.

The set temperature, air temperature, skin temperature, oxygen concentration, oxygen set value, humidity value, humidity and weight (if it is applicable) can be indicated separately.

3.2 TEMPERATURE CONTROL PRINCIPLE

The control of temperature, humidity and oxygen concentration inside hood is achieved by means of the forced air circulation system as shown in Figure 3.1.

When the oxygen control function is locked, the outside air is filtered, it will flow through the heater which can heat the air, and then the air enters into the hood through the inlet port under the drive of fan motor, after then, it will be cycled back to the fan motor through the inlet port to form the heat air cycle flow. And this heat air flow will come to the top of water tank and enter into the hood with the vapor above the water.

When turning on the oxygen control function, oxygen flows through the oxygen input connector, then passes the electromagnetism valve and enters into the air-oxygen separating device through the oxygen input connector, after then, it enters into the heat air cycle flow under the drive of the fan motor to supply the oxygen in the incubator.

In addition, the air curtain outfitted in the incubator will drive the air circle inside flow upwards and form a heat air circle flow at the access panel when the access panel of the hood is open, thereby the temperature inside the hood will fall down.

Access panel close

Access door open

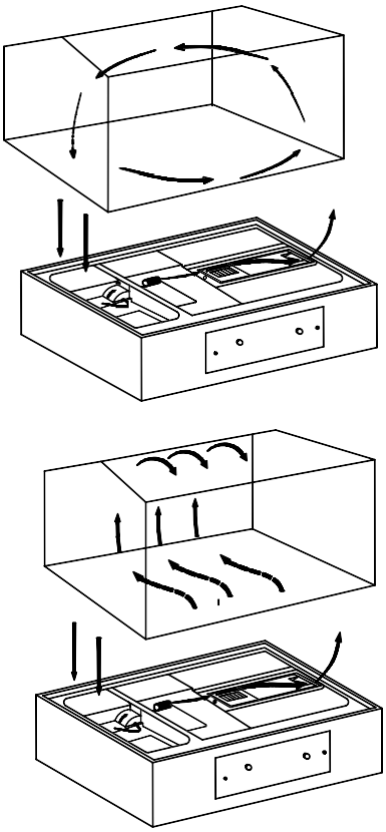


FIGURE 3.1

3.3 DATA COMMUNICATION CONNECTOR

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

1. If connecting the auxiliary equipment on this interface, the assembly of ME SYSTEMS and modifications during the actual service life require evaluation on 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 RS-232 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 usage of the data communication must be performed by special trained medical personnel, and the personnel should clear and definite the risk of data communication.

6. Do not touch RS-232 data communication connector and patient simultaneously.

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

3.4 ALARMING AND SYSTEM INDICATION INFORMATION

STATE

1. Alarm information

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

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

Medium priority: Medium priority information, yellow alarm light flashing, alarm sounds more than 65dB; alarm in three tones order, and every 7.5 seconds to repeat again.

Low priority: Low priority information, the yellow alarm light is continued on, alarm sounds more than 65dB; two tones order alarm, and every 20 seconds to repeat again.

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

ALARM INTRODUCTION

Alarm no.	Alarm information	Alarm character	Alarm activation conditions	Control mode	Heater state	Alarm level	Alarm delay time
1	Power failure alarm	Power failure alarm light is oh, Red alarm light flashes, sound alarm start	Turn on the switch when no power supply	All	Off	High priority	<5s
2	Sensor box is not in position	Red alarm light flashes, the information indicator shows "Box Position", sound alarm start	Sensor box is not in position	All	Off	High priority	<5s
3	Air sensor failure alarm	Red alarm light flashes, the information indicator shows "Air Sensor", sound alarm start	Short-circuit, open circuit or bad connection inside the air temperature sensor	All	Off	High priority	<5s
4	Isolated sensor failure alarm	Red alarm light flashes, the information indicator shows "Isolated Sensor", sound alarm start	Short-circuit, open circuit or bad connection inside the isolated temperature sensor	All	Off	High priority	<5s
5	Alarm air sensor is different from isolated sensor	Red alarm light flashes, the information indicator shows "Temp. Not Same", sound alarm start	The difference between air sensor and isolated sensor above 0.8℃	All	Off	High priority	<40s

ALARM INTRODUCTION (continued)

Alarm no.	Alarm information	Alarm character	Alarm activation conditions	Control mode	Heater state	Alarm level	Alarm delay time
6	Airflow sensor failure alarm	Red alarm light flashes, the information indicator shows "Airflow Sensor", sound alarm start	Short-circuit, open circuit or bad connection inside the air flow temperature sensor	All	Off	High priority	<5s
7	Skin sensor failure alarm	Red alarm light flashes, the information indicator shows "Skin Sensor ", sound alarm start	Short-circuit, open circuit or bad connection inside the skin temperature sensor 1	Baby	Off	High priority	<5s
8	Over temperature alarm	Red alarm light flashes, t the information indicator shows "Over Temp.", sound alarm start	Temperature of incubator is not over 38℃ (set temperature is less than 37℃), or not over 39.5℃ (set temperature is more than 37℃)	All	Off	High priority	<10s
9	Airflow error alarm	Red alarm light flashes, the information indicator shows "Airflow Error", sound alarm start	Temperature measured by airflow sensor is over 45℃ (set temperature is less than 37℃), or over 47℃ (set temperature is more than 37℃)	All	Off	High priority	<10s
10	Alarm skin sensor is placed wrong	Red alarm light flashes, the information indicator shows "Skin Position", sound alarm start	The temperature measured by skin sensor 1 is always lower 2℃ than set temperature, the temperature measured by air sensor is lower between 3.5℃ and 4.5℃ than set temperature	Baby	On	High priority	<5s
11	Alarm error motor	Red alarm light flashes, the information indicator shows "Motor Error", sound alarm start	Motor stopped running or the speed is lower than 800r/m	All	Off	High priority	<5s
12	Alarm error fan in the sensor box	Red alarm light flashes, the information indicator shows "Fan Error", sound alarm start	Fan inside the sensor box failure	All	Off	High priority	<5s

ALARM INTRODUCTION (continued)

Alarm no.	Alarm information	Alarm character	Alarm activation conditions	Control mode	Heater state	Alarm level	Alarm delay time
13	Alarm temperature high deviation	Red alarm light flashes, the information indicator shows "High Temp.", sound alarm start	Temperature measured by air sensor is 3℃ higher than set temperature	Air	Off	High priority	<5s
		Red alarm light flashes, the information indicator shows "High Temp.", sound alarm start	Temperature measured by skin sensor 1 is 1℃ higher than set temperature	Baby	Off	High priority	<5s
14	Alarm temperature low deviation	Red alarm light flashes, the information indicator shows "Low Temp.", sound alarm start	Temperature measured by air sensor is 3℃ lower than set temperature	Air	On	High priority	<5s
		Red alarm light flashes, the information indicator shows "Low Temp.", sound alarm start	Temperature measured by skin sensor 1 is 1℃ lower than set temperature	Baby	On	High priority	<5s
15	Alarm error O_2 sensor 1	Red alarm light flashes, the information indicator shows "Oxygen Sensor 1", sound alarm start	Short-circuit, open-circuit inside the oxygen sensor 1 or own fault	All	On	High priority	<5s
16	Alarm error O_2 sensor 2	Red alarm light flashes, the information indicator shows "Oxygen Sensor 2", sound alarm start	Short-circuit, open-circuit inside the oxygen sensor 2 or own fault	All	On	High priority	<5s
17	Alarm O_2 Sensors are different	Red alarm light flashes, the information indicator shows "Oxygen Not Same", sound alarm start	The difference between oxygen 1 and oxygen 2 is 3%O_2	All	On	High priority	<5s
18	Alarm O_2high Deviation	Red alarm light flashes, the information indicator shows "High Oxygen", sound alarm start	The oxygen concentration value measured by oxygen concentration sensor 1 is 5%O_2 higher than set value	All	On	High priority	<5s
19	Alarm O_2 low Deviation	Red alarm light flashes, the information indicator shows "Low Oxygen", sound alarm start	The oxygen concentration value measured by oxygen concentration sensor 1 is 5%O_2 less than set value	All	On	High priority	<5s
20	Alarm Error Humidity sensor	Yellow alarm light flashes, the information indicator shows "Humidity Sensor", sound alarm start	Short-circuit, open-circuit inside the humidity sensor or own fault	All	On	Medium priority	<5s

ALARM INTRODUCTION (continued)

Alarm no.	Alarm information	Alarm character	Alarm activation conditions	Control mode	Heater state	Alarm level	Alarm delay time
21	Alarm Humidity high Deviation	Yellow alarm light flashes, the information indicator shows "High Humidity", sound alarm start	Humidity display value is higher 15%RH than set value	All	On	Medium priority	<5s
22	Alarm Humidity low Deviation	Yellow alarm light flashes, the information indicator shows "Low Humidity", sound alarm start	Humidity display value is lower 15%RH than set value	All	On	Medium priority	<5s
23	Alarm Water reservoir is empty	Yellow alarm light is continued on, the information indicator shows "Low Water", sound alarm start	Water reservoir is lack of water	All	On	Low priority	<5min
24	Alarm Water reservoir is placed incorrectly	Yellow alarm light is continued on, the information indicator shows "Tank Postion", 4 minutes later, sound alarm start	Bad connection between water tank and base	All	On	Low priority	<5s
Alarm information		**Detail description**					
System failure		When including System Fail 1, System Fail 2, System Fail 3, System Fail 4, System Fail 5, System Fail 6, System Fail 7, System Fail 8, System Fail 9, System Fail 10, System Fail 11, System Fail 12, System Fail 13, System Fail 14, System Fail 15, System Fail 16, System Fail 17, the alarm indicator light flash and cause sound alarm, the information indicator shows system alarm message at the same time. When has system fault alarm, the incubator can not normal work, please stop using it and call authorized maintenance personnel to repair. Service manual has detail description of alarm delay time and alarm activation conditions.					

NOTE: 1. When system alarm appears, should stop using the incubator immediately, and maintain the equipment by authorized qualified personnel.

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

3. Except for the power failure alarm, the other alarms all can be silenced by pressing silence/reset key, the time for silence is 4mins (the alarm about oxygen concentration silence time is about 115s) . When the silence time is over, if the alarm condition is still not solved, the alarm will have to activate. If multiple alarm occurs at the same time, the device will give an alarm firstly for the higher grade. Pressing the silence /reset key twice can cancel the alarm state then the equipment will be back to the set condition to monitor the alarm.

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

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

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

SECTION 4
OPERATION

4.1 GENERAL

This section provides operation procedures for Infant Incubator.

4.2 POWER SUPPLY CONNECTION AND SWITCH CONTROL

As shown in Figure 4.1, the general power switch and the general power socket of an incubator are located at back of the cabinet. As shown in Figure 4.2, the controller switch, power supply socket and auxiliary mains output socket of an incubator are on the right side of the controller.

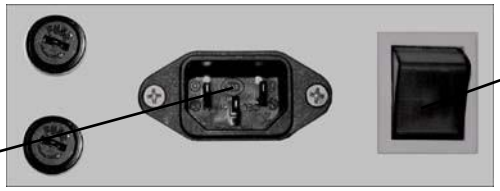


FIGURE 4.1

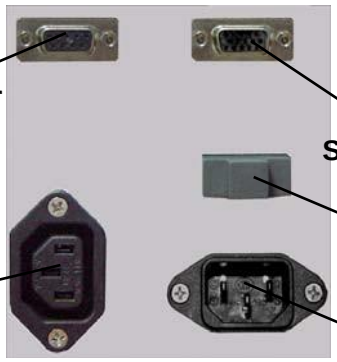


FIGURE 4.2

WARNNING: The auxiliary mains output socket of the infant incubator is only for the neonate bilirubin phototherapy equipment of XHZ-90 or XHZ-90L which are produced by our company. If the medical system is made up of it and other equipment, it will reduce the safety.

See figure 4.3, for the infant incubator with VHA stand, the height adjustment foot button is on the bottom of stand.

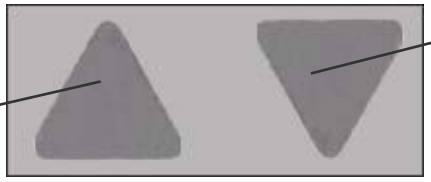


FIGURE 4.3

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

I4-1

When transport the equipment, please adjust vertical height to the lowest, or it will lead to the equipment out of balance.

4.3 CONTROLLER AND INDICATORS

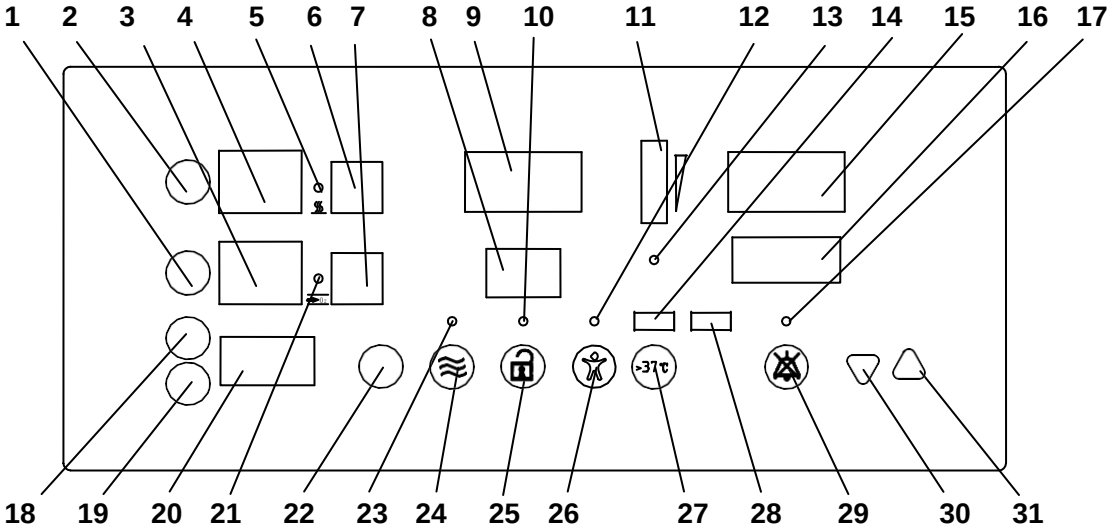


FIGURE 4.4

1. Oxygen concentration indicator key

Press this key to turn on or off the oxygen concentration indicator and oxygen concentration control system.

2. Humidity indicator key

Press this key to turn on or off the humidity indicator and humidity control system.

3. Oxygen concentration indicator

Turning the oxygen concentration indicator on to observe current oxygen concentration value detected by oxygen concentration sensor, turning it off, it indicates "OF".

4. Humidity indicator

Display the current humidity value detected by the humidity sensor when it is on，when turning it off, it displays "OF".

5. Humidifying indicator light

This light on indicates the humidifying system is working.

6. Humidity set indicator

When the humidity control is turned on, it displays the humidity value.

7. Oxygen concentration set indicator

When the oxygen concentration control is turned on, it displays the oxygen concentration value.

8. Set temperature indicator

Indicates the control value of air temperature in Air Mode; indicate the control value of baby temperature in Baby Mode.

9. Air temperature indicator

Display the air temperature sensor measured temperature.

10. Keypad lock indicator

If this light is on, it means entering into the set state and all functional keys are active; if the light is off, it means the system is not in set state, and all keys are locked.

（**NOTE: Except for the Oxygen Concentration Indicator key, Humidity Indicator key, Zero key and Calibration key**.）

11. Heater power indicator

Indicate the heater output proportion.

12. Baby mode indication light

This light is on when it is in Baby Mode.

13. Battery condition indication light

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

14. ＞37℃ indicator

This light is on which means the incubator is working under the state of ＞37℃, and the patient is in the environment of high temperature.

15. Skin temperature indicator

Display the baby temperature detected by skin temperature sensor 1, press Baby Mode key and Set Up key, it displays the baby temperature detected by skin temperature sensor 2.

16. Information indicator

When the device is normally working, it displays the current time. When the device is alarming, it displays the alarm information.

17. Alarm light

When device failure, the light is on.

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

18. Zero key

Press this key to reset the weight display on the indicator，the reset range is 0~2000g.

19. Calibration key

This key is used only for calibrating the weigh sensor，do not press in the normal operation.

20. Weight indicator

Display the weight tested by weighing system

21. Oxygen supplement indicating light

When the light of this indicator is enlightened, the oxygen supplement system is working.

22. Switch setting indicator key

Press this key to select the set value of temperature, humidity and oxygen concentration are displayed in the indicator in turn.

23. Air temperature mode indication light

This light is on when it is in Air Mode.

24. Air mode key

In set state, press to come into Air Mode.

25. Keypad lock

Press to activate all functional keys.

（**NOTE: Except for the Oxygen Concentration Indicator key, Humidity Indicator key, Zero key and Calibration key**.）

26. Baby mode key

In set state, press this key to enter into Baby Mode.

27. ＞37℃ key

When incubator works under the state of ＞37℃, in set state, press to make the control value override ＞37℃ to set temperature.

NOTE: Before setting temperature at 37℃, pressing this key does not work.

Under the state of ＞37℃, the patient is in the environment of high temperature, and the nurse should examine the patient carefully.

28. Power failure alarm indicating light

This light enlightening when the power failure alarm activities.

29. Silence /Reset key

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

30. Set down key

In set state, press this key to decrease the set temperature. Press this key constantly to speed the decreasing temperature.

31. Set up key

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

4.4 OPERATION CHECKOUT PROCEDURE

WARNING

1. Please stop using this device once some functions are lost or the spare parts for fixing the front panel are loose.

2. Set temperature must be 3℃ higher than ambient temperature. And then you can proceed this checkout procedure.

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

Incubator should be only operated by trained personnel who are familiar with the general risk of operating the incubator and under the instructions of medical practitioner.

Please do the following checkout procedure each time before operation.

The operator should operate the device in front of it about 20cm, the specific distance between the equipment and the operator should depend on the operation comfort.

4.4.1 CHECK THE INTEGRITY OF INCUBATOR

- Make sure that the device has been sterilized;
- Make sure that the hood is locked firmly;
- Make sure that there is no crack or the sharp edge on the hood;
- Make sure that the I.V.Pole and shelf are locked firmly;
- Make sure that fasteners are installed firmly;
- 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 is safe.
- Make sure that the casters are installed well.

Check whether the casters can drop or not when lifting the incubator 2cm above the ground. The drop of the casters will cause danger during transporting the incubator through the electric cable, threshold or threshold of lift. Please do not use the incubator before replacing the casters.

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 incubator. The equipment can not use the extended power cord.

A. START-UP THE CONTROLLER

Under the condition of power supply, turn on the main power switch (if it is applicable) and the power switch of the controller. The controller will briefly sound like "Ding" as well as the information indicator displays "system Test……", that shows the controller is in the self-checking mode which will last for 5sec. After the self-checking process finishes, the Set Temperature indicator shines and displays the set temperature for latest time before the device stops working, the Keypad Lock indicator is enlightened, Air Temperature indicator displays the real temperature detected by the air sensor, the Skin Temperature indicator displays the real temperature detected by the skin sensor1 and the Weight indicator displays the real weight detected by the weighing sensor. If the indicators for humidity and oxygen concentration is off, it display "OF", if they are on working, they display the real value detected by the humidity sensor and the oxygen sensor separately, and Humidity Set indicator and Oxygen Concentration Set indicator display the value. If something abnormal or the displayed numbers are incomplete, the controller needs to be maintained.

B. CHECK POWER FAILURE ALARM

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

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℃ ~ 26℃, and choose the Air Mode, and set the temperature at 33.0℃, and all heat power indicators are on, and heater will output heat completely.

NOTE: When the incubator works under the set state, continue the following operation procedure.

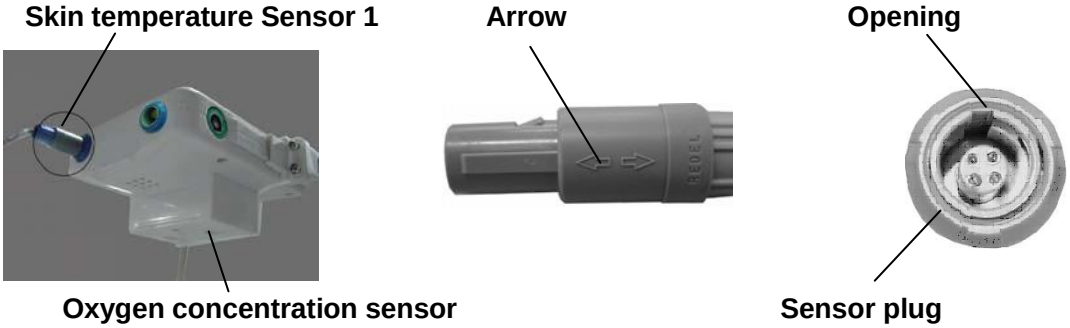
D. CHECK THE ACCURACY OF TEMPERATURE CONTROL

Select the Air Mode, and set the air temperature at 36℃, after the air temperature enters into the STEADY TEMPERATURE CONDITION, put the calibrated temperature measuring device on the position above 10cm from the center of mattress to measure the air temperature, compared with the indicated air temperature to check whether the deviation between them is within 0.8℃.

I4-1

E. CHECK BABY MODE

Insert two skin temperature sensors into the socket of skin sensor1 and skin sensor2 separately, the arrow sign on the plug should aim to the opening on the sensor socket so that the sensor is inserted correctly.



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

When the Air Mode works stably, change it into the Baby Mode, set temperature at 37℃. Keep the temperature detected by skin temperature sensor is 2℃ lower than the set temperature while making the displayed air temperature 4℃ lower than the set skin temperature. The incubator should give a high priority alarm sound, the information indicator shows "Skin Position", and the alarm character should be consistent with the description of section 3.4.

Pull off the skin temperature sensor1, the device should give a high priority alarm sound, the information indicator shows "Skin Sensor ", and the alarm character should be consistent with the description of section 3.4.

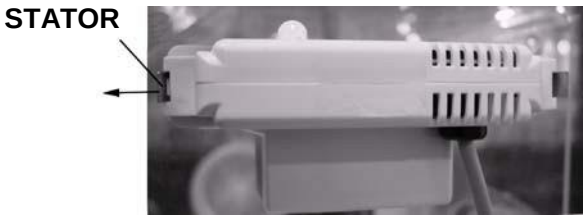
F. CHECK PRECISION OF SKIN TEMPERATURE SENSOR

Put the skin temperature sensor and the mercury thermograph for the accuracy with ±0.1℃ into the warm water cup. To make the probe of the skin temperature sensor and the mercury ball as closely as possible, please stir enough and then read the value of mercury thermograph. Compare the value of the skin temperature sensor 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 allowable deviation. Please let the professional personnel maintain machine if the accuracy of the skin temperature sensor still exceeds the allowable deviation after double check.

G. CHECK THE SENSOR BOX

Check the connection between the modular and its socket. Only when the interface of the sensor box is correctly facing the interface of the sensor socket, they can be successfully connected.



Undraw the left stator of sensor box as the arrow indicates, under the condition of stator undrawing, undraw the sensor box outwards, to check if the Sensor box slides in or out of the hood smoothly. When the modular falls off from the hood, the device should give a high priority alarm sound, the information indicator shows "Box Position", and the alarm character should be consistent with the description of section 3.4. After the modular being put into the correct location and being fixed by stator, the alarm cancels automatically as well as the sensor connect indicating light off.

WARNING: 1. All gaps in the sensor module must not be blocked.

2. Please pull out and plug in the sensor module correctly.

3. Sensor Module is an important part which supplies Temperature Control to Incubator, and must be operated carefully.

H. CHECK FAN MOTOR ALARM

Block the inlet port and outlet port on the left and right side of main deck, after several minutes, the device should give a high priority alarm sound, the information indicator shows "Airflow Error", and the alarm character should be consistent with the description of section 3.4.

Turn off the power supply of controller, and pull off the power cord, and take out the controller. Reconnect the power cord, and hold the fan slightly, and turn on the switch of controller, the device should give a high priority alarm sound, the information indicator shows "Motor Error", and the alarm character should be consistent with the description of section 3.4.

WARNING: 1. The temperature of the heater inside the controller is high, only can take out the controller or touch the heater after at least 45 minutes, to avoid the burns cause by overheating of the heater.

2. Restart the controller after taking out, should avoid the electric shock of power plug for oxygen control and humidity control.

I. CHECK OVER-TEMPERATURE ALARM

The device into the working state, press Up, Down and Silence/Reset key, there is no indication on the Set Temperature indicator, and the heat power indicator is on in full, and the controller has entered into the over-temp checkout state, and when the incubator temperature is less than 38.0℃, the device should give a high priority alarm sound, the information indicator shows "Over Temp.", and the alarm character should be consistent with the description of section 3.4. In the state of ＞37℃ Override Mode, enter into the working state, press Up, Down and Silence/Reset key, there is no indication on the Set Temperature indicator, and the heat power indicator is on in full, and the controller has entered into the overtemp checkout state, and when the incubator temperature is less than 39.5℃, the device should give a high priority alarm sound, the information indicator shows "Over Temp.", and the alarm character should be consistent with the description of section 3.4.

Select the skin temperature mode, press Up, Down and Silence/Reset key, there is no indication on the Set Temperature indicator, and the heat power indicator is on in full, and the controller has entered into the over-temp checkout state, and when the incubator temperature is less than 39.5℃, the device should give a high priority alarm sound, the information indicator shows "Over Temp.", and the alarm character should be consistent with the description of section 3.4.

J.CHECK DEVIATION ALARM

In Air Mode, close all doors and panels, set the temperature at 32℃. Enter TEMPERATURE ALARM CHECKOUT STATE（refer to descriptions of terms and symbols concerned）, fan into the hot air inside the hood. When the air temperature indicates 35.1℃, the device should give a high priority alarm sound, the information indicator shows "High Temp.", and the alarm character should be consistent with the description of section 3.4; set the temperature at 35℃, after the device enters into the temperature alarming checkout state, open the front access panel, when the air temperature indicates 31.9℃, the device should give a high priority alarm sound, the

information indicator shows "Low Temp.", and the alarm character should be consistent with the description of section 3.4.

NOTE: If the system can not enter into the TEMPERATURE ALARM CHECKOUT STATE or the air Temperature does vary within ±3℃ than the setting temperature, the deviation alarm can not occur.

In Baby Mode, set the temperature at 35℃. Enter TEMPERATURE ALARM CHECKOUT STATE, put the skin sensor into the water cup at 37℃. When the skin temperature indicates 36.1℃, the device should give a high priority alarm sound, the information indicator shows "High Temp.", and the alarm character should be consistent with the description of section 3.4; set the temperature at 35℃, after the device enters into the temperature alarming checkout state, put the skin sensor into the water cup at temperature 33℃, when the skin temperature indicates to 33.9℃, the device should give a high priority alarm sound, the information indicator shows "Low Temp.", and the alarm character should be consistent with the description of section 3.4.

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

K. CHECK THE WATER LACKING ALARM

When humidifying system is on working, pour out the water in the water tank. The device should give a low priority alarm sound, yellow alarm indication light is on continuously, the information indicator shows "**Low Water**", and the alarm character should be consistent with the description of section 3.4.

L. CHECK THE WATER TANK IN INCORRECT LACATION ALARM

When the incubator is in the working state, pulling out the water tank, the device should give a low priority alarm sound, yellow alarm indication light is on continuously, and the information indicator shows "**Tank Position**", and the alarm character should be consistent with the description of section 3.4. 4 minutes later, if the water tank is still not in position, the alarm sounds response immediately.

M. CHECK THE TIMER

When the controller is normally working, the Message shall display the current time. If the displayed time is not correct, please reset the time. The setting method is as following:

Press Air Mode key while putting the power of the controller on for more than 3 seconds until the set interface appears. At that time, the Set Temperature indicator displays the set code and Air Temperature indicator displays the corresponding value of each set item (the set code, set item and set range please refer to the following table), the Skin Temperature indicator displays

P02 (which means the system has entered into the time setting interface). The operator could select the set items through pressing the Baby Mode key or the Air Mode key and set the item value through pressing Up Key or Down Key. After setting one item, press Keypad Lock key to save the set value as well as pressing Silence/Reset key after setting all items for exit the setting interface. If putting off the power directly without pressing Keypad Lock key or Silence/Reset key after setting, the time set will fail this time, system keeps the previous set value.

TABLE OF TIME SETING ITEMS

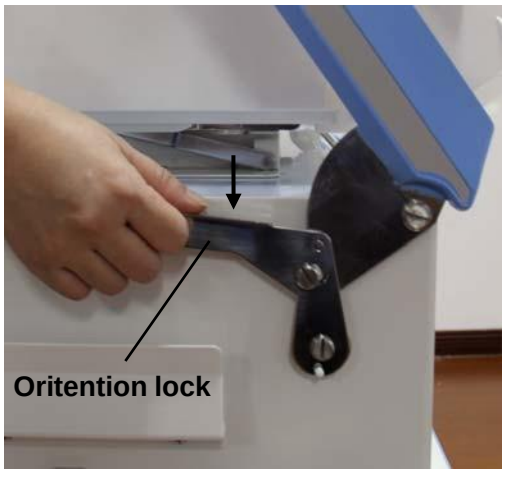
Set Code	Indicating Items	Set Range
001	two front numbers of year	19 ~20
002	two back numbers of year	00 ~99
003	month	01 ~12
004	day	01 ~31
005	week	01~07（01stand for Sunday, deduced accordingly）
006	hour	00~23 (for 24hours)
007	minute	00~59
008	second	00~59

4.4.3 MECHANICAL EXAMINATION

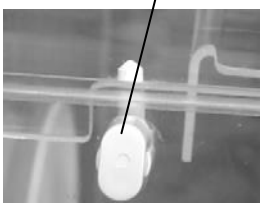
A. CHECK THE HOOD OPERATION

See the following figure, raise the hood until you hear the sound "kata", and the hood is in the lock state. Press the lock downward as the arrow indicates so that the hood can return to the original position.

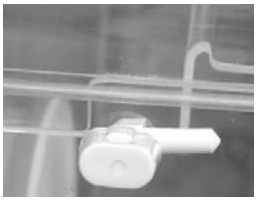
CAUTION: Before raising the hood, ensure all accessories are disconnected to avoid interfering operation.



B. CHECK FRONT ACCESS PANEL



LOCKED



UNLOCK

Rotate the panel Latches and make it stay opening. Press the latch seat to open the Access Panel to the full open position (rotate downward). If the Access Panel has panel damping system, you can release the panel after opening to a certain angle and the panel will descend to maximum state slowly and automatically. Close the Access Panel, the latch seat is fastened automatically and then rotate both latches until they are fully locked. Both latches and the seat latch must be fully locked to avoid accidental opening of the panel.

C. CHECK IRIS ENTRY PORTS

Rotate the outer ring of each entry Port, the port should be open and close as rotation is continuing through 360 degree.

D. CHECK THE LATCH AND GASKET OF ACCESS DOOR

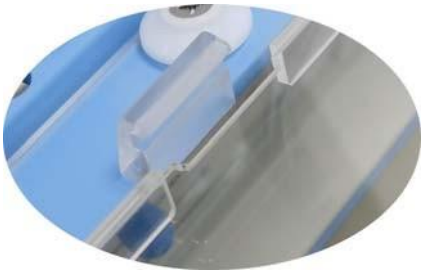
I4-1

Press on-off of each access door to open it automatically and check the seal of gaskets.

E. CHECK THE INNER WALL

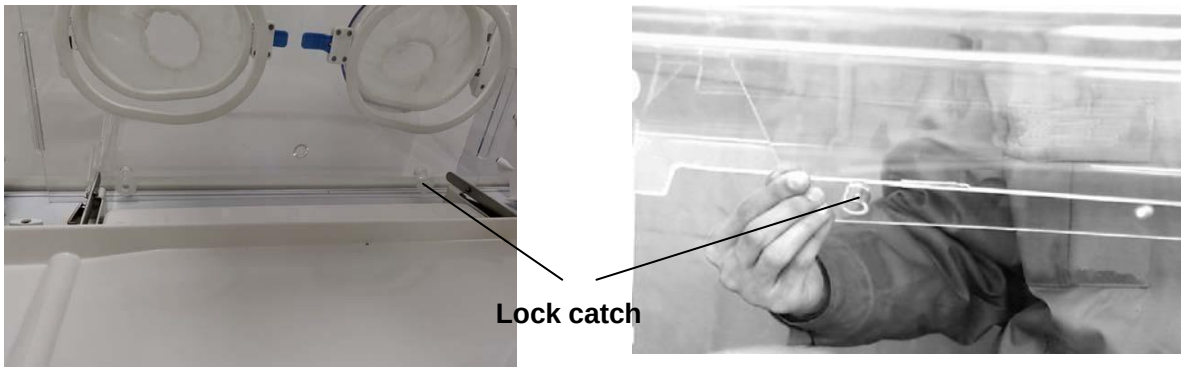
Inner wall in front access panel:

Enlarged figure



Open the front access panel, as shown in the figure, and remove the inner wall. When putting back into the inner wall, insert the bottom of the inner wall into the fixing slot (see enlarged figure), then lock the inner wall to ensure that the inner wall does not fall off.

Back inner wall：



Pull out the mattress, again as shown, and remove the back inner wall. When putting back into the inner wall, make sure that the top and bottom are locked and do not fall off.

UNLOCK

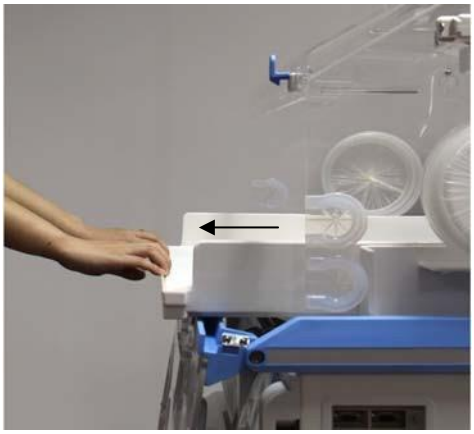
LOCKED

I4-1

F. CHECK MATTRESS TILT MECHANISM

Rotate the mattress tilt mechanism to adjust it.

G. CHECK BASSINET

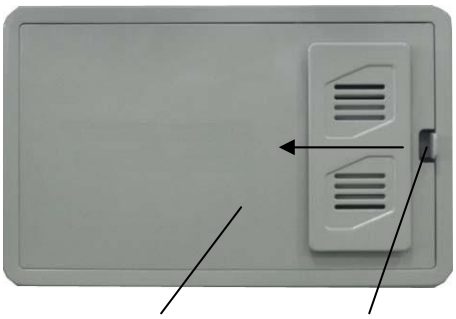


Open the Access Panel and slide it out to the fully extended position indicated by the arrow. The mattress of the bassinet is the applied part. Lean on Mattress Tray to make sure it is properly supported to provide a firm infant platform. Return the mattress and close Access Panel.

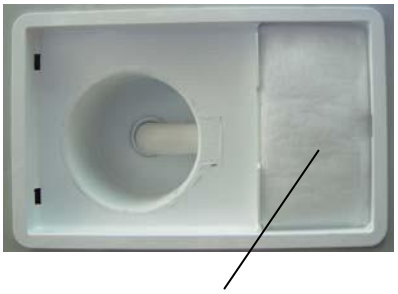
WARNING: Do not block the air-vent, or it will lead to overheating of a baby, and cause damage or burns.

H. CHECK THE AIR INTAKE FILTER

Hold the buckle of air filter cover in the direction of the arrow, remove the cover. Check the air intake filter, if there is dirt should be replaced.



Air filter cover Buckle



Air intake filter

WARNING: A dirty Air Intake filter may affect oxygen concentration and /or cause Carbon Dioxide build-up. The filter must be checked on a routine basis and changed at least every two months.

I. CHECK THE HIGHT ADJUSTMENT OF THE VHA STAND

Step the Up and Down button with your feet in figure 4.3 to adjust the height of whole unit.

4.5 GENERAL OPERATION 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 be 3℃ higher than environment temperature.

4. The display module of the controller is susceptible to the electromagnetic interference, so please do not use it under high electromagetic field. If an equipment which can send or receive a weak signal is installed near this device, it will be affected by electromagnetic wave sent by this device. Before using it, please check if the equipment around is affected or not.

4.5.1 PREPARATION

4.5.1.1 Connect the power supply cord, sensor modular and skin temperature sensor1 correctly.

4.5.1.2 Pre-warm the incubator, put the patient on the bassinet after the air temperature reaches the stable temperature to avoid the body temperature of the patient decreasing in the incubator that is not preheated. The specific pre-warm method is as follows:

Choose Air Mode, and set a proper control temperature, and make the device continue working until the air temperature reaches the control value.

IMPORTANT: Please ask the physician to decide the set temperature.

4.5.2 OPERATION

4.5.2.1 AIR MODE

Air Mode means the controller will control the incubator temperature automatically to keep the air temperature close to set temperature.

Incubator temperature is monitored by the sensor probe and compared with the set air temperature. The result of comparation is passed to the heater control circuit to control the heat for keeping the set air temperature. The isolated temperature sensor as backup can control the maximum incubator temperature. If the temperature is over high, and the heat protective device will be activated, and the heater is cut off.

Press the Keypad Lock key to select the Air Mode. Set the temperature at the wanted one. The air temperature will keep within the range of ±0.2℃ compared to the set temperature.

When the incubator is working, if the set temperature needs to change (decrease or increase), press the Keypad Lock key to enlighten its indicating light, choose the Air Mode key to adjust the set temperature through pressing Up and Down Key. Set ＞37℃ Override Mode, you need to press the Up key until the air temperature indicates 37℃, press ＞37℃ key , and the device will enter into the temperature override mode, and ＞37℃ indicator is on, press Up key to set. After choosing the proper temperature, press Keypad Lock key to enter into the control mode, or without pressing any key for 10s, and the controller will enter into the control mode automatically. Set Temperature indicator displays the set temperature, and Air Temperature indicator displays the air temperature, and Skin Temperature indicator displays the baby temperature tested by skin temperature sensor1 (If the sensor is connected).

4.5.2.2 BABY MODE

Baby Mode is one temperature control method which means the controller will control the incubator temperature automatically to keep the baby temperature close to set temperature. Skin temperature sensor is the applied part.

There are two skin sensors equipped in the device, one is skin sensor 1 and the other is skin sensor 2. Between which skin sensor1 works as the temperature controlling sensor, which makes the controller control the temperature according to its detected temperature; skin sensor 2 is for the clinical requirement which is used for the assistant observation for the infant temperature (the detailed observation method for skin sensor 2 please refer to the section 4.3). The probe of Skin

temperature sensor 1 required closely attached to the skin of patient and the information from probe is passed to the heater control circuit to control the heat for keeping the set baby temperature. The isolated temperature sensor as backup can control the maximum incubator temperature. If the temperature is over high, and the heat protective device will be activated, and the heater is cut off.

When the incubator is working, if the set temperature needs to change (decrease or increase), press the Keypad Lock key, choose the Baby Mode key to adjust the set temperature through pressing Up and Down Key. Set ＞37℃ Override Mode, you need to press the Up key until the baby temperature indicates 37℃, press ＞37℃key, and the device will enter into the temperature override mode, and ＞37℃ indicator is on, press Up key to set . After choosing the proper temperature, press Keypad Lock key to enter into the control mode, or without pressing any key for 10s, and the controller will enter into the control mode automatically. Set Temperature indicator displays the set temperature, and Air Temperature indicator displays the air temperature, and Skin Temperature indicator displays the baby temperature tested by skin temperature sensor1.

For setting the appropriate temperature and correctly controlling the baby temperature of the infant, the incubator holds the following functions:

When the temperature detected by the skin temperature sensor 1 is always below the set temperature for more than 2℃, the incubator will raise the air temperature in the incubator in the speed of 1℃ per hour to enable the slowly rising of the infant's temperature and avoid the damage caused by the rapid rising of the temperature as well. If the baby temperature detected is always 2℃ below the set temperature in 1 hour, "Skin Sensor 1 Position" alarm will be activated by system. At that time, the incubator still raises the air temperature in the hood slowly until the air temperature reaches the STEADY TEMPERATURE CONDITION which its temperature is equal to " set skin temperature -4℃". For example, in Baby Mode, if the set temperature is 36.5℃, finally the air temperature in the incubator will reach the STEADY TEMPERATURE CONDITION which its temperature is 32.5℃.

For avoiding the incubator unnecessarily decreases its temperature for the reason of infant pyrexia or something else, the incubator holds the following functions:

If the baby skin temperature surpasses the set temperature for less than 0.5℃, the air temperature in the incubator will not be 5℃ lower than the baby skin temperature. If the baby skin temperature surpasses the set temperature for over than 0.5℃, the air temperature in the incubator will not be below 25℃.

For example, in Baby Mode, if the set temperature is 36℃ while the baby temperature rising to 36.3℃, the air temperature in the incubator will not be lower than 31.3℃; while the baby temperature rises to 36.7℃ which is higher 0.5℃ than the set temperature, the air temperature in the incubator will not be lower than 25℃.

CONNECT THE PROBE OF SKIN TEMPERATURE SENSOR TO THE PATIENT:

In 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 is located and the metal surface of skin sensor probe with alcohol or the moderate water to wipe off the grease and dirt. In order to fix the probe's position, medical tape or the like can be used to fix it（Disposable skin temperature sensor can be fixed with its glue）. If the patient lies on 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 back, as for the position of probe, please follow the instruction of doctor.

NOTE: 1. Skin temperature sensor must be cleaned and disinfected before use.

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

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

WARNING

- **Make sure that the probe of skin sensor is attached closely on the skin of patient. If the probe falls off the patient, the measured temperature from sensor is not the real skin 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.**
- **Please do not cover the blanket or diaper on the probe of skin sensor, because it will affect the accuracy of temperature.**
- **Skin sensor will measure the skin 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.**

4.5.3 OTHER OPERATION

A. Raise the head or foot of patient

Please raise the head or foot of patient according to the step F 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.

B. Operation to the oxygen concentration control system

Please refer to the section 6.

C. Operation to the humidity control system

Please refer to the section 7.

D. Operation of Neonate Bilirubin Phototherapy Equipment (if applicable)

Please find the accompany documents, the user's manual for NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT BABYGUARD U-1131, BABYGUARD U-1133.

E. Operation to the weighting control system (if applicable)

Please refer to the section 8.

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.

SECTION 5
CLEANING AND MAINTENANCE

5.1 GENERAL

This section provides cleaning and maintenance instructions.

WARNING

1. Disconnect all the connections with oxygen feeding device before cleaning and maintenance. Cleaning or maintenance in the environment full with oxygen will cause fire or explosion.

2. The incubator with cabinet adopts the connector of power cord as the isolation mains power supply, therefore, to make sure the safety, and pull off all power cords before cleaning.

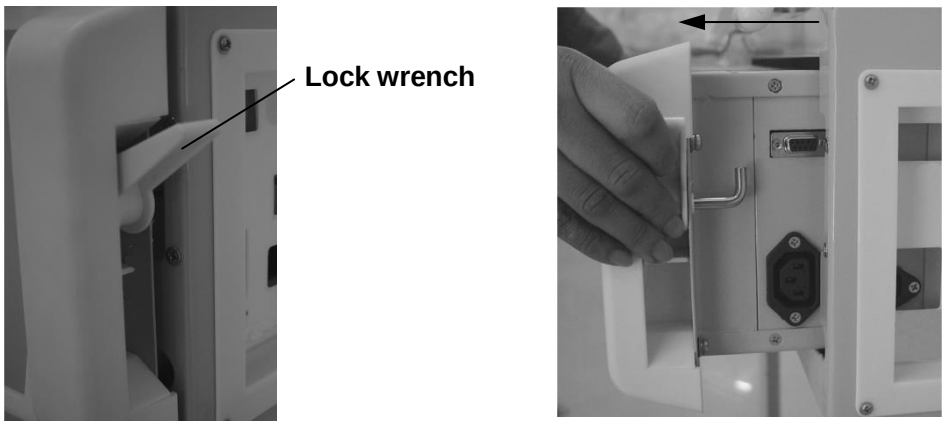
5.2 CLEANING

This device must be cleaned and sterilized for the first time for initial use, or after usage for one week.

5.2.1 DISASSEMBLY BEFORE CLEANING

A. Remove The Controller

Disconnect the Power Cord and Sensor box from the side of the Incubator, then push the decorative face frame which is located in the left side of controller to the left. Release the lock wrench position as shown in Figure 5.1, and then take out the controller following the arrow direction.



The controller can be taken out from the incubator, when the Spanner pulls out to >90° direction.

WARNING: The heater inside the controller is in high temperature, only can take out the controller or touch the heater after at least 45mins, to avoid the burns caused by overheating of heater.

FIGURE 5.1

B. Remove the bassinet

Push the bassinet inside to the position, as the figure 5.2 shows, raising the right side of the bassinet as the arrow 1, after the bassinet is higher than the air return inlet, and then take out the bassinet as arrow 2.

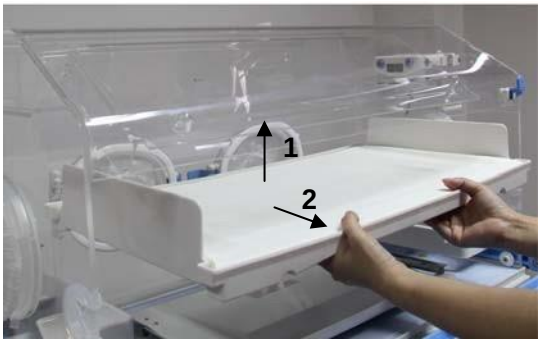


FIGURE 5.2

C. Remove the air curtain

Raise the hood slowly as figure 5.3 directed, make the air curtain upright to the bassinet shelf and move it out following the direction of the arrow.

CAUTION: Before raising the hood,make sure that all installed accessories are all cut off.

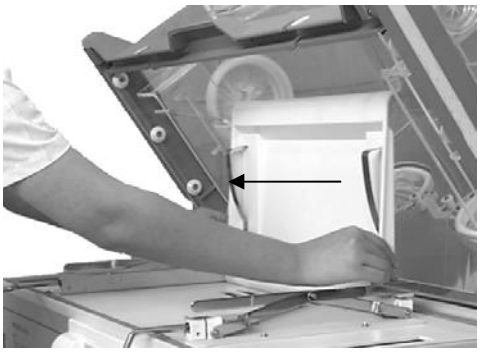


FIGURE 5.3

D. Remove the Main Deck

Refer to figure 5.4, rotate the knob to the unlocked position and take out the Main Deck.

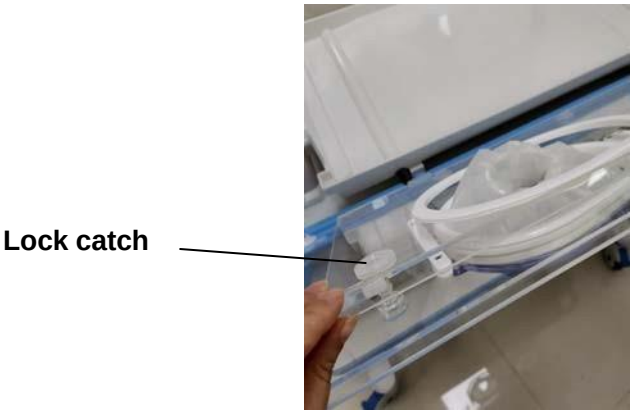
Locked

Unlocked

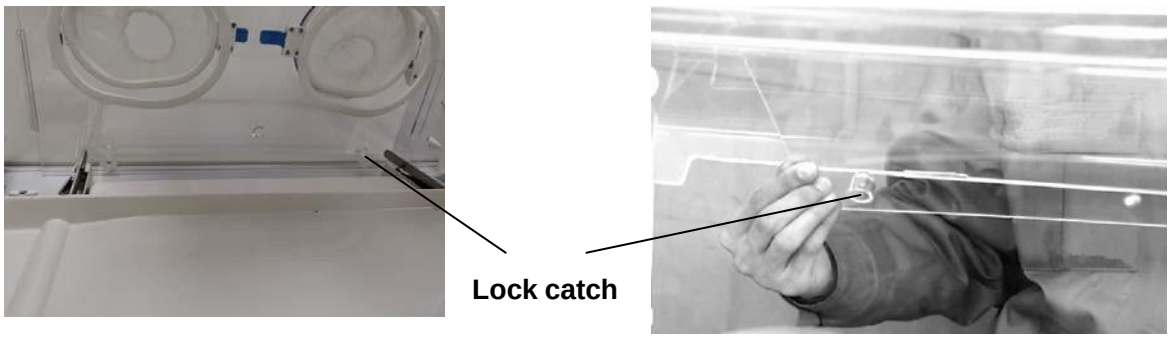
FIGURE 5.4

E. Remove the inner wall

Remove the hood inner wall as figure 5.5 directs.



Step 1: Open the lock catch on both sides of the front access panel inner wall and remove the front access panel inner wall.



Step 2: Pull out the mattress, open the bottom and top lock catch of the inner wall, and remove the inner wall from the hood.

FIGURE 5.5

F. Remove Air Intake Tube Connector

See Figure 5.6, move the Air Intake Tube out in direction of arrow 2 after disconnecting Air Intake Tube from Air Tube Connector in direction of arrow 1.

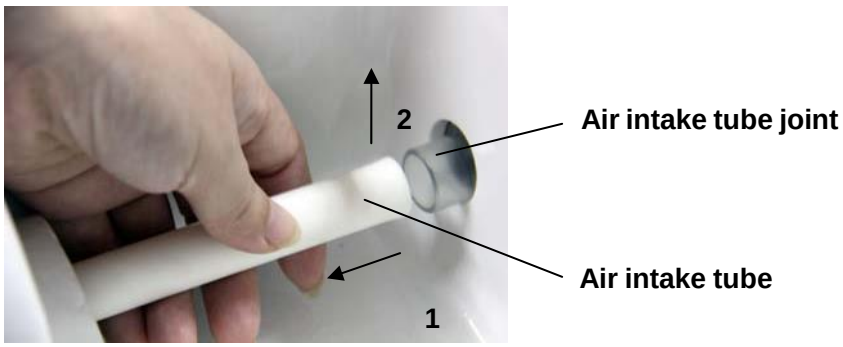


FIGURE 5.6

G. Remove Reservoir

Pull the Reservoir out slowly till it is locked as the figure 5.7 directs, then press it down slightly, it can be pulled out.

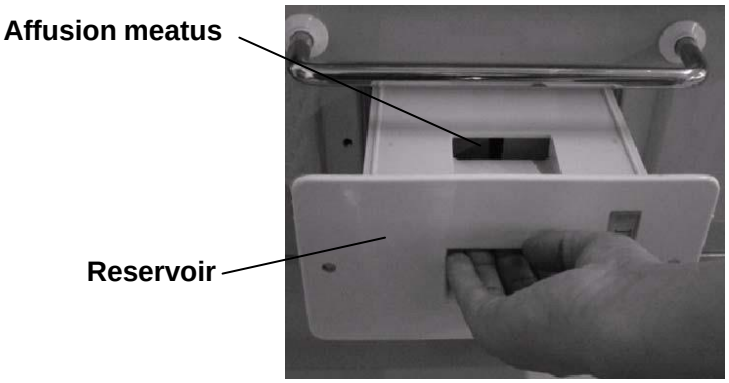


FIGURE 5.7

CAUTION: 1. Because the temperature of the water tank is high after the power of the device is on as well as the heating groups are tightened then, so please take out the water tank after it is totally cooling down to avoid damage to the heating group.

2. The humidifying system is in the bottom of the reservoir. Don't put hands into the reservoir to avoid being burned.

H. Remove the Access door gasket and Access door cuff, and Iris port sleeve from hood.

I. Remove the soft tubing from hood.

5.2.2 CLEANING PROCEDURE

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

A. Clean the skin temperature sensor

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

B. Clean the Soft tubing, Gaskets, Iris Port Sleeves, air intake tube

Allow parts to soak as neutral disinfectant-detergent, after that clean them with clear water, then remove them and dry completely with a clean cloth or paper tower.

C. Clean the Hood, inner wall and sensor modular

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

CAUTION:1. Alcohol can cause crazing of the clear Acrylic panel. Do not use alcohol, acetone, or any organic solvents for cleaning. Do not expose the panel assembly to direct ultraviolet radiation.

2. Please avoid the liquid flowing into the sensor box.

D. Clean the controller

Use neutral disinfectant-detergent to clean the all surfaces thoroughly of the face frame. Especially be careful about cleaning the surface of Fan blade and Heater. Then dry them with clean cloth. During the cleaning, please do not get wet with the electric interface.

CAUTION:Pay particular attention to avoid liquid seeping into the Controller Shell.

Please clean the heater after it is totally cooled down.

WARNNING: Not cleaning the heater and fan will result in accumulation of fibre dust, baffle the air flow. That will influence the temperature control and result in high CO_2 concentration.

E. Clean the bassinet, Main Deck, shelf and air curtain

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

CAUTION: Do not lubricate the Mattress Tilt Mechanism with oil or other potentially

F. Clean the mattress

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

G. Clean Air filter

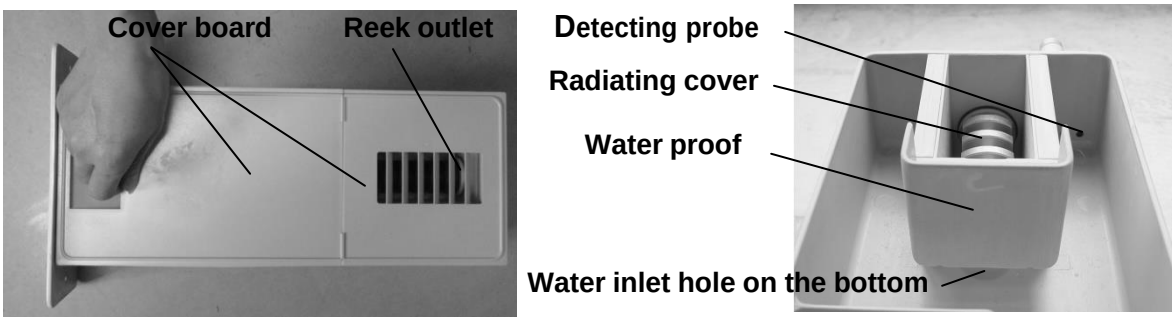
Use neutral disinfectant-detergent to thoroughly clean all surfaces, and then dry them with a clean cloth or paper towel. If the air filter is dirt or is used for more than 2 months, please replace it.

H. Clean Water tank

Open the two cover boards on the humidifying chamber and pull up the water proof as figure5.8 indicates. Use the neutral disinfectant-detergent to clean the all surfaces and cupped place thoroughly. Clean it again with clean water and then dry it with clean cloth or paper.

Please pay special attention to cleaning the inner and outer surface of the probe with the around the detect point can control the microorganism breed in the water tank and ensure the accuracy of the water level detection.

When the scale appears visibly on the radiating cover inside the water tank, it is recommended to soak it with table vinegar or the scale cleaning detergents which is used exclusively for casting water dispenser. The soaking time is about 15min to 20 min. (The longer the radiating cover be soaked, the better) .In the process of soaking, make sure that the cover is immersed entirely. After soaking, scrub with bottle brush and rinse the cover till the scale is cleaned completely.



CAUTION: 1. Please clean the water tank after the radiating cover inside the water tank totally cooled down.

2. Make sure the water inlet hole on the bottom and the reek outlet hole of tank through after cleaning.

3. If the water tank is uncleaned, especially there are dusts near the probe, there will be a possibility that water-lacking alarm failure.

4. Please use soft cloth to wipe the surface of the probe when it is covered by noble metal. Do not use the hard material to scrape the probe so as not to damage it.

5.When the scale appears on the radiating cover visibly, you must clean it in time, or it will easily breed ground for bacterium and affect the humidification.

FIGURE 5.8

The water tank can use steam sterilization. The way of steam sterilization: before steam sterilization, should clean and dry the water tank thoroughly. The duration of steam sterilization is: 132℃ for 3 to 5 minutes; 121℃ for 15 to 20 minutes. Repeating sterilization will lead to crack for some parts, will damage the water tank and will eventually need to change the water tank.

I. Clean NEONATE BILIRUBIN OHOTOTHERAPY EQUIPMENT

See the user's manual for BABYGUARD U-1131 and

BABYGUARD U-1133.

J. Clean surface of device

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

5.2.3 REASSEMBLY AFTER CLEANING

NOTE: Before reassembling parts into Incubator, check carefully if there is any crack or damage. Some disinfectant-detergent may cause crazing of plastic parts in Incubator.

A.Install Humidity chamber fill spout in the reverse steps as they are moved out.

B. Install Air Intake Tube in the reverse steps as they are moved out. Installed Air Intake Tube must comply to Figure 5.9.

WARNING: Air Intake Tube must be placed inside the Air Intake Tube Connector and completely sealed.

FIGURE 5.9

C. Place Main Deck back.

Be sure the thumbs screws that hold the mattress tray are tightened. Otherwise the air circulation system will be influenced.

D. Install the air curtain and the inner wall as figure 5.3 and 5.4 direct.

WARNING: The air curtain should be installed properly, or it will affect the accuracy of the temperature control.

E. Install the controller as the figure 5.1 directs

Controller is the key unit of Incubator and must be installed carefully.

Insert Controller into Base Assembly. After the whole part is inserted into Base Assembly, depress the snaps at both sides of Controller until they are parallel to the side then pull the Controller outward. If the Controller is not loosened, it is already locked. (See Figure 5.10)

Correct installation state

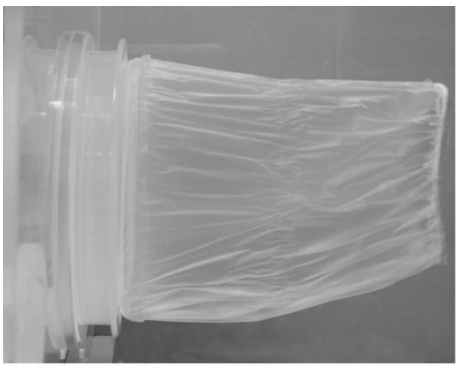
Power socket of humidity control on the base

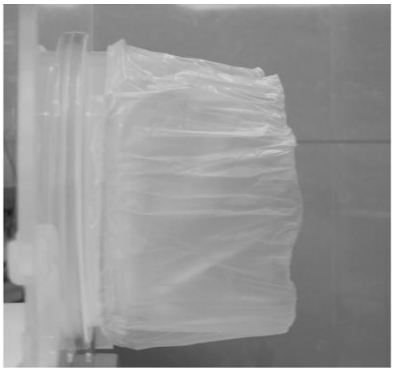
Power socket of humidity control on the controller

CAUTION: Power socket and plug of the humidity control are the power supply of the incubator's humidity control system. Do not force the controller in, or else the power supply system will be damaged.

FIGURE 5.10

F. Rotating the iris entry sleeves, see figure 5.11.





Step 1: Install the elastic band over the inner ring of the port housing. Fold back and slip elastic band over the outer ring of the port housing.

Step 2: Rotate outer ring. If properly installed, the sleeve will open when reversing the rotation.

FIGURE 5.11

G. See figure 5.12, install the Access door gasket, and then install the Access door cuff.

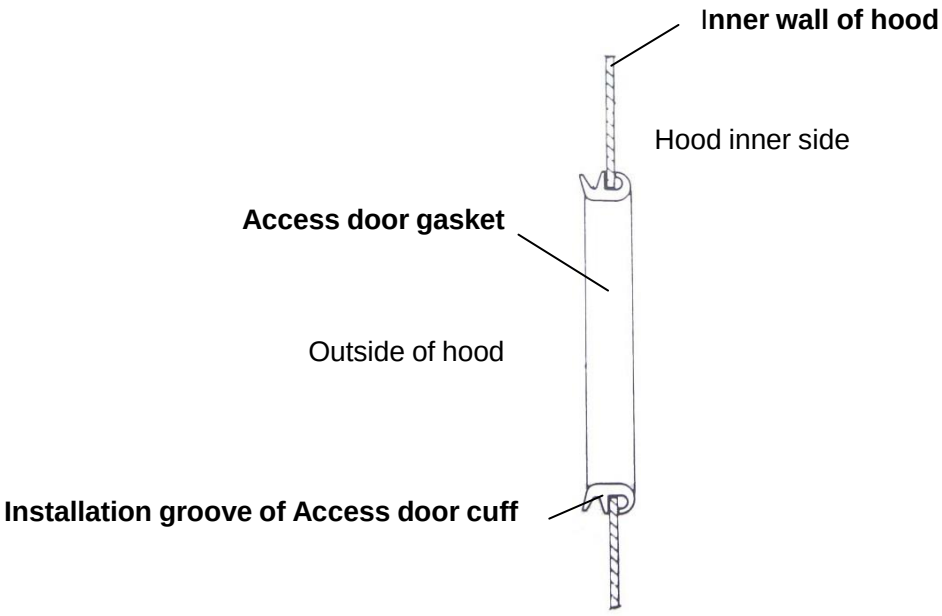


FIGURE 5.12

H. Install the soft tubing in figure 5.13.

NOTE: The opening of soft tubing should face outward.

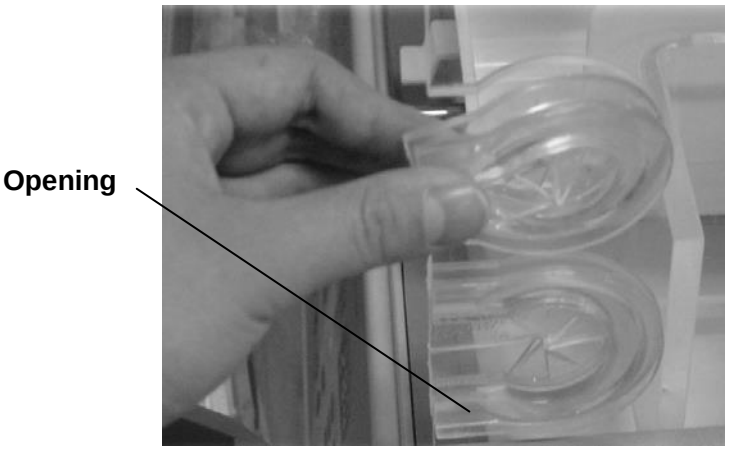


FIGURE 5.13

I. Put the mattress back to the bassinet, then put the bassinet the back to the hood in the in the reverse steps as the figure 5.2 shows.

When placing the bassinet, please pay attention to the direction, and follow the label instruction of the bassinet.

5.3 MAINTENANCE

WARNING: To ensure the safety of using the equipment is not affected, the modification of incubator is forbidden.

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

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

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

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

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

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

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

5.4 TROUBLE SHOOTING

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

TROUBLESHOOTING TABLE

SYMPTOM	POSSIBLE CAUSE	REMEDY
No indication, no alarm	Power switched off	Switch on the power
Power failure alarm light is on, red alarm light flashes, power failure alarm	Power off	Switch off the power
	Power cord disconnected	Connect the power cord
Red alarm light flashes, the information indicator shows "Box Position"	The sensor box wrongly placed	The sensor box right placed
Red alarm light flashes, the information indicator shows "Skin Sensor 1"	Skin temperature sensor1 disconnect or not connect well	Connect the Skin temperature sensor1 correctly
	Skin temperature sensor1 damaged	Replace the skin temperature sensor1
Red alarm light flashes, the information indicator shows"Oxygen Sensor 1"	Oxygen sensor 1 not installed	Install the oxygen sensor1 correctly
	Oxygen sensor 1 damaged	Replace the Oxygen sensor1
Red alarm light flashes, the indicator shows "Oxygen Sensor 2"	Oxygen sensor2 not installed	Install the oxygen sensor2 correctly
	Oxygen sensor 2 damaged	Replace the Oxygen sensor2

TROUBLESHOOTING TABLE (continued)

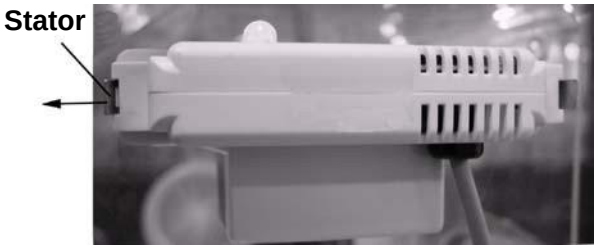
SYMPTOM	POSSIBLE CAUSE	REMEDY
Red alarm light flashes, the information indicator shows "Over Temp."	Ambient temperature too high	Far away from the heat source or decrease the ambient temperature
	High humidity	Decrease the humidity inside hood
Red alarm light flashes, the information indicator shows "Low Temp"	Door or panel of hood is open	Close the door or panel of hood
	Ambient temperature changes a lot	Check the Ambient temperature
Red alarm light flashes, the information indicator shows "High Temp"	Heat source nearby	Far away from the heat source
	Ambient temperature changes a lot	Check the Ambient temperature
VHA stand can't work up and down (if applicable)	Power cord disconnected	Connect the power cord
	Power switched off	Switch on the power

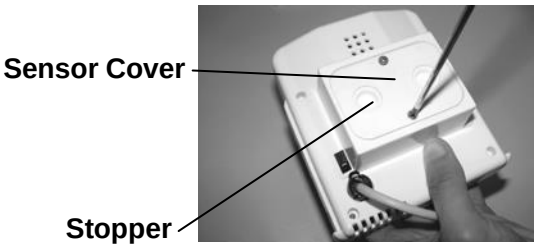
SECTION 6
OXYGEN CONCENTRATION CONTROL SYSTEM

6.1 GENERAL

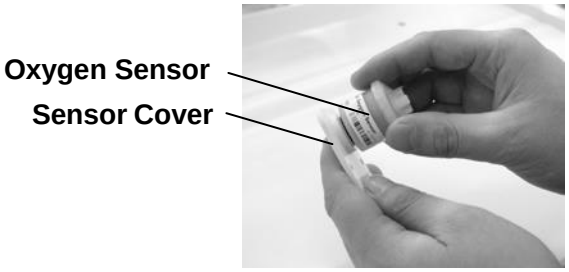
This Section provides operation checkout procedure and operation instruction for the Oxygen concentration control system.

6.2 INSTALLATION OF OXYGEN SENSOR





Pull out the stator on the left side of sensor box as the arrow indicates, and pull out the sensor box, unscrew 2 Cross groove countersunk head bolts, and take out the sensor cover, and then unscrew the stopper on it.



Screw 2 oxygen sensors into the sensor cover clockwise.

Pull the connecting wire of oxygen sensor out and connect the sensor with the double wire of green and black, and please connect another oxygen sensor with the other double wire of yellow and black. After correctly connecting them, screw the sensor cover board down with two M3×8 cross groove head bolt, then push the sensor box into the original place in the hood.

CAUTION: 1. Do not block any of the holes on the sensor box.

2. Please pull out and push in the sensor box in correct way.

3. Sensor box is the important part of controlling the temperature of the incubator, please treat it carefully.

FIGURE 6.1

I4

6.3 FUNCTION DESCRIPTION

The incubator has the function of controlling the oxygen concentration. The "Oxygen Sensor 1" alarm, the "Oxygen Sensor 2" alarm, "Oxygen Not Same" alarm, "High Oxygen" alarm and "Low Oxygen" alarm are all applying for the function of controlling. The details of alarm message, please see the section 3.4. If the above alarms are active, press the Silence /Reset key to stop alarming for about 110s. The power of the heater is not cut off, and the oxygen control system will cut off the oxygen supplying automatically (Except for "Low Oxygen" alarm).

6.4 CONNECTION OF OXYGEN INPUT CONNECTOR

WARNING

1. Please read the operation manual carefully before operating.

2. Oxygen concentration control system must use oxygen analyzer to supply oxygen through the oxygen input connector , the relative operation must refer to the operation manual of oxygen analyzer or other documents similarly.

3. Only given decompress valve or pressure adjusting valve can be used on the oxygen cylinder.

4. According to the theory that the oxygen concentration breathed in by the patient can not judge his artery PaO_2 accurately, so other acceptable clinical measures should be taken to testify the patient's artery PaO_2.

Connect the oxygen input tube which passes through the monitor with the oxygen input valve on the left of the base (see the figure 6.2). Ensure they are sealed while connecting.

FIGURE 6.2

6.5 OPERATION AND CALIBRATION PROCEDURES

Before the first using of incubator and the reuse after maintenance, should perform the oxygen concentration calibration system operating process.

The system support with two kind's oxygen concentration calibration: 21% oxygen concentration and 100% oxygen concentration. When the oxygen concentration of the environment is below 21%, we suggest using 100% oxygen concentration calibration.

21% OXYGEN CONCENTRATION CALIBRATION

Keep the incubator in the environment which oxygen concentration is 21%.

a. Take out the sensor box under the condition of controller is turned off.

b. After pressing Oxygen Concentration Indicator key, turning the controller on to enter the interface of 21% oxygen concentration calibration. The Oxygen Concentration indicator displays "CA", Set Temperature indicator displays "21". Press the Keypad Lock key, system starts calibrating the 21% oxygen concentration automatically. If the calibration is correct, the Oxygen Concentration indicator displays "21", if not, it displays "Er". When the displayed value is incorrect, please calibrate the system again according to the steps listed above. If the displayed value by the indicator is still incorrect, please ask the qualified service personnel to mend it.

100% OXYGEN CONCENTRATION CALIBRATION

a. Turn off the controller, pull the sensor box out as figure 6.3 shows, connect the oxygen calibration device which is equipped with oxygen connecting pipe with sensor box, supplying the 100% oxygen and maintain for more than 2min.

b. Press the Oxygen Concentration Indication key and turn on the power switch of the controller, the system will enter into Oxygen Concentration calibration interface and the Oxygen Concentration indicator displays "CA", press Set Up key or Set Down key until the Set Temperature indicator displays "100". Press the Keypad Lock key, system starts calibrating the 100% oxygen concentration automatically. If the calibration is correct, the Oxygen Concentration indicator displays "99", if not, it displays "Er". When the displayed value is incorrect, please calibrate the system again according to the steps listed above. If the displayed value by the indicator is still incorrect, please ask the qualified service personnel to mend it.

FIGURE 6.3

I4

CHECK THE OXYGEN CONCENTRATION MONITOR FUNCTION

1. Place a calibrated oxygen concentration analyzer in the middle of the bassinet.

2. Connect the oxygen input system, waiting until the oxygen concentration steady, between the value displays in the Oxygen Concentration indicator and the oxygen concentration analyzer displays should in the range of ±3%.

CHECK THE FUNCTION OF OXYGEN CONCENTRATION DEVIATION ALARM

Connect the oxygen supply system with oxygen input connector and set the oxygen concentration basic value at 30%. Waiting until the oxygen concentration display value reach the basic value, then increase the oxygen flow rate rapidly. When the displayed oxygen concentration value deviates the basic value to +5%, the device should give a high priority alarm sound, the information indicator shows "High Oxygen", the alarm character should be consistent with the description of section 3.4.. Set the oxygen concentration basic value at 30%. Waiting until the oxygen concentration display value reaching the basic value, then decrease the oxygen flow rate rapidly. When the displayed oxygen concentration value deviates the basic value to -5%, the device should give a high priority alarm sound, the information indicator shows "Low Oxygen", the alarm character should be consistent with the description of section 3.4. When alarm activates, press Silence /Reset key to stop alarming, but the alarm indicator light continuously shines until the deviation is less than ±5%.

6.6 USING OF OXYGEN SUPPLY SYSTEM

6.6.1 Preparation

Connecting the oxygen flowmeter and oxygen input valve with one PU-10×6.5 medical pipe.

6.6.2 Operation

Select the oxygen concentration control value according to the requirement of the chief doctor. Turn on the Oxygen Concentration indicator and press the Keypad Lock key, keypad lock indicating light brighten up then. Press the Switch Setting Indicator key, and select the oxygen concentration set indicator, which light will brighten up then. Press the Up/Down key to set the oxygen concentration value. Select the suitable setting value, then press Keypad Lock key to start work directly, or waiting for 10s without pressing any key to start working.

WARNING : Over-high oxygen concentration will damage the patient seriously, so follow the doctor's requirement while using it and taking the relevant oxygen input monitor to ensure oxygen flow and its concentration is settled by the doctor.

6.7 MAINTENANCE

A. Oxygen concentration sensor

When the oxygen concentration lifetime is in due, replace it even it is workable to ensure the veracity of the detecting value. That is because:

The detecting accuracy of oxygen concentration sensor is influenced by the electrolyte inside the sensor modular, and the electrolyte will be consumed along with the working time. So using the over lifetime oxygen concentration sensor will result in wrong detected value.

B. Troubleshooting

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

SYMPTOM	POSSIBLE CAUSE	REMEDY
No indication of oxygen concentration value	Not install the oxygen sensor	install the oxygen sensor
The "Alarm" light will flash, and the Message indicator will show "High Oxygen"	Displayed oxygen concentration too high	Please calibrate the oxygen sensor again
		Adjust the proper oxygen flow
The "Alarm" light will flash, and the Message indicator will show "Low Oxygen"	Displayed oxygen concentration too low	Please calibrate the oxygen sensor again
		Adjust the proper oxygen flow
	Open the access door	Close the access door

SECTION 7
HUMIDITY CONTROL SYSTEM

7.1 GENERAL

This section provides operation and checkout procedures and operation manual about humidity control system.

7.2 FUNCTION DESCRIPTION

The humidity display range of the incubator ranges from 0%RH to 99%RH, with a setting range of 0% to 90%RH (Note: If environmental humidity is relatively high it may not be able to achieve relatively low humidity control). The deviation alarm is pre-set to ± 15% RH, which means in humidity steady condition, the humidity deviation alarm will occur if the humidity value is above or below the selected humidity setting range ± 15% RH.

Vapour produced when the water in the humidity chamber flow by the heat pipe located on the bottom of the chamber, enters into the hood by vapour outlet port. The humidity control system enables the humidity increasing inside the chamber. The evaporating speed decided by the power of the heater. There's a humidity sensor inside the temperature controller which adjusts the output power of the evaporator. Please see the alarm introduction of section 3.4. If the alarms about humidity are active, press silence/reset key, cancel the alarm sound for 4mins, if the power of the temperature heater is not cut off, the power of the humidity heater will automatic cut off when the high humidity deviation alarm is active.

7.3 OPERATION AND CALIBRATION PROCEDURES

Apply the humidity calibration and operation procedure when first using the incubator or reuse it after disassembly, clean, and maintain.

A. Raising the water in humidity chamber to the highest level, place a calibrated humidity analyzer in the middle 10cm of the bassinet.

B. Pre-warm the incubator to 36℃, set the humidity value to 50%RH.

C. After temperature and humidity reach stable state, the readings on both the hygrometer and the humidity display indicator should display 50%RH±5%RH.

D. Check the humidity deviation alarm

Turn on the controller, in the condition of starting the humidity indicator, it should display the value of humidity sensor automatically. When the humidity system is on working, set the humidity value to 40%RH, waiting until the humidity display value reaching the humidity set value, then increase the humidity display value to make it +15%RH higher than the set value, the incubator should occur medium priority alarm, the Message indicator will show "High Humidity", and the alarm character should be consistent with the section 3.4 expression. Set the humidity value to 40%RH, Waiting until the humidity display value reaching the set value, then decrease the humidity display value to make it -15%RH lower than the set value, the incubator should occur medium priority alarm, the Message indicator will show "Low Humidity", and the alarm character should be consistent with the section 3.4 expression. Press the Silence /Reset key to stop alarming, but the alarm indicator light continuously shines until the deviation is less than ±15%RH. If after 4m, the alarming condition still exists, it will alarm again.

7.4 USING OF HUMIDITY CONTROL SYSTEM

WARNING：In any temperature, the relatively high humidity in the incubator will decrease the heat vaporing from the patient and result in increasing the patient's temperature. This is especially distinct in the neonate. Therefore, temperature control mode, temperature value and humidity value should be certified by the chief doctor. Monitor the patient's recta and armpit temperature according to the doctor's instruction.

A. Connect the humidity control power plug of the controller with the humidity control power socket inside the base (See figure 5.10) to complete the humidity control system.

B. Set the incubator in Air Mode and pre-warm it according to the doctor's director.

C. Pull the water tank out as figure 5.7 indicates, adding proper distilled water into the tank.

1. Please do not use "humidity" function under the water-lacking condition, or else the humidify system will be damaged.

2. While the incubator is working, please make sure the water tank is pushed to the correct location. Or else, it will effect the normally working of the controller.

3. For prolonging the humidity device's lifetime, using clean distilled water only, does not replace it with disinfected water.

4. Please clean the water tank and change the distilled water every 24 hours to avoid the breed of microorganism and the pollution to the humidifying chamber. Please wait to change the water until the water tank cools down, so as not to get burned. Do not exceed maximum water level.

IMPORTANT：1. Please clean the water tank every time before adding water in the tank. Dry it with a clean cloth or paper towel for both inside and outside of the water tank to ensure that water lacking alarm will normally working.

2. Please set the humidity value to 0%RH when you're not using the "humidify" function. (Or close it by pressing the switch on the humidity display window)

D. Turn on the Humidity Indicator key and press the Keypad Lock to enlighten its indicating light. Press the Switch Setting Indicator key to select the humidity set indicator to make it shining. Then set the humidity value by pressing Up/Down key. Select the suitable setting value, then press Keypad Lock to start work directly, or waiting for 10s without pressing any key to start working.

NOTE：The actual humidity in the system is determined by the set humidity of the incubator and the surrounding condition.

7.5 MAINTENANCE

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

SYMPTOM	POSSIBLE CAUSE	REMEDY
Red alarm light flashes, the indicator shows "High Humidity"	Environmental humidity change greatly	Check the surrounding humidity condition
Red alarm light flashes, the indicator shows "Low Humidity"	No distilled water in the tank	Add distilled water into the tank
Red alarm light flashes, the indicator shows "Low Water"	No distilled water in the tank	Add distilled water into the tank （Wash it when there's a need.）
Red alarm light flashes, the indicator shows "Tank Position"	Bad connection between water tank and the main body of the device	Push the water tank to the correct position to fully connecting with the main body of the device.
Alarm not be active when the water tank is lack of water	Excessive microorganism breed in the water tank or the water tank haven't been cleaned for many days.	Thoroughly clean the water tank and clean around the detect point with soft cloth in disinfector.
After filling water to the water tank after "Low water" alarm active, the function of "humidify" can't be started immediately	Humidifier over-heat protection unrecovered	Waiting for about 10 minutes

SECTION 8
WEIGHING SYSTEM

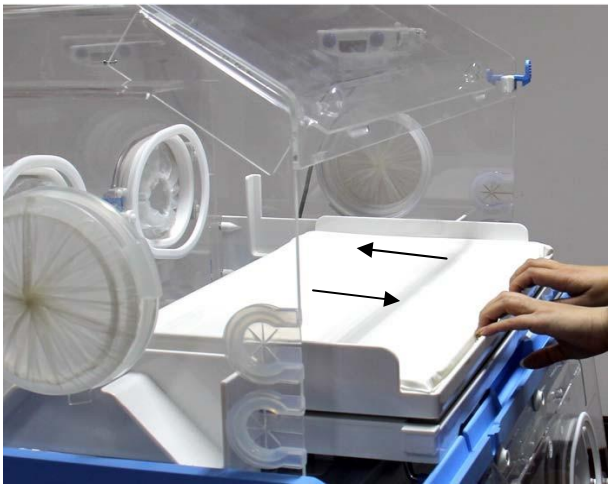
8.1 GENERAL

This section provides operation and checkout procedures and operation manual about weighing system.

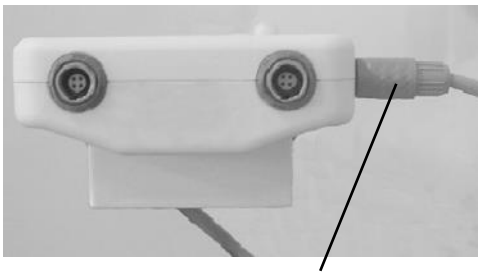
Weighing system is optional.

8.2 INSTALLATION

Install the weighing system in the incubator as figure 8.1 directs.

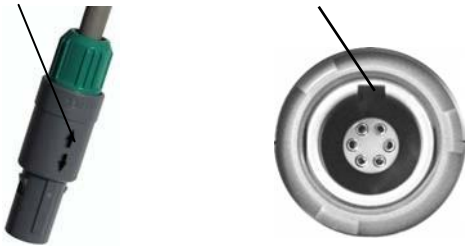


Refer the F in section 4.4.3, Rotate the mattress mechanism to the lowest, then open the front access panel, place the bassinet accessory with electrical scale on the mattress mechanism and make sure it can be pushed in and pulled out as the arrow1 and arrow2 figure.



Weight sensor

Arrow **Opening**



The arrow on the weight sensor must be coherent to the opening on the sensor socket to enable insert correctly.

WARNING: 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.

Insert the sensor plug of the electrical scale into the socket on the sensor modular correctly

FIGURE 8.1

8.3 FUNCTION DESCRIPTION

The weighing system has the function of celebration and reset. These operations can be actualized by operating the Zero key and Calibration key on the controller board. The display range of weighing system is 100~8000g, and its display distinguish rate is 1g, the display precision is ±1%, and the reset range is 0~2000g.

8.4 OPERATION AND CALIBRATION PROCEDURES

NOTE：First time installation or maintenance of the equipment, please calibrate the weight sensor.

CALIBRATE THE WEIGHING SYSTEM

A. Take out all articles on the bassinet and make sure the mattress is clean.

B. Zero. Press the Zero key, the weighing value displayed by Weight indicator should be in the range of 0000g±5g, if not, please press the key again. If the reset value is over 0~2000g, after pressing the key, the Weight indicator displays "Err" which means the reset for the weighing system failure.

C. Calibration. After resetting the weighing system, please place standard poise of 5000g on the center of the bassinet and press the Calibration key for more than 10 seconds. After hearing the sound like "Ding", calibration is over. Then the Weight indicator should display the value in the range of 5000±5g, if not, please calibrate the weighing system again until the displayed value is in the range of 5000±5g. If the displayed value cannot reach the standard value range, please ask the qualified personnel to mend it.

CHECK THE CONNECTING CIRCUITRY OF THE WEIGHT SENSOR

If the connection between the weight sensor and the sensor modular failure, the Weight indicator displays "Err", when reconnecting them, the indicator displays the actual weight weighing by sensor.

8.5 OPERATION OF WEIGHING SYSTEM

After calibrating and resetting the weighing system, lay the patient in, the **Weight** indicator will display the patient's weight by weight sensor.

8.6 MAINTENANCE

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

SYMPTOM	POSSIBLE CAUSE	REMEDY
No indication on Weight indicator	No power supply	Turn on the power of the controller
Weight indicator displays"Err"	The reset range is over 0~2000g	Take out every article on the bassinet and keep the mattress clean
	The connection of weight sensor is failure	Connect the weight sensor correctly
Weighing inaccurate	The bassinet is not placed horizontally	Adjust the bassinet into horizontal position
	Infant is not placed in the center of the mattress	Lay the infant in the center of the mattress
	Environmental temperature varies greatly	Check the environmental temperature

SECTION 9
THE SYSTEM OF MEDICAL DEVICE

9.1 GENERAL

This section provides the description of the system for medical device of infant incubator with neonate bilirubin phototherapy equipment configuration.

9.2 THE SPECIFICATIONS OF SYSTEM

The auxiliary output socket of the infant incubator is supposed to provide the power supply for neonate bilirubin phototherapy equipment of BABYGUARD U-1131 or BABYGUARD U-1133 (About the use of the neonate bilirubin phototherapy equipment, please see the operator's manual of BABYGUARD U-1131 or BABYGUARD U-1133). The medical device system is made up of the infant incubator and the BABYGUARD U-1131 or BABYGUARD U-1133 neonate bilirubin phototherapy equipment.

9.3 THE INSTALLATION OF THE SYSTEM

NOTE: In order to make sure that fit for the standard IEC60601-1, when the system is made up of neonate bilirubin phototherapy equipment and infant incubator, you must install the neonate bilirubin phototherapy equipment according to the following provisions. The users can not assemble or change the system themselves.

A. When fixing the neonate bilirubin phototherapy equipment to the infant incubator, you must use the fixed part carried by the equipment itself, and the specific way of installation, please see the section "The installation of fixed phototherapy equipment" of operator's manual.

B. The power supply of the phototherapy equipment must be provided by the output socket of auxiliary power supply of infant incubator, you can not connect it to the other socket; and also you can not connect output socket of auxiliary power supply of infant incubator to the other equipment.

The system only can be made up of the infant incubator and the neonate bilirubin phototherapy equipment which is produced by our company, if the system is made up of the infant incubator and the other products, our company can not make sure the security.

SECTION 10
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	Air filter material	Apparently dirty or broken or used over 2 months
4	Access door gasket	If damaged
5	Plastic sleeve of access door	
6	Access door sleeve iris port	
7	Power cable	
8	Oxygen sensor	Up to 10,000 hours at 100% oxygen concentration

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

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

DIXION

DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

Schiessstraße 55, 40549 Düsseldorf, Germany

Tel: +4921138838868, Fax: +4921138838697