DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

CE 0483

INFANT INCUBATOR

BabyGuard I-1120

Operator's Manual

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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.

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.

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. Operators for the device should be special trained and operate the device under the instruction of medical practitioner.

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

3. Please stop using the device when it failure or disfunction. 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. Portable and mobile RF communication devices may have an impact on this device.

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 Front and Back Access Panels are open, the temperature from the air temperature indicator maybe not the real temperature inside incubator. Therefore, do not leave the Access Panels open in a long period.

13. All access panel‘s latch should be firm plugged, in case accidental open.

14. For infant safety, DO NOT leave the infant unattended when the Front and Back Access Panels are open.

15. Other accessories within the incubator which can alter the air flow pattern may affect temperature uniformity and temperature variability. In addition, we suggest the incubator run on skin temperature mode. Otherwise, according to the baby temperature measurement result, the incubator temperature set value must be reduce.

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

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

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

19. To prevent the harm on patient for accidental moving, please lock the casters during usage.

20. 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.

21. 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.

22. Do not switch on for longer time than essential, when the machine not connect to the power supply, otherwise, power supply failure alarm will be actively and the internal battery current waste.

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

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

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

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

27. Only the authorized and qualified maintenance personnel can replace the fuse according to the specification. When replace the fuse, you should disconnect the power supply of the incubator first, and can not touch the patients and metal parts at the same time.
28. 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.
29. Please use the neutral deterge/ disinfectant registered by nation. Other disinfectant (like alcohol) will destroy some parts of the incubator. Please follow the instruction for detergent usage.
30. 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.
31. Please only use skin temperature sensor, rechargeable battery,power cord or other accessories provided by our company. Otherwise, it may reduce the safety and noise immunity of the equipment or increase the equipment lauch.
32. The lifetime of incubator internal rechargeable battery is usually 3 years. Before using it every time, we should inspect the status of internal rechargeable battery according to the requirement in section 5.3. If it isn't getting through the inspection or the battery has been used more than three years, it must be replaced. The internal rechargeable battery should be replaced by authorized qualified service personnel.
33. The device should not be close to or use with other device. If have to, please observed to verify that in its use of configuration can run normally or not.
34. Damages will be easily caused if using the incubator after it reached its lifetime. Previous capability guideline and requirement cannot be reached as well.
35. 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 assembly 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. 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.

5. Power of incubator is supplyed by the net power from VHA stand. Please unplug the power cable when stop using or maintain incubators.

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. Additional equipment connected to the medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (See the chapter 16 of the IEC 60601-1). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.

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

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. At high humidity levels within the incubator hood (typically more than 80%RH), condensation may form on the inside walls of the hood.

7. When there is much more difference between the humidity setting value and the humidity of environment, it is very difficult to reach the needed control value of the humidity inside of the incubator.

8. 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 8kg, 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: Limit 0.1Ω.

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

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

○,8. Test the patient leakage current according IEC 60601-1:2005: 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: Limit: for a.c.:500μA (BF), for d.c.: 50μA (BF).

○,10. According to the test methods of IEC 60601-1:2005, 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: Limit: NC for a.c.: 100μA (BF), for d.c.: 10μA (BF).SFC for a.c.: 500μA (BF), for d.c.: 50μA (BF).

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 set at the temperature control.

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℃ and such state lasts for over 10 minutes. The equipment must stay in such state when check up the alarm about temperature

TEMPERATURE UNIFORMITY: The amount by which the average temperature at each of four points 10cm above the mattress surface differs from the Average incubator Temperature at steady Temperature Condition. The four points are the centers of four quadrants formed by lines that divide the width and length of the mattress surface.

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		Refer to instruction manual
CLASS I	Class I equipment		Type BF Applied part
	Main power on		Main power off
	On (only for a part of equipment)		Off (only for a part of equipment)
	User-Defined key		Keypad lock
	Set temperature up key		Set temperature down key
	Silence /Reset Key	**RS232**	RS232 Connector
	Socket for skin temperature 1		Socket for skin temperature 2
	High water level		Low water level
	Caution, hot surface		Mattress tilt direction
	The VHA stand rising key		The VHA stand falling key
220-230V~ 50Hz	AC Power 220-230V/50Hz	**F 6.3AH/250V**	F Type Fuse 6.3AH/250V
220-230V~ 50Hz MAX:3A	Assistant net power outlet, MAX: 3A		Loading prohibited
SN	Serial Number		Date of manufacture
	Manufacturer	EC REP	Authorized representative in the European community
CE 0483	CE Marking		

TABLE OF CONTENTS

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

SECTION 1
GENERAL INFORMATION

1.1 INTRODUCTION

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 of the content of this manual.

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

Monitoring tray, oxygen concentration control system and the weighing system are the optional accessories for the product. We also provide Disposable skin temperature sensor for your choice. If you don't purchase the optional part, please omit it.

1.2 PRODUCT CONTRAINDICATIONS

It is not clear now.

1.3 INTENDED USE

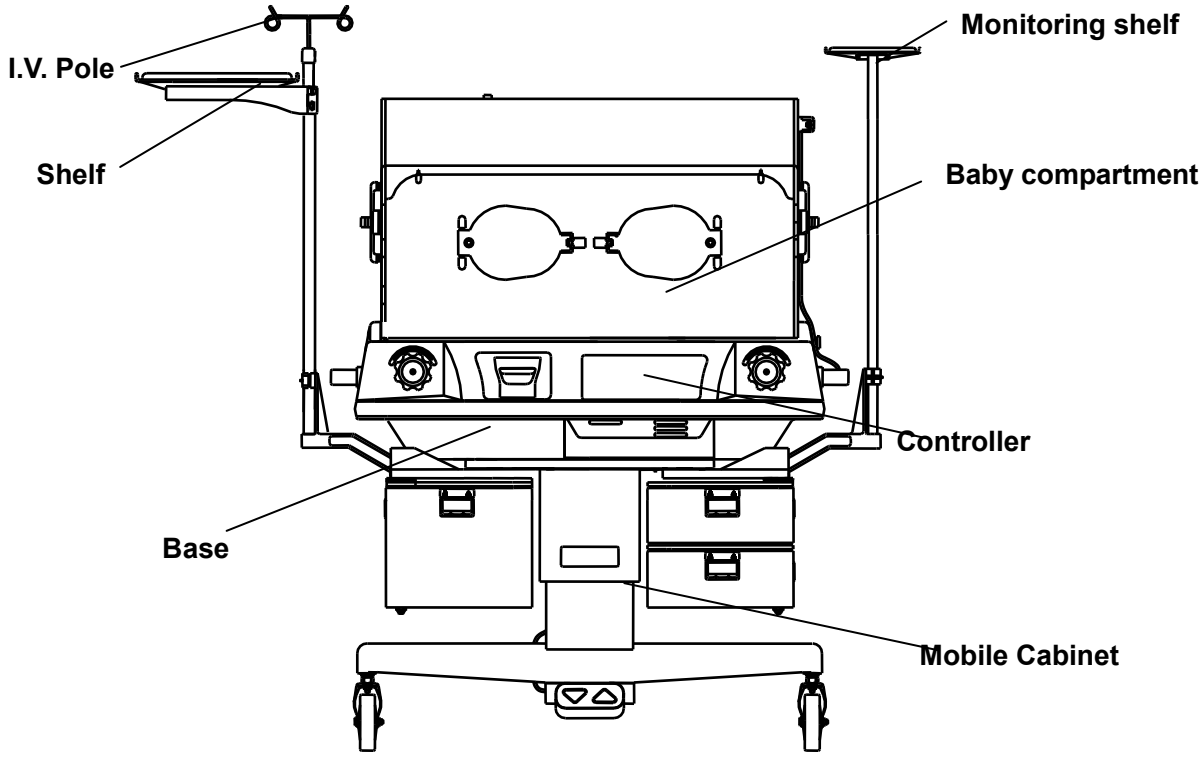
The Infant Incubator is intended to provide a controlled thermal environment and isolation from ambient air for premature and neonatal infants. The infant incubator is not intended for the transport of infants.

1.4 COMPOSITION OF PRODUCTS

The infant incubator consists of four components: the double wall hood, the base, the VHA stand, and the controller. The sponge based mattress positions centrally within the confines of the hood.

1.5 DESCRIPTION

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



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 have the function of weighing, humidity control and oxygen concentration controling system which are used for autocontrol 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
Monitoring shelf	A kind of bearing part, which is used for putting Infant monitor system. Max. Load: 8Kg
Baby compartment	It is used for placing the infant inside, including the Double-wall Acrylic hood, bassinet, and so on. 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 mattress with weighing system configuration: 8kg. Size of mattress: 740mm×376mm
Base	An important part of Infant Incubator, which mainly composed of the oxygen device, humidity chamber, air filter, and so on.
Mobile Cabinet	A part which can support the main body of Infant Incubator. Cabinets are supplied in VHA stand which including large and small storage compartment. Big storage compartment Max. load: 4 Kg. Small storage compartment Max. load: 2 Kg. Storage cover Max. load: 1 Kg.

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

NOTE: Size of Infant Incubator: L1500× W675×H1800mm ~L1500× W675×H1650mm.

Distance from the bassinet to the floor: 980mm ~ 1130mm.

Weight of Infant Incubator: 117Kg.

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, 1300VA
Maximum Heater Power Output	350W/240V
Auxiliary Mains Power Output	AC220V-230V/50Hz, MAX. CURRENT 3A
Heater power display	0 to 100%, adjustable in 10% increments
Temperature control modes	Air mode
	Baby mode
Air Temperature Control range	25℃~37℃
	37℃~39℃(override mode)
Baby Temperature Control range	34℃~37℃
	37℃~38℃(override mode)
Temperature sensor display range	5℃~65℃
Temperature rise Time* (environment temperature is +22℃)	≤40min
Temperature variability*	≤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℃
Skin temperature sensor precision	±0.2℃
ALARM(See 3.4 section)	
General alarm	Power failure alarm
	Fan motor alarm
	Sensor failure alarm
	Deviation alarm
	Over temperature alarm
	The sensor box position alarm
	Tank position alarm
	Water shortage alarm

TABLE 1.1 SPECIFICATIONS（continued）

System alarm……ROM failure alarm
Internal system failure Alarm
SRAM failure Alarm
EEPROM failure Alarm
Real time clock failure alarm
Communication failure alarm
ADC failure alarm
Key- board failure alarm
Battery failure alarm
LCD display failure alarm
Temperature heater failure alarm
Humidity heater failure alarm

HUMIDITY CONTROLLING

Running time after the Reservoir filled by distilled water……Humidity<70%RH, 24h at least

Reservoir's cubage……1200ml

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%～99%

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% ）

Oxygen concentration control precision……Within ±4% oxygen Volume concentration

Oxygen concentration setting range……20%～60%（adjustable in 1% each time）

Life time of oxygen sensor……10000h MAX. with 100% oxygen

WEIGHING DISPLAY

Weight range……100～8000g

Weight display resolution……1g

Weight display precision……±1%

TABLE 1.1 SPECIFICATIONS（continued）

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 PRESSURE

Shipment 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.

SECTION 2
INSTALLATION

2.1 GENERAL

This section provides installing procedures about Infant Incubator.

2.2 UNPACKING

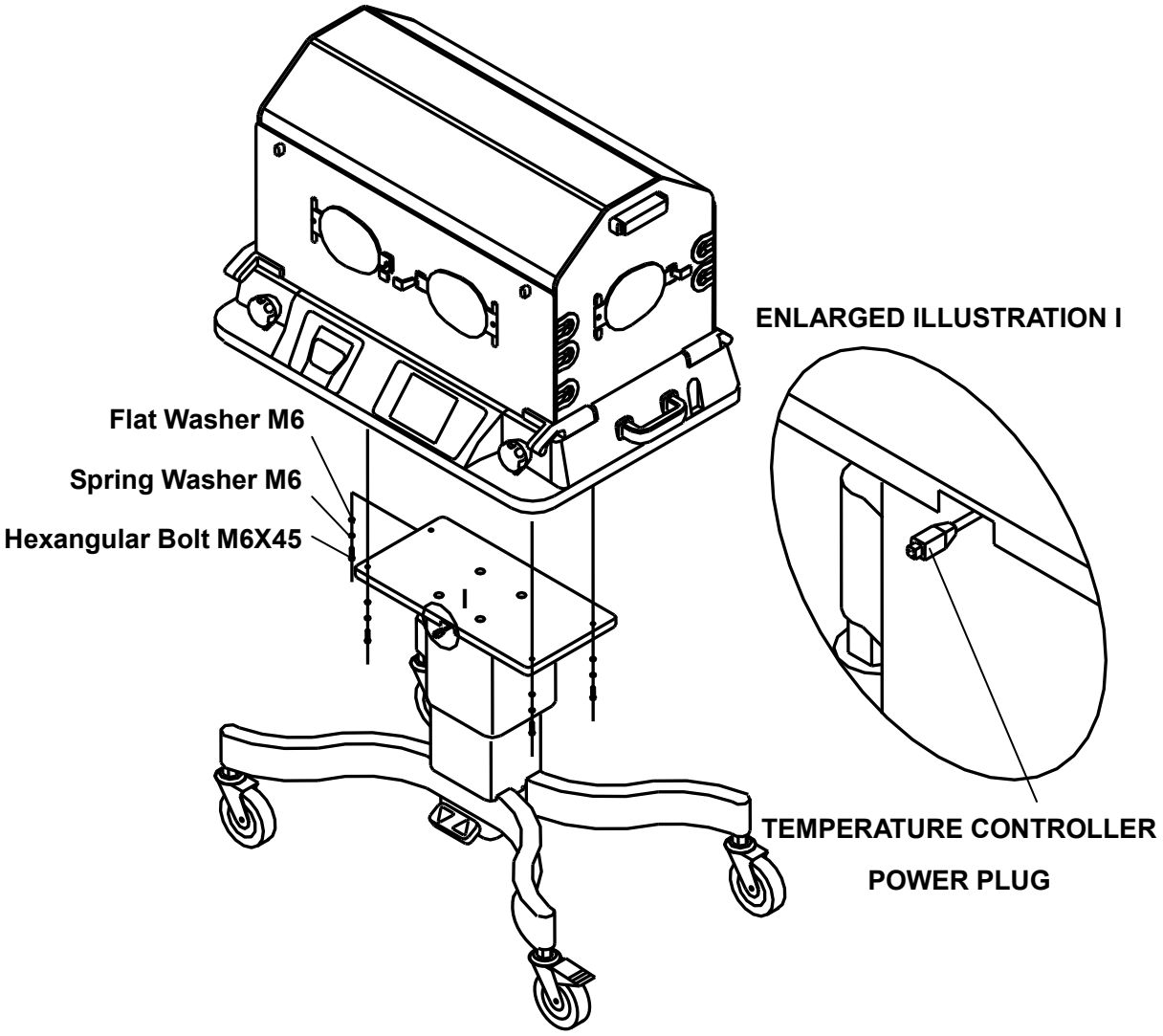
Generally, the Infant Incubator is usually packed to two cartons: main body and VHA stand. When taking out the equipment from the cartons, take care not to damage the spare parts of the Infant Incubator.

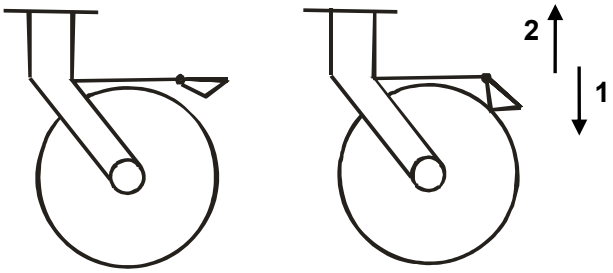
2.3 INSTALLATION

At least two professionals are required to do the installation of the Infant Incubator with spanners.

A. Install the main body onto the VHA stand

Mount the main body on the VHA stand using the four hexangular bolts M6X45, spring washer M6, flat washer M6 by the equipment provided figured as 2.1.





WHEEL UNLOCKED WHEEL LOCKED

Insert the temperature controller power Cord to the socket.

NOTE: The Pedestal front locking casters must be facing down to be locked indicated by arrow 1. The Pedestal front locking casters must be facing down to be unlocked indicated by arrow 2.

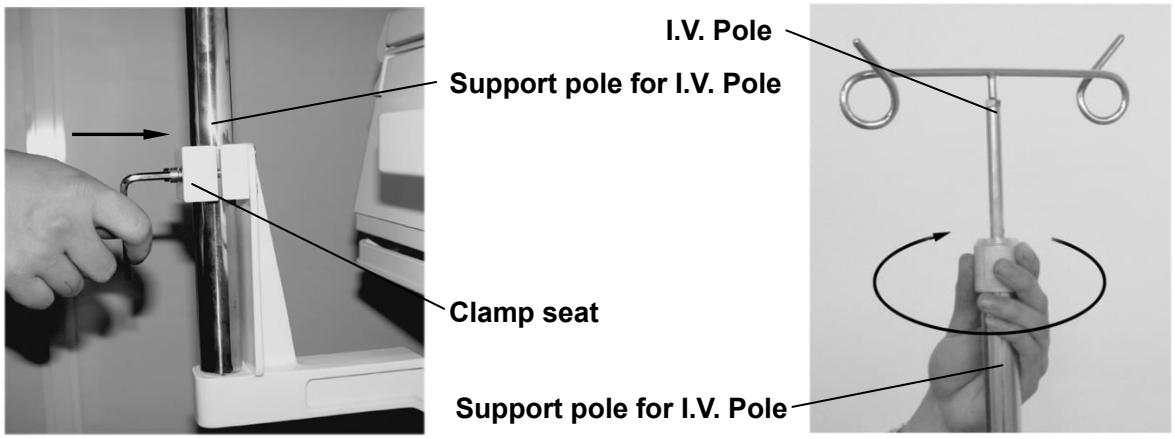
FIGURE 2.1

IMPORTANT: The main body can be installed on the VHA stand only if the power cord of temperature controller from the VHA stand is located on the same side as the temperature controller.

WARNING: 1. The incubator must be attached to the VHA stand using the bolts provided. Failure to do so could result in the incubator separating from the VHA stand if the VHA stand is tilted, particularly when the hood is opened.
2. To prevent the incubator from sliding when parked on an incline, the front locking caster for the VHA stand must be facing down the incline and locked.

B. Install the I.V. Pole

Step 1: Fix the seat for monitoring shelf on the right and left sides of the main body with the inner hexagon bolts.



Step 2: Fix the I.V. Pole on the Seat for the monitor shelf with latch seat and the inner hexagon bolts as the arrow indicates.

Step 3: Adjust the proper height of I.V. Pole, and tighten it as the arrow indicates.

FIGURE 2.2

C. Install Shelf

As figure 2.3 indicates, Use inner hexagon bolt and fix seat1 to fix the shelf on the I.V. support.

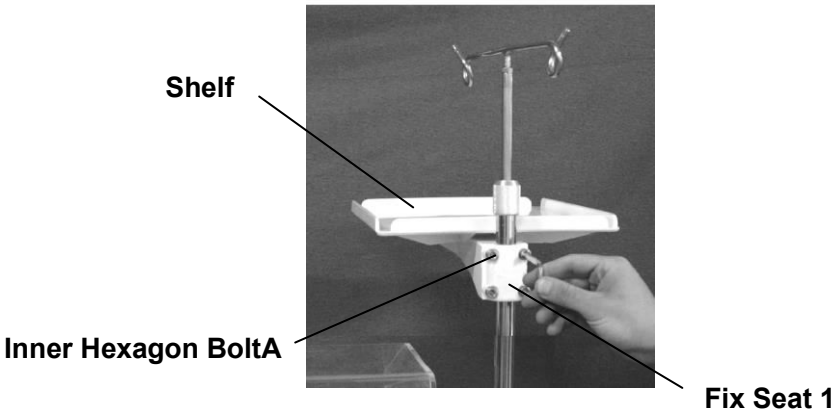


FIGURE 2.3

The side with note label of shelf must be installed in front of the incubator.

D. Install Monitoring Shelf

See figure 2.4, the fixing method of support pole for I.V. pole, fix the support pole for shelf on the seat for monitoring. Insert the one terminal of tray with hole into the hole of support pole of monitor, and fasten it with inner hexagon bolt tightly.

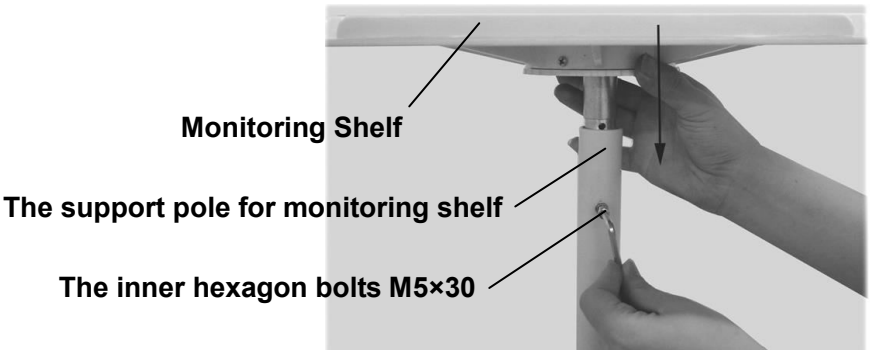


FIGURE 2.4

E. Install the storage

Put Φ6 spring washer, Φ6 flat washer and Φ6 outer sawtooth tighten washer onto the four inner hexagon bolt M6X20 by turn as figure 2.5 shows. Then fix the small storage and big storage to both sides of VHA stand separately by inner hexagon spanner.

FIGURE 2.5

F. Connect the sensor

Connect the sensor connector with sensor socket which is on the side of the incubator's main body as figure 2.6 directed. Then tighten the bolt in the connector.

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

FIGURE 2.6

G. Install oxygen sensor

Refer to the section 6 to see the detail.

H. Install weighing system

Refer to the section 8 to see the detail.

I. Insert the power cord

Insert the power cord into the socket of general power supply.

Check the INCUBATOR according to the instruction in section 4.3.

NOTE：The main power switch of the incubator is located in the VHA stand, not to position incubator to make it difficult to operate the power switch.

SECTION 3
FUNCTIONAL DESCRIPTION

3.1 GENERAL FUNCTIONAL DESCRIPTION

The Infant Incubator adopts temperature control system (**Air Mode** and **Baby Mode**), humidity controlling system, and 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 4.4.2.1;

Heat output control in Baby Mode: It will control the heater's output automatically according to the Skin temperature sensor, see instruction in section 4.4.2.2.

Oxygen input control：Auto control the valve according to the oxygen concentration in the incubator which 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 detected by the humidity sensor. Please refer the section 7 to see the details.

The infant incubator controller provides displays of Air temperature and skin temperature on an electro-luminescent display. Optional displays of humidity and oxygen concentration levels within the hood environment are available. In addition, trend displays of 2, 4, 8, 12, 24 of all parameters are user selectable, among which, the curve trend of weight measured by baby scale can indicate 1 week and 7 weeks.

To indicate which parameter (air or skin) is controlling, the rotating wheel in the air or skin soft key designator of display (figure 4.2 A) rotates.

Except for the listed parts in section 1.5, the Infant Incubator also has 4pcs casters. (Two of them with brakes)

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 flow through the oxygen input connector, then pass 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.

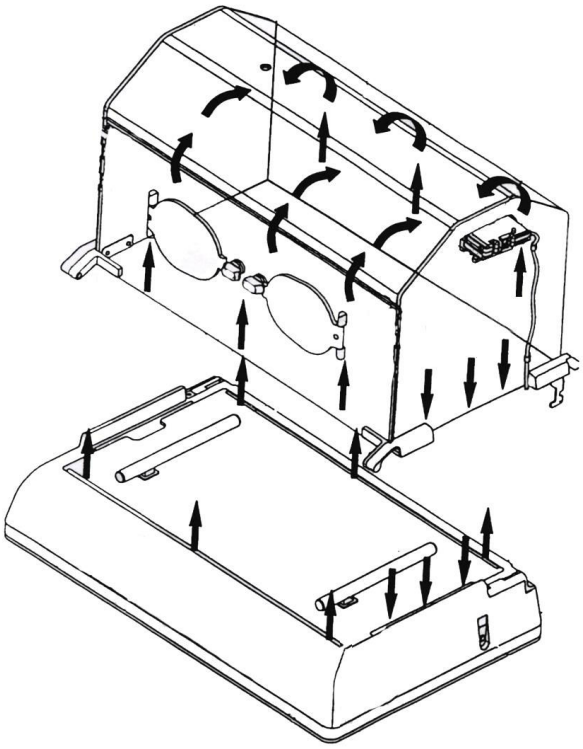


FIGURE 3.1

3.3 DATA COMMUNICATION CONNECTOR

The incubator is equipped with RS232 data communication connector and used for data terminal output.

1. If connect the auxiliary equipment on this interface, the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of IEC60601-1, clause 16.
2. Everyone should be responsible for the safety of the whole system requirements.
3. Only the equipment provided by our company can be connected with RS232 data communication connector. When using, must ensure the reliable connection.
4. The service department should be responsible for the maintenance of data communication connector, and inspect the data communication every year.
5. The connection and using of the data communication must be performed by special trained medical personnel, and the personnel should clear and definite the risk of data communication.
6. Do not touch RS232 data communication connector and patient simultaneously.
7. If have any question, please contact with the agency or the service department of our company.

3.4 ALARMING AND SYSTEM INDICATION INFORMATION

STATE

1. Alarm information

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

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

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

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 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 flashing, sound alarm start	Turn on the switch when without power supply	All	Off	High priority	<5s
2	Alarm sensor box is placed wrong	Red alarm light flashes, the indicator shows “Alarm Sensor box is placed wrong”, sound alarm start	Sensor box is placed wrong	All	Off	High priority	<5s
3	Alarm error air sensor	Red alarm light flashes, the indicator shows “Alarm Air Sensor Fault”, sound alarm start	Short-circuit, open circuit or bad connection inside the air temperature sensor	All	Off	High priority	<5s
4	Alarm error isolated sensor	Red alarm light flashes, the indicator shows “Alarm Isolated Sensor Fault”, 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 indicator shows “Alarm Air Sensor is different from Isolated sensor ”, sound alarm start	The difference between air sensor and isolated sensor above 0.8℃	All	Off	High priority	<2min

ALARM INTRODUCTION（continued）

Alarm no.	Alarm information	Alarm character	Alarm activation conditions	Control mode	Heater state	Alarm level	Alarm delay time
6	Alarm error air flow temp. sensor	Red alarm light flashes, the indicator shows “Alarm Air flow temp. sensor Fault”, sound alarm start	Short-circuit, open circuit or bad connection inside the air flow temperature sensor	All	Off	High priority	<5s
7	Alarm error skin sensor 1	Red alarm light flashes, the indicator shows “Alarm error Skin Sensor 1”, sound alarm start	Short-circuit, open circuit or bad connection inside the skin temperature sensor 1	Baby mode	Off	High priority	<5s
8	Alarm over temperature	Red alarm light flashes, the indicator shows “Alarm Over Temperature”, 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	<5s
9	Alarm error air flow	Red alarm light flashes, the indicator shows “Alarm Air flow Temp. Over Fault”, 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	<5s
10	Alarm skin sensor 1 is placed wrong	Red alarm light flashes, the indicator shows “Alarm Skin sensor 1 is placed wrong”, 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 mode	On	High priority	<15min
11	Alarm error motor	Red alarm light flashes, the indicator shows “Alarm Motor Fault”, sound alarm start	Motor stopped running or the speed is lower than 800r/m	All	Off	High priority	<15s
12	Alarm error fan in the sensor box	Red alarm light flashes, the indicator shows “Alarm Fan 2 Fault”, 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 deviation	Red alarm light flashes, the indicator shows “Alarm Temp. Deviation”, sound alarm start	Display temperature is 3℃higher than set temperature	Air mode	Off	High priority	<5s
			Display temperature is 3℃lower than set temperature	Air mode	On	High priority	<5s
			Display temperature of sensor 1 is higher 1℃ than set temperature	Baby mode	Off	High priority	<5s
			Display temperature of sensor 1 is lower 1℃ than set temperature	Baby mode	On	High priority	<5s
14	Alarm error O_2 sensor 1	Red alarm light flashes, the indicator shows “Alarm O_2 sensor 1 Fault”, sound alarm start	Short-circuit, open-circuit inside the oxygen sensor 1 or own fault	All	On	High priority	<5s
15	Alarm error O_2 sensor 2	Red alarm light flashes, the indicator shows “Alarm O_2 sensor 2 Fault”, sound alarm start	Short-circuit, open-circuit inside the oxygen sensor 2 or own fault	All	On	High priority	<5s
16	Alarm O_2 Sensors are different	Red alarm light flashes, the indicator shows “ Alarm O_2 sensors are different”, sound alarm start	The difference between oxygen 1 and oxygen 2 is 3%O_2	All	On	High priority	<10s
17	Alarm O_2 Deviation	Red alarm light flashes, the indicator shows “Alarm O_2 Deviation”, sound alarm start	Oxygen display value is 5%O_2 higher than set value	All	On	High priority	<5s
			Oxygen display value is 5%O_2 lower than set value	All	On	High priority	<5s
18	Alarm Error Fan in the Control Unit	Yellow alarm light flashes, the indicator shows “Alarm Fan 1 Fault”, sound alarm start	Fan inside the controller failure	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
19	Alarm Error Humidity Sensor	Yellow alarm light flashes, the indicator shows “Alarm Humidity Sensor Fault”, sound alarm start	Short-circuit, open-circuit inside the humidity sensor or own fault	All	On	Medium priority	<30s
20	Alarm Humidity Deviation	Yellow alarm light flashes, the indicator shows “Alarm Humidity Deviation”, sound alarm start	Humidity display value is higher 15%RH than set value	All	On	Medium priority	<5s
			Humidity display value is lower 15%RH than set value	All	On	Medium priority	<5s
21	Alarm Water reservoir is empty	Yellow alarm light is continued on, the indicator shows “Alarm Water Shortage”, sound alarm start	Water reservoir is lack of water	All	On	Low priority	<5s
22	Alarm Water reservoir is placed incorrectly	Yellow alarm light is continued on, the indicator shows “Alarm water Reservoir is placed wrong”, 4 minutes later, sound alarm start	Bad connection between water tank and base	All	On	Low priority	<5min

Alarm information	Detail description
System failure	When including Alarm ROM of main MCU Fault, Alarm Internal System of main MCU Fault, Alarm Communication A Fault, Alarm ROM of client MCU A Fault, Alarm Internal System of client MCU A Fault, Alarm Communication B Fault, Alarm ROM of client MCU B Fault, Alarm Internal System of client MCU B Fault, Alarm EEPROM Fault, Alarm SRAM Fault, Alarm ADC 1 Fault, Alarm ADC 2 Fault, Alarm ADC 3 Fault, Alarm Temperature Heater System Fault, Alarm Real Time Clock Fault, Alarm Humidity Heater System Fault, Alarm Battery Fault, Alarm Keyboard Fault, Alarm LCD display Fault, the alarm indicator light flash and cause sound alarm, the display 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 failure appears, should stop using the incubator immediately, and maintance the equipment by authorized qualified personnel.

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

3. Except for the power failure alarm, the other alarms are all can silence 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 occur multiple alarm at the same time, the device will give an alarm firstly for the higher grade. Press the twice of silence /reset key can cancel the alarm state then the equipment back to the set condition to monitor the alarm.

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

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

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

SECTION 4
OPERATION

4.1 GENERAL

This section provides operating procedures for the infant incubator.

4.2 POWER SUPPLY CONNECTION AND SWITCH CONTROL

As figure 4.1 indicates, Controls, indicators and connecters for the controller are presented in figure 4.1 and 4.2. As for the connection of oxygen input, please refer to the figure 4.3. The connection for the sensor module, and the connection and control of the VHA stand are presented respectively in figure4.4 and 4.5.

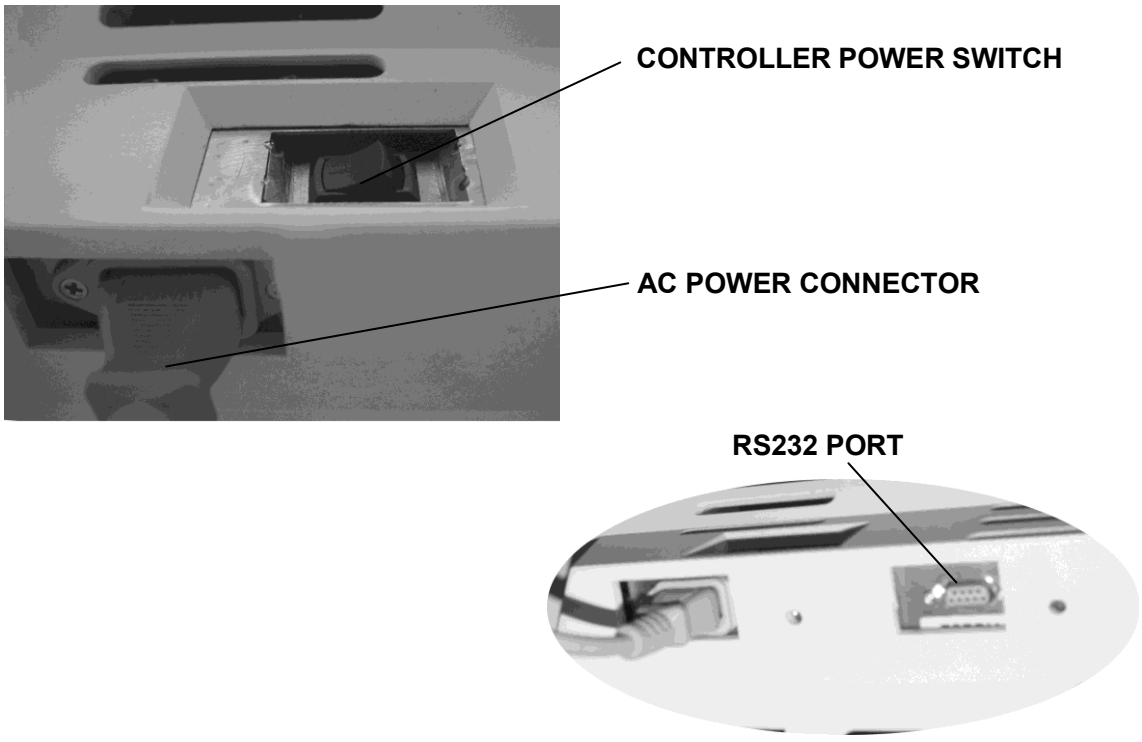
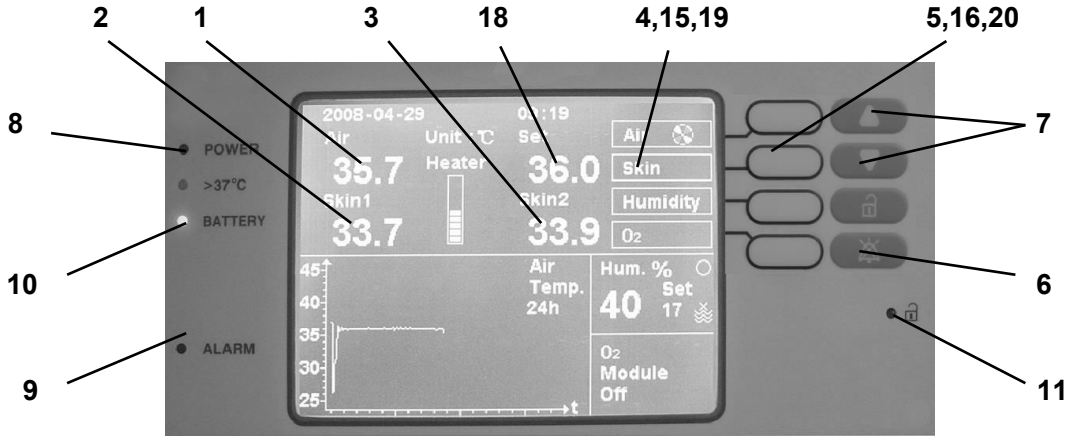


FIGURE 4.1

FIRST INDICATION INTERFACE
AIR, SKIN, OXYGEN AND HUMIDITY



1 Displays Air temperature
During alarm condition, the displayed temperature is the real temperature where locates the probe of air sensor.

2 Displays skin temperature on Probe No.1. "--.-" will be displayed when Skin Probe is disconnected.

3 Displays skin temperature on Probe No.2. "--.-" will be displayed when Skin Probe is disconnected.

4 self-definite function key
On first indication interface designates air, skin, humidity, and oxygen concentration. Press the air or skin key to enter into the second interface A, Press the humidity key to enter into the second interface B, press the oxygen concentration key to enter into the second interface C. As for the details, please refer to the relevant instruction.
Rotating wheel indicates air or skin control mode is active.

5 Self-definite function key.
On first indication interface, press to select one of the following parameter displays: Air temperature, skin temperature, oxygen concentration, and humidity.
Press Air temperature, skin temperature keys to enter into the second indication interface A, press humidity to enter into the second indication interface B, press oxygen concentration to enter into the second indication interface C.
Refer to other items for additional selections and other functions.

6 Silence /Reset Key
This key has two functions, when occurs alarm, press this key once to stop alarm, press this key twice to reset the alarm status , the incubator will back to the set state and monitor the alarm again.

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

8 Power alarm indicator
When flashing, illuminates along with audible alarm to indicate a power failure.

9 Alarm indicator

When it lights, please stop using it immediately and refer to the 3.4 chapter of alarm and system prompt information related contents in the specification.

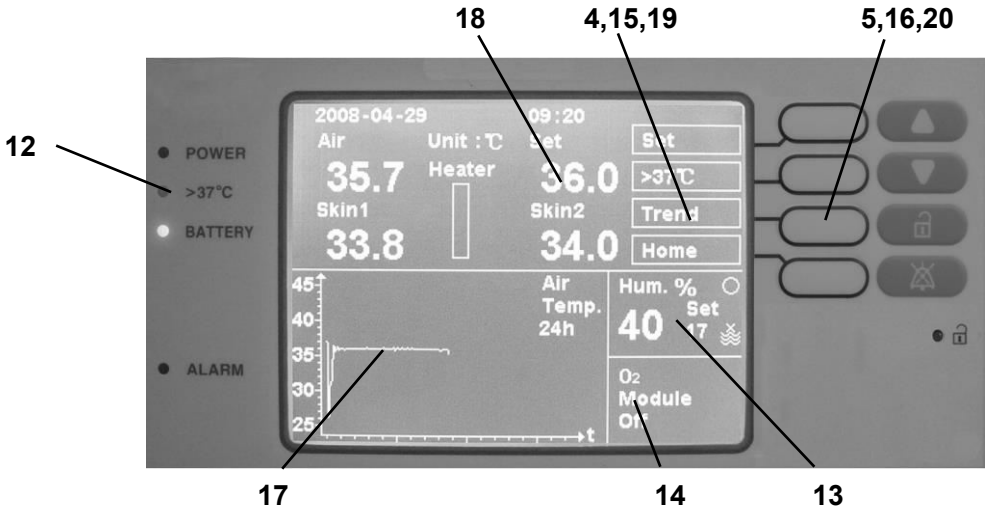
When the incubator occur failure alarm, the lamp will light. Alarm messages substitute for Trend displays.(Except for the power failure alarm)

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

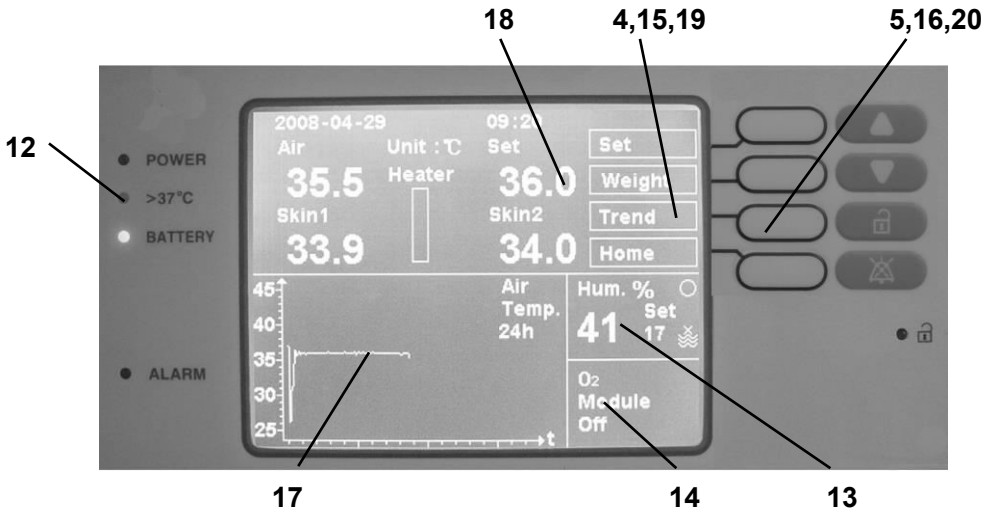
11 Keypad lock indicator light
When the lamp lights, the system in can set up state and all the function keys are in commission. when the lamp goes out, the system in can not set up sate and all the function keys are locked.

FIGURE 4.2 A

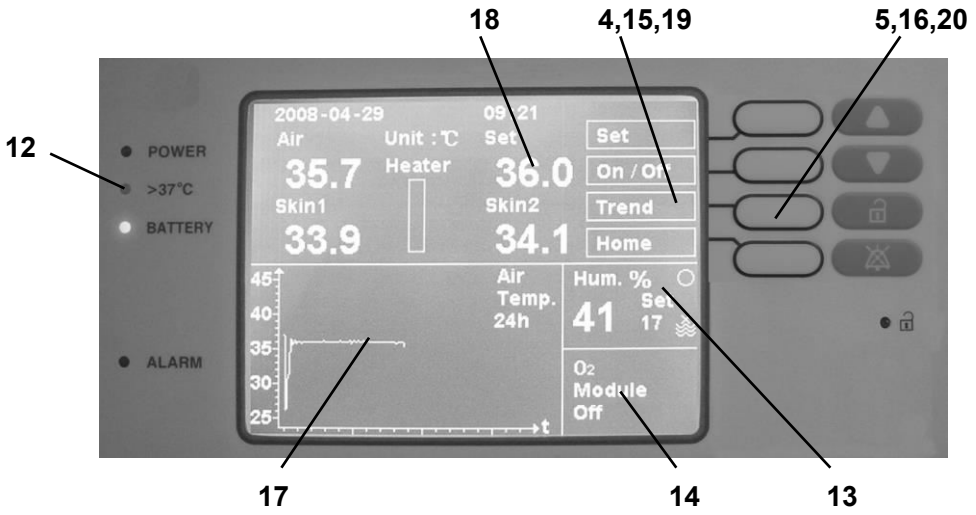
SECOND INDICATION INTERFACE A
TEMPERATURE SET



SECOND INDICATION INTERFACE B
HUMIDITY SET



SECOND INDICATION INTERFACE C
OXYGEN SELECTIVE FUNCTION SET



12 Lights to indicate temperature override mode >37℃ has been selected.

Notice: Before setting temperature value is set to 37℃, this key is invalid.

When in >37℃ Mode, the Infant is in high temperature condition, Physicians and Nurses should pay more attention to the Infant.

13 Humidity display- Display % RH within the hood environment and humidity set point. During alarm condition it displays % RH on Humidity Probe.

14 When this model is ready for shipping, the Oxygen concentration module is in the state of closing, and you need to start this function to use the Oxygen concentration module . Under the condition of starting the Oxygen concentration module, the system can indicate the Oxygen concentration inside of hood and the oxygen concentration setting value. As for the details, please refer to the Oxygen concentration monitoring /control system in section 6.

15 Self-definite function key On second indication interface A, designates: Set temperature, >37℃,Trend and Home. On second indication interface B, designates: set, weight, trends, return. On second indication interface C, designates: set, on/off, trends, return. Please refer to the item 4 about the nominated function of first interface. Also refer to individual parameter displays for other designations.

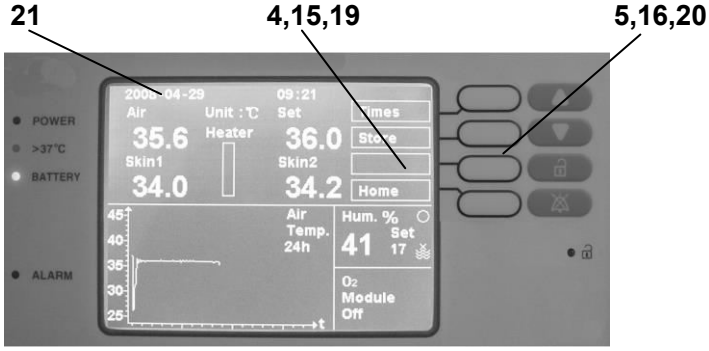
16 Self-definite function key. On second indication interface A, designates: Set temperature, >37℃,Trend and Home. On second indication interface B, designates: press this key can select the set value or humidity or oxygen concentration, weight function set, humidity or oxygen concentration curve, and return to the first interface, press the trend key to enter into the third interface A, and press the weight key to enter into the third interface B. Please refer to the section 4.4. Please refer to the item 5 about the nominated function of first interface. Also refer to individual parameter displays for other designations.

17 Displays one of the following Trends: air temp, skin temp 1, oxygen concentration, humidity, weight. The curve trend can indicate time intervals consult in 2hrs, 4hrs, 8hrs, 12hrs, and 24hrs.among which, the weight curve intervals are 7days, 2weeks, 3weeks, 4weeks, 5weeks, 6weeks and 7weeks In normal working condition, it can indicate the chosen trend.

18 Temperature Set Point Display
The Set Point is under this Working Mode.

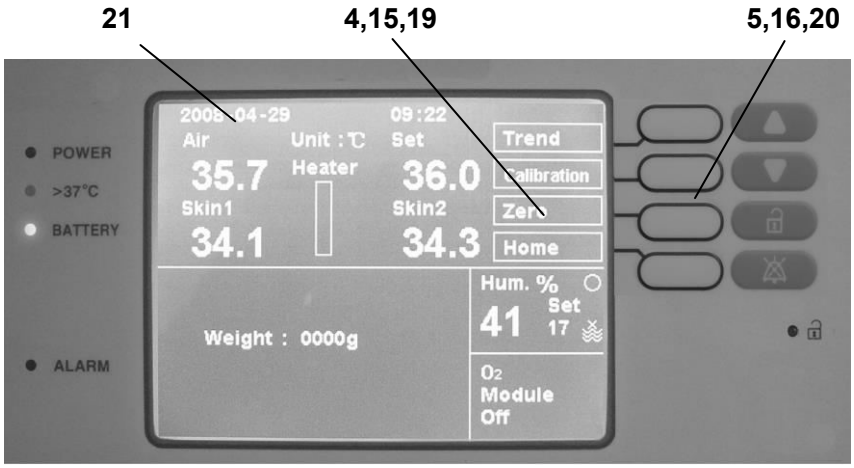
FIGURE 4.2B

THIRD INDICATION INTERFACE A
INTERVAL OF THE TREND TIME SET



THIRD INDICATION INTERFACE B

WEIGHT SETTING



19 self-definite function key. on the third interface A, you can specify : the trend intervals and the restore. on the third interface B, you can specify : weight trend setting, calibration, be to zero. Refer to item 4, item 15 for the functions on first indication interface and second indication interface. Also refer to individual parameter for other designations.

21 time indication
Please refer to the section 4.3.2 for current timer indication, and the user can reset according to the local time.

20 self-definite function key. on the third interface A, press this key to select the trend intervals, restore setting and the setting of returning to the first interface, on the third interface B, press this key to weight trend setting, calibration, be to zero and the setting of returning to the first interface.
Refer to item 5, item 16 for selective function of first indication interface and second indication interface. Also refer to individual parameter for other designations.

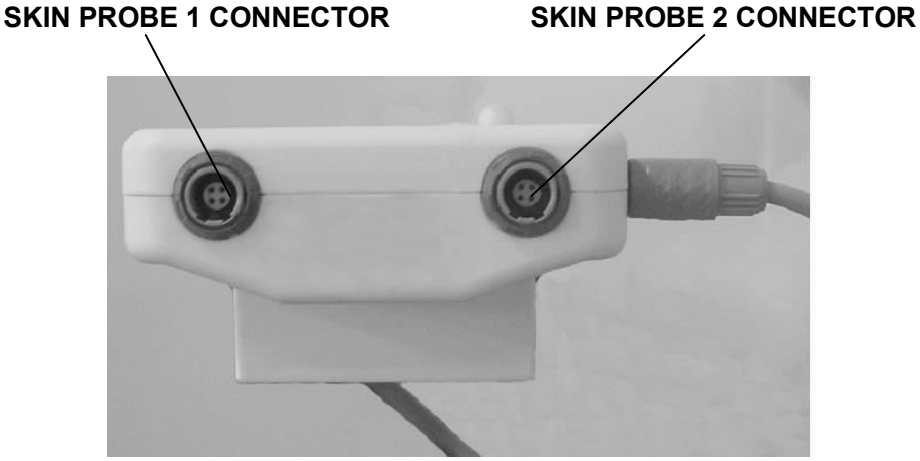
WARNING: To operate the Controller strictly as described in this Manual. Don't press any key optionally on the panel.

FIGURE 4.2C

Manual Oxygen Input Port

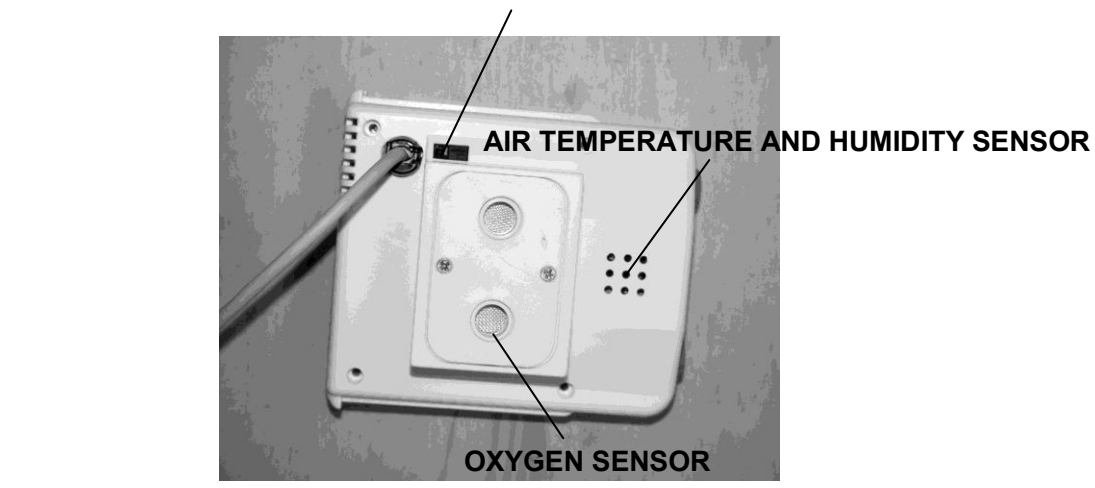
Servo Control Oxygen Input Port

FIGURE 4.3



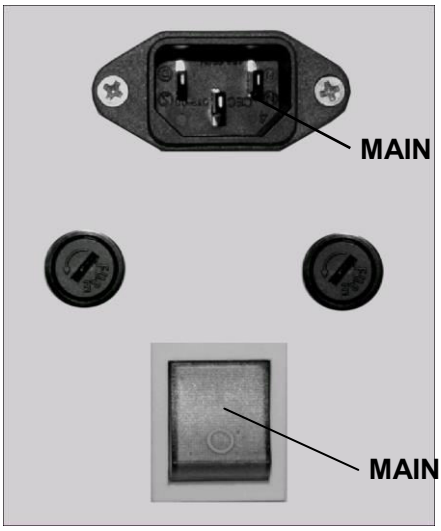
SKIN TEMPERATURE PROBE CONNECTORS

FIGURE 4.4A

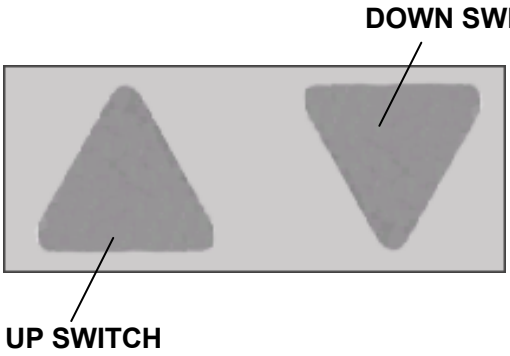


DISTRIBUTION OF SENSORS

FIGURE 4.4B

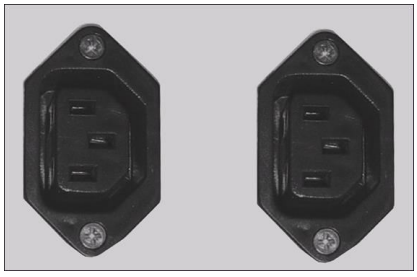


MAIN POWER SWITCH CONNECTOR



THE VHA STAND CONTROL

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



AC OUTPUT RECEPTACLES

FIGURE 4.5

WARNING: Connecting electrical equipment to the SOCKET-OUTLET effectively leads to creating an ME SYSTEM and the result can be a reduced level of safety. To complete the ME SYSTEM requires evaluation to the requirements of IEC60601-1, clause 16.

4.3 OPERATIONAL CHECKOUT PROCEDURE

WARNING

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

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

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

Incubator should be only operated by trained personnel who knows familiar about 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 equipment within 20cm in front of the device, and the specific distance between the device and operator with the operation comfort level.

4.3.1 CHECK THE INTEGRITY OF INCUBATOR

- Make sure that the device has been sterilized;
- Make sure that the hood are 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 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 caster can drop when lifting the incubator 2cm above the ground. In the process of moving, when the loose caster dorp during the incubator crossed the cable, threshold or elevator threshold, it would case dangerous. Please do not move incubator before replace the loose caster.

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 lapelled on the incubator. The equipment can not use the extension power cord.

A. START-UP THE CONTROLLER

Open the power switch (If applicable) and the contorller power switch when the power is supply, the device sounds like "di..." and company's label and the system edition will be displayed. Then self-check being carried for RAM, SRAM, REAL TIME CLOCK, EEPROM and communication system by the main body of the device. After through self-inspection can access control interface, keyboard lock indicator light shine, or else, the screen indicates the reason for not passing the self-check procedure and display the words of "**Please repair it by professional maintenance man**".

B. CHECK THE POWER FAILURE ALARM

Disconnect the power supply of whole unit; the device should give a power failure alarm, the power failure alarm 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 indicator are on, and heater will output heat completely.

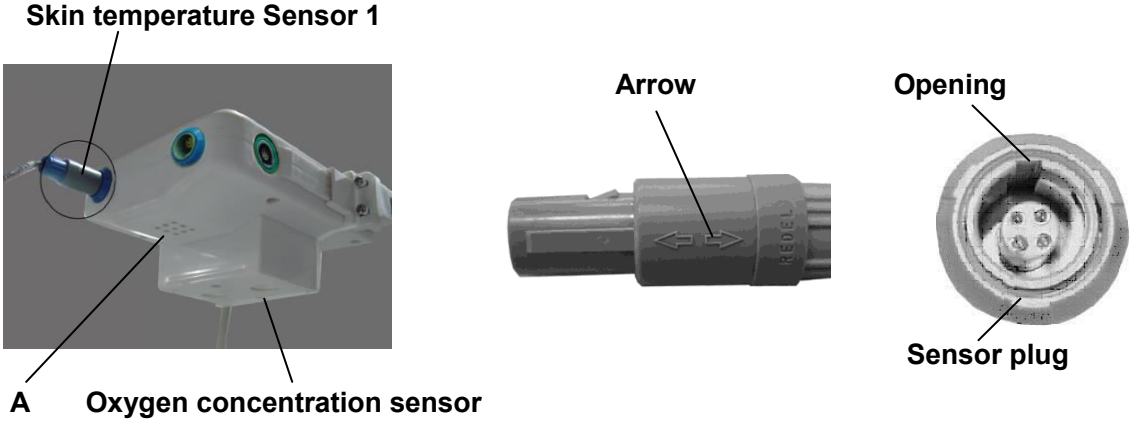
NOTE: When the incubator works under the set state, and continue the following operation procedure.

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℃.

E. CHECK BABY MODE

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



Humidity sensor and air temperature sensor are located in the position A

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 stablly, 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. After a while the incubator can give a high priority alarm sound, "**Alarm Skin sensor 1 is placed wrong**" information will replace the curve indication on the screen, the alarm character should be consistent with the description of section 3.4.

Disconnect the connection of skin temperature sensor and socket 1. The device should give a high priority alarm sound, "**Alarm Error Skin Sensor 1**" information will replace the curve indication on the screen, and the alarm character should be consistent with the description of section 3.4.

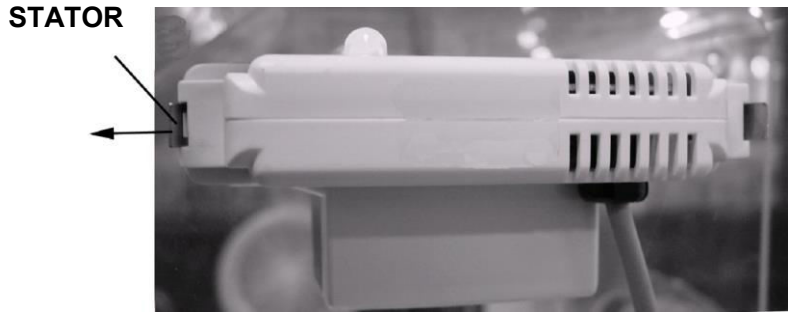
F. CHECK PRECISION OF SKIN TEMPERATURE SENSOR

Put the skin temperature sensor with the mercury thermograph for the accuracy with ±0.1ºC into the water cup with warm water. 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 permissibility deviation. Please let the professional maintenance man service machine if the accuracy the skin temperature sensor exceeds the permissibility of deviation again.

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 controller can give a high priority alarm sound and indicates "**Alarm Sensor Box is placed wrong**" information, and alarm character should be consistent in the description of section 3.4. The sensor connection light is on. After the modular being put into the correct location and being fixed by stator, the alarm cancels automaticly as well as the sensor connect indicating light off.

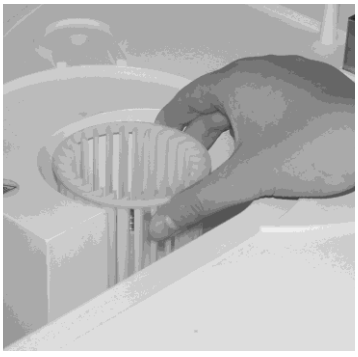
WARNING: 1. All gaps in the sensor module must not be blocked.

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

3. Sensor Module is an important part which supply Temperature Control to Incubator, and must operate carefully.

H. CHECK FAN MOTOR ALARM

Refer to paragraph 4.3.3 A, open the hood, and take out Infant Mattress, Mattress Tilt Mechanism, Mattress Tray, and the heater cover. According to the operations sequence of section 5.2.1. As the follow figure, hold the Motor Fan on hand carefully, turn on the switch of the controller power, the device should give a high priority alarm sound, "**Alarm Motor Fault**" information will replace the curve indication on the screen, the alarm character should be consistent with the description of section 3.4. Press the Silence/Reset key, alarm is over and the Controller return to operation status.



NOTE: It must take at least 45 minutes after the incubator stopped working to perform this operation.

I. CHECK OVER-TEMPERATURE ALARM

The device into the working state, press the air temperature self-definite function key and set value increasing key in figure 4.2A, at this time, all heating indicators are on, If the set temperature is no indication, it means that the controller has entered into the over-temp test state. After a long time, the device should give a high priority alarm sound, "**Alarm Over Temperature**" information will replace the curve on the screen, and the alarm character should be consistent with the description of section 3.4. Press silence/reset key, alarm is over and the Controller return to operation status.

J. CHECK DEVIATION ALARM

In **Air Mode**, close all door 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 can give a high priority alarm sound, "**Alarm Temp. Deviation**" information will replace the curve indicator on the screen, 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 can give a high priority alarm sound, "**Alarm Temp. Deviation**" information will replace the curve indicator on the screen, 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 can give a high priority alarm sound, "**Alarm Temp. Deviation**" information will replace the curve indicator on the screen, 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 can give a high priority alarm sound, "**Alarm Temp. Deviation**" information will replace the curve indicator on the screen, 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 can give a low priority alarm sound, "**Alarm Water Shortage**" information will replace the curve indication on the screen, and the alarm character should be consistent with the description of section 3.4.

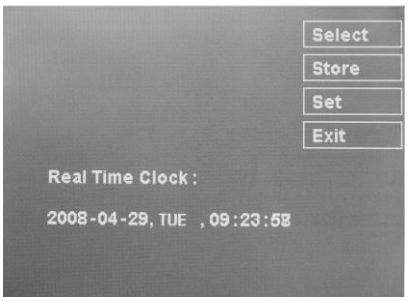
L. CHECK THE WATER RESERVOIR POSITION WRONG ALARM

When the incubator is in the working state, pulling out the water tank, the device should give a low priority alarm sound, the yellow alarm light continue on, "**Alarm water Reservoir is placed wrong**" information will replace the curve indication on the screen, and the alarm character should be consistent with the description of section 3.4. 4 minutes later, the water tank is still not in position, the alarm sound start immediately.

M. CHECK THE TIMER

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

Press the first soft key(from top to bottom) of the controller in close state and then open the controller, the controller will enter as follow figure interface and set the record time. The controller's time display in turn order is year, month, day, week,hour,minute and second, year is displayed by four digits, the first two on behalf of the century value and last two on behalf of year.



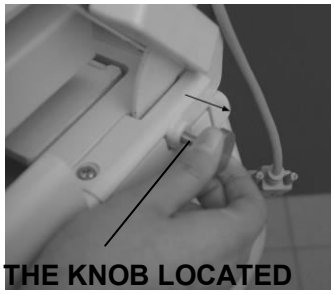
Press set self-definite function key, the underlined century can indicate, and then press the select self-definite function key, the underline can move with the time indication, press the increasing key or the decreasing key can change the underlined information, after correction, press the store key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

4.3.3 MECHANICAL EXAMINATION

A. CHECK THE HOOD OPERATION

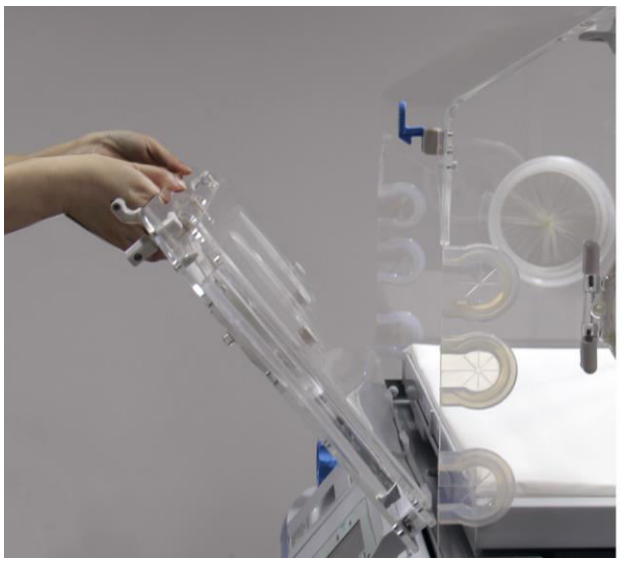
NOTE: Make sure all cables are disconnected from the all accessories before raising the hood in order to avoid interfering with raising the Hood.

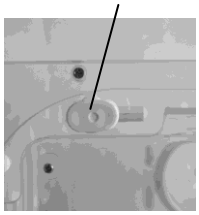
Disconnect the cord of sensor module.



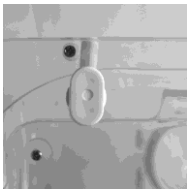
Disconnect the cord of the Sensor Module. Slowly tilt the Hood back until the Hood locks in place. Release the Hood by pulling on and holding the knob located on the right rear hinge while closing the Hood.

B. CHECK THE ACCESS PANEL





UNLOCK



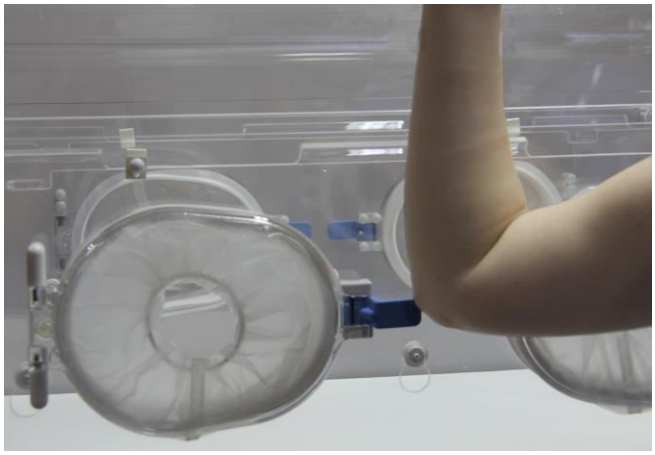
LATCHED

Rotate the panel Latches and make it stays opening. Press the latch seat to open the Access Panel to the full open position (rotate downward). Close the Access Panel, the seat latch 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

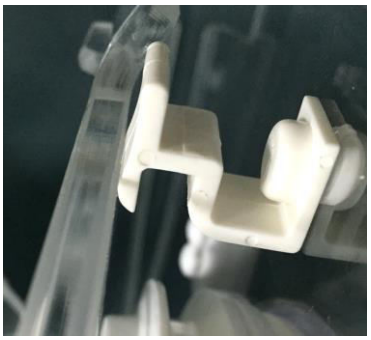
Rotate the outer ring of each enrty Port, the port should be open and close as rotation is continued through 360 degree.

D. CHECK THE LATCH AND GASKET OF ACCESS DOOR



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

E. CHECK INNER WALLS ARE PROPERLY LATCHED



INNER WALL UNLATCHED

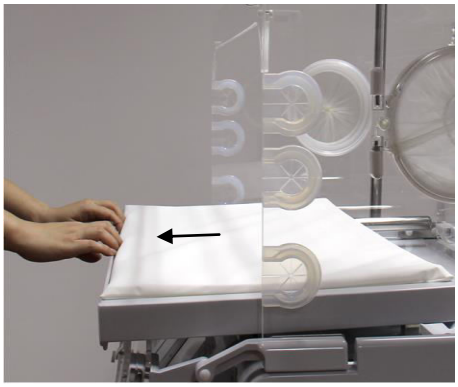
INNER WALL LOCKED

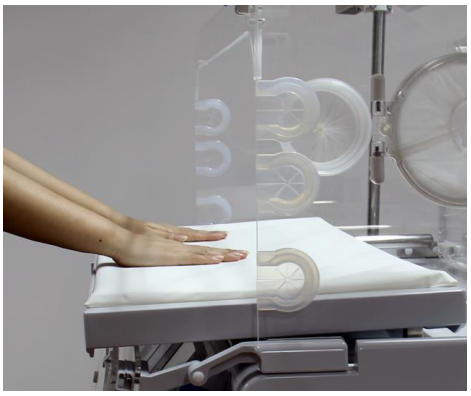
Open the Access Panels and check that the front and rear inner walls are properly latched.

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.

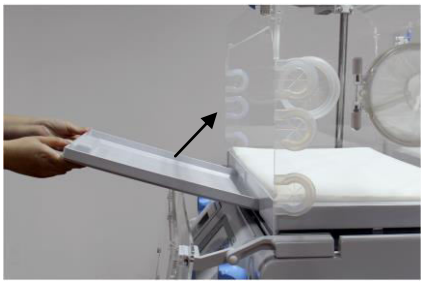
H. CHECK THE AIR INTAKE FILTER

Loosen the two thumb screws of the Air Intake Filter Cover and remove the cover and inspect the filter, if dirty, it should be cleaned. Put the filter cover back.

A dirty air filtering material will increase the concentration of carbon dioxide inside the hood, according to the actual condition, must check the air filter materials regularly. If the air filters materials look dirty or used more than 2 months, should replace it.

I. CHECK THE X-RAY TRAY

Open the Access Panel and withdraw the X-Ray Tray.



The X-Ray Tray can be pull out easily Indicated as the arrow.

J. CHECK THE HIGH ADJUSTMENT OF THE VHA STAND

Step the Up and Down button with your feet in figure 4.5 to adjust the height of whole unit.

4.4 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 3℃ higher than environment temperature.**
4. **The display module of the controller is susceptible to electromagnetic interference, so can not use the controller under the high electromagnetic field. If a device which sends or receive weak signal installed in the equipment nearby, it may be affected by the electromagnetic wave sent by this equipment. Before using, please check if the device has been affected.**

4.4.1 PREPARATION

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

4.4.1.2 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 non-prewarm incubator. The specific prewarm method is as follows:

See section 4.4.2.1, set a proper control temperature, and make the device continue working until the air temperature reaches the control value.

IMPORTANT: 1. The temperature of the warm air entering the Patient Compartment at the front and rear of Incubator is higher than the typical air Incubator temperature; therefore, keep the infant clear of the slots where the warm air enters the Patient Compartment.

2. Please ask the physician to decide the set temperature.

4.4.2 OPERATION

4.4.2.1 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 the sensor probe and compared with the set air temperature. The result of comparing 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 active, and the heater is cut off.

SELECT AIR TEMPERATURE CONTROL AND SET POINT

On first indication interface, the keypad lock indicator light is on (If not on, press the keypad key); press the Air self-definite function key to enter into the second interface A (Temperature setting interface). Refer to Figure 4.6, and set the Air Temperature to the prescribed temperature. Once stabilized, the air temperature will be maintained within± 0.2℃of the set temperature.

Air temperature is trended over periods of 2, 4, 8, 12 and 24 hours. Refer to Paragraph 4.4.2.3 to select Air-Trend Display.

In the air temperature control mode a sign of moving caster is running means the incubator is operating by air temperature mode. Air temperature and set temperature are display in air temperature and set position at same time.If skin temperature sensor 1 and 2 respective connect with socket 1 and 2, the skin temperature sensor probe temperature is display skin temperature 1 and 2 position, if not connected, the display is“--.-”。

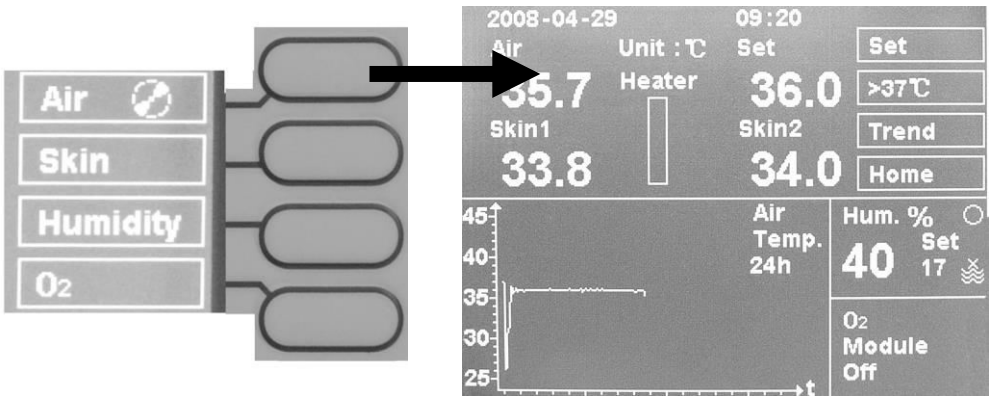
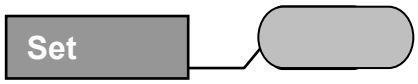


FIGURE 4.6

NOTE: 1. All setting should be operating under the keypad lock indicator light is on.

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

1 

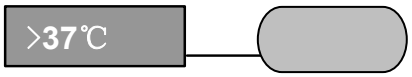
Press this key to enter the Air Temperature Setting, the Indicator “Set” flashes.

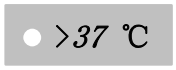
2 
Set
32.0

Press Up Arrow to raise set temperature to 37℃. In Temperature Override Mode (Step 4), press to raise set temperature from 37℃ to 39℃. Press one time to raise set temperature setting in 0.1℃ increments. If press this key continuously, the setting temperature can rise rapidly.

3 
Set
32.0

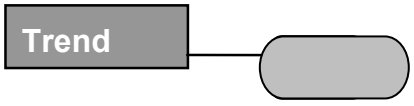
Press Down Arrow to lower set temperature to 25℃. Press one time to lower set temperature setting in 0.1℃ increments. If press this key continuously, the setting temperature can decrease rapidly.

4 

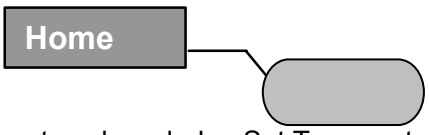


Press to place Air Set Temperature in Temperature Override Mode, >37℃ Indicator lights and the actual air temperature on the probe is displayed. If press this key continuously, the setting temperature can decrease rapidly.

NOTE: This key is inoperative until the air set temperature has been set to 37℃.

5 

Press to enter the third indication interface A curve set Refer to Paragraph 4.4.2.3 for details.

6 

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

7 

Press this key, the keypad lock indicator light will shine and access controller set state. After setting back to first interface, press keypad lock to control area, and keypad lock indicator light goes out, or don’t press any key it will return to control state automatically and keypad lock indicator light goes out after 15 seconds.

8 ● ALARM 

Under the alarm condition, the alarm light will flash and sound alarm calls, the alarm message instead of the curve display(expect outage alarm). Please refer to the specific description of 3.4 chapter. Alarm mute/reset key has two functions, when occurs alarm, press this key once to stop alarm, press this key twice to reset the alarm status , the incubator will back to the set state and monitor the alarm again.

4.4.2.2 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.

Refer to the step B in section 4.4.2.1, Connect the Skin sensor to the socket 1 on the sensor box correctly. On first indication interface, press SKIN self-definite function key to select **Baby Mode**, the controller can enter into the second indication interface A. Please refer to the figure 4.7 and the skin temperature setting part. Once stabilized, the infant probe temperature will be automatically controlled within ±0.2℃ of the set temperature. When the wheel in the screen is running beside the skin temperature control mode, and it means that the incubator is working in the **Baby Mode**.

IMPORTANT: The controller of Infant incubator controls the temperature in the incubator by sensor inserted in sensor socket 1. Therefore, the sensor must be connected to sensor socket 1 when the controller controls the temperature in the incubator by skin temperature. The sensor connect to sensor socket 2 couldn't control the temperature but only display detected temperature.

In **Baby Mode**, Skin Temperature 1, Air Temperature and Set Point Temperature are displayed at the same display. If the Skin Probe is connected with Skin Connector 2, the temperature from the Skin Probe 2 will also be displayed there.

In the **baby mode**,the skin temperature sensor 1 should be closed to baby skin.The incubator internal controller compare the skin temperature sensor 1 detect temperature value with the set skin temperature,and according to the comparison result output control signal control temperature heater of heating rate, eventually make the skin temperature 1 sensor detects the temperature stability near the set value.

Infant skin temperature is trended over periods of 2, 4, 8, 12 and 24 hours. Refer to paragraph 4.4.2.3 to select Skin Trend Display.

For seting the appropriate temperature and correctly control the baby temperature of the infant, the incubator hold 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 rise the air temperature in the incubator in the speed of 1℃ per hour to enable the slowly rising of the infant's temperature and avoids the damage bringed by the rapid rising of the temperature as well. If the baby temperature detected is always 2℃ below the set temperature in 1 hour, "**Alarm Skin sensor 1 is placed wrong**" alarm will be actived by system. At that time, the incubator still rise the air temperature in the hood slowly until the air temperature reaches the **STEADY TEMPERATURE CONDITION** which its temperature is equal to " set skin temperatur -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 lower 5℃ 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 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 lower than 31.3℃; while the baby temperature rising to 36.7℃ which is higher 0.5℃ than the set temperature, the air temperature in the incubator will not lower than 25℃.

CONNECT THE PROBE OF SKIN TEMPERATURE SENSOR TO THE PATIENT:

In **Baby Mode**, make sure that the probe of skin temperature sensor 1 is attached closely on the skin of patient. Put the probe on the right position of skin, and clean the position of skin where the skin sensor located and the metal surface of skin sensor probe with alcohol or the moderate water to wipe off the grease and dirt. In order to fix the probe' 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

1. **Make sure that the probe of skin sensor 1 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.**
2. **Please do not cover the blanket or diaper on the probe of skin sensor, because it will affect the accuracy of temperature.**
3. **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.**

SELECT BABY MODE AND SET POINT

Press the Skin Temperature Soft key to enter the interface as figure 4.7 when the keypad lock indicator light is on.

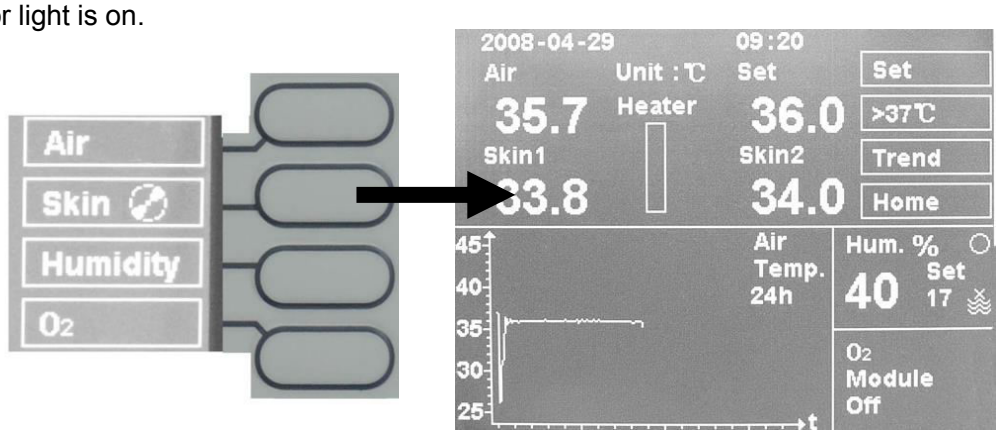
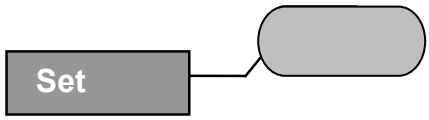


FIGURE 4.7

NOTE: 1. All setting should be operating under the keypad lock indicator light is on.

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

1 

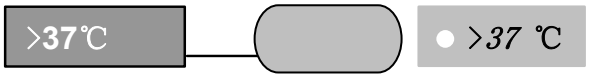
Press this key to enter the Skin Temperature Setting, the Indicator “Set” flashes.

2 

Press Up Arrow to raise set temperature to 37℃. In Temperature Override Mode (Step 4), press to raise set temperature from 37℃ to 38℃. Press one time to raise set temperature setting in 0.1℃ increments. If press this key continuously, the setting temperature can rise rapidly.

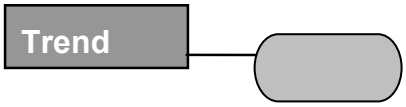
3  Set 34.0

Press Down Arrow to lower set temperature to 34℃. Press one time to lower set temperature setting in 0.1℃ increments. If press this key continuously, the setting temperature can decrease rapidly.

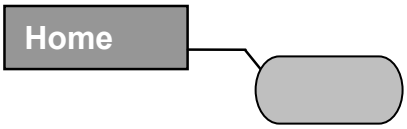
4 

Press this key, the device enters into the Temperature Override Mode, >37℃ Indicator lights and the controller can working the >37℃ temperature setting.

NOTE: This key is inoperative until the skin set temperature has been set to 37℃.

5 

Press to enter the third indication interface A curve trend setting. Refer to Paragraph 4.5 for details.

6 

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

7 

Press this key, the keypad lock indicator light will shine and access controller set state. After setting back to first interface, press keypad lock to control area, and keypad lock indicator light goes out, or don't press any key it will return to control state automatically and keypad lock indicator light goes out after 15 seconds.

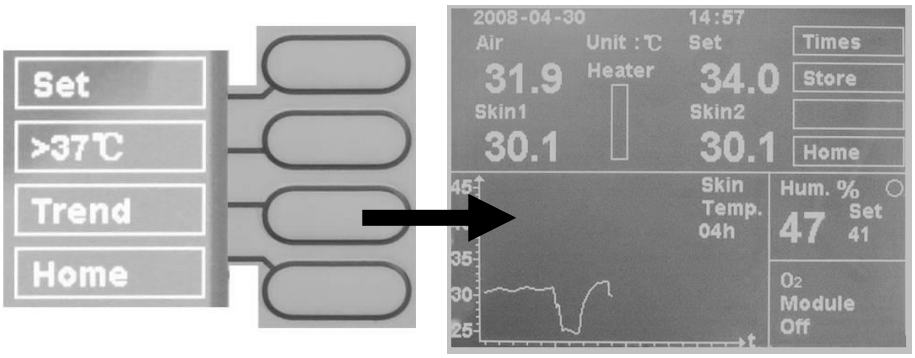
8 

Under the alarm condition, the alarm light will flash and sound alarm calls, the alarm message instead of the curve display(expect outage alarm). Please refer to the specific description of 3.4 chapter. Alarm mute/reset key has two functions, When occurs alarm, press this key once to stop alarm, press this key twice to reset the alarm status , the incubator will back to the set state and monitor the alarm again.

4.4.2.3 TREND DISPLAYS

On second interface A, press the curve self-definite function key to select the menu of the following curve indicates.

SELECT TREND ON SECOND INDICATION INTERFACE A

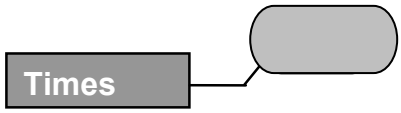


NOTE: 1. All setting should be operating under the keypad lock indicator light is on.

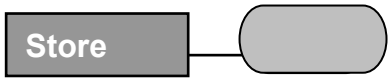
2. In the state of air temperature control, press the curve self-definite function key, and then the choice is the air temperature curve indication, while in the state of skin temperature control, press the curve self-definite function key, and then the choice is the skin temperature curve indication.

3. If no keys are pressed within 15 seconds of selecting this Display, it will automatically revert to first indication interface and restore the last operation results. (Except the step2: like are you sure question, and return the last interface)

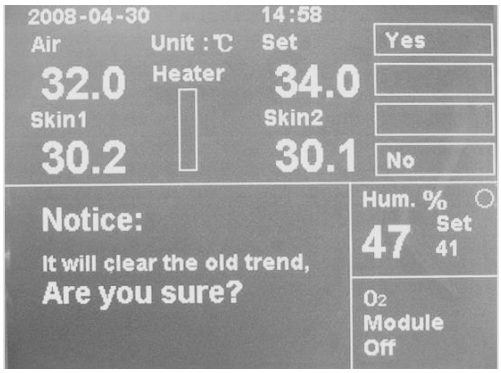
FIGURE 4.8

1 

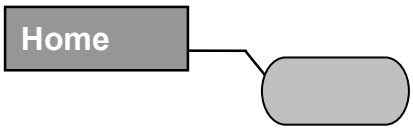
Press this key continuously to select the time intervals of curve trend, curve indication area can indicate 2 hrs, 4 hrs, 8 hrs, 12 hrs, and 24hrs.

2 

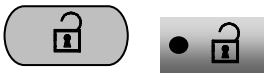
Press this key to restore from the current state, meanwhile, the following interface can be indicated, and inquiry the operator YES or No.



Press Yes key to return to the last screen, the controller can restore the infirmation in cancelling the original infirmation, Press NO key to return to the the last screen, the controller can restore the infirmation on basis of the original infirmation.

3 

press this key to return to the first interface, the curve indicator can display the control mode.

4 

Press this key, the keypad lock indicator light will shine and access controller set state. After setting back to first interface, press keypad lock to control area, and keypad lock indicator light goes out, or don't press any key it will return to control state automatically and keypad lock indicator light goes out after 15 seconds.

4.4.3 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 4.3.3.

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. X-RAY PROCEDURES

1. Open the Access Panel and withdraw the X-ray Tray from under the mattress.

2. Place the X-ray Cassette in the center of the X-ray Tray.

3. Place the Infant at center Mattress. Close the Access Panel. When the X-Ray is complete remove the X-ray cassette from the tray and return the tray.

C. Operation to the oxygen concentration control system.

Please reffer to the section 6.

D. Operation to the humidity control system

Please reffer to the section 7.

E. Operation to the weighting control system

Please reffer to the section 8.

4.4.4 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: 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.

5.2 CLEANING

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

5.2.1 DISASSEMBLY BEFORE CLEANING

1. Turn off the Power Switch on the VHA stand and remove the Power Cord. Refer to Paragraph 4.3.3, Step A, and disconnect the cables from the Sensor Module and slowly raise the Hood.

CAUTION: Before lifting Incubator Hood for cleaning, ensure that all mounted accessories have been removed to prevent possible interference with the raised Hood.

2. Refer to Paragraph 4.3.3, Step I, and remove the X-ray Tray from the Mattress Tray.

3. Refer to Figure 5.1 and remove the Mattress Tray. (For the bed with the baby scale, please see the figure 8.1, disconnect the weight sensor and take the baby scale out. Then lift the raise the Hood.)

Push the Mattress Tray to end following as the arrow 1, raising the Mattress Tray like the arrow 2, then pull out it as the arrow 3.

FIGURE 5.1

4. Refer to Figure 5.2, pull out the mattress tilt bars left and right sides.

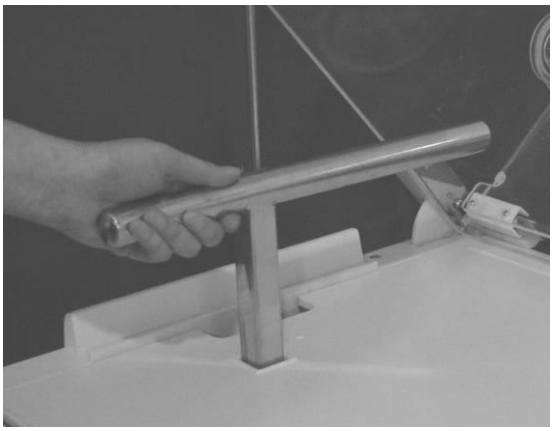


FIGURE 5.2

5. Refer to Figure 5.3 and take out the Main Deck by rotate the knob to the unlocked position.

FIGURE 5.3

6. Refer to Figure 5.4 and remove the Heater Cover.

FIGURE 5.4

The Heater can be sufficiently hot to cause burns. Avoid removing or touching the Heater until the unit has been switched off for at least 45 minutes.

7. As the figure 5.5 shows, press down the latch on the access panel to unfold the inner wall.

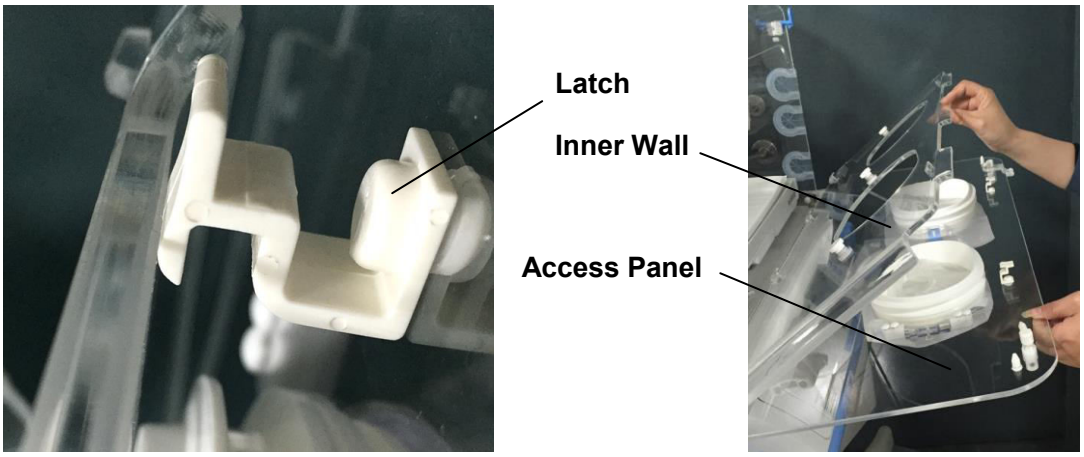


FIGURE 5.5

8. Refer to figure 5.6 and take out the water reservoir.

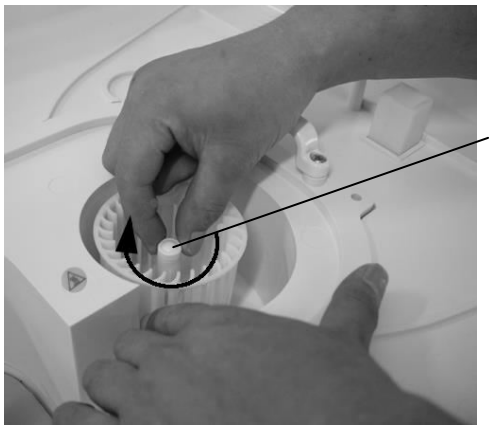
Rotate the spanner of the water tank to the horizontal position and pull the water tank out then. (Please keep the water tank flat and straight and don't move it up towards when it been pulled out, or else it will be hard to pulled out).

FIGURE 5.6

WARNING: 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 tighten 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.

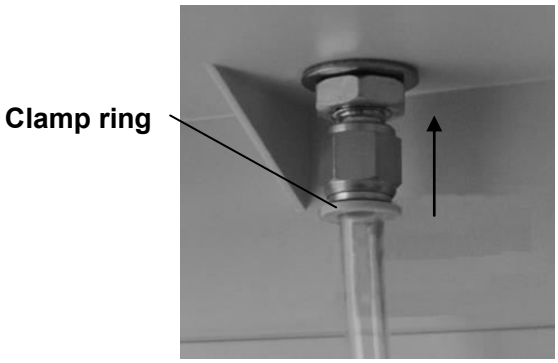
9. Refer to figure 5.7 and take out the fan.



Hold the fan, and loose the cover for bolt indicated as the arrow, draw the fan upward

FIGURE 5.7

10. As the figure 5.8, take out the oxygen transfusion tube.



Toward the arrow director to push the clamp ring, and take it out

FIGURE 5.8

11. Remove all Access Door Sleeves, Cuff and Gaskets from each side of the Hood by pulling them free.

12. Remove Tubing Access Ports from the Hood by pulling them free.

13. Remove the Air Intake Micro filter Cover by loosening the two thumbscrews. Refer to Paragraph 4.3.3 Step H.

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 neutral disinfectant-detergent to thoroughly clean the skin temperature (including detector), then disinfect it with neutral disinfectant or ultraviolet.

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

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

B. Clean the Soft tubing, Gaskets, Iris Port Sleeves

Soak and cleaning them in neutral disinfectant-detergent vessel, then clean with water and use clean cloth to dry.

C. Clean the hood, inner wall and sensor box

Use neutral disinfectant-detergent to thoroughly clean all surfaces, including sensor box, inner wall and all contacted doors and windows, ensure clean all holes and sag places, then dry with a clean cloth and 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. Then dry it with clean cloth.

E. Clean the heater radiator and fan impeller

Remove any lint build-up on the Heater Radiator and Fan Impeller.

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

F. Clean the mattress, mattress tilt bars, main deck, shelf, storage compartment and heater cover.

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

G. Clean the infant bed

Separate the upper bed and the lower bed, clean the dirt's inside the bed, clean the surface of bed and baby scale (accessory) with the cloth dipping into the national registered neutral disinfectant-detergent, and dry it with clean cloth.

NOTE: There is weight sensor inside of bed, clean and place carefully, do not put it into the detergent and sterilized liquid.

H. Clean air filter

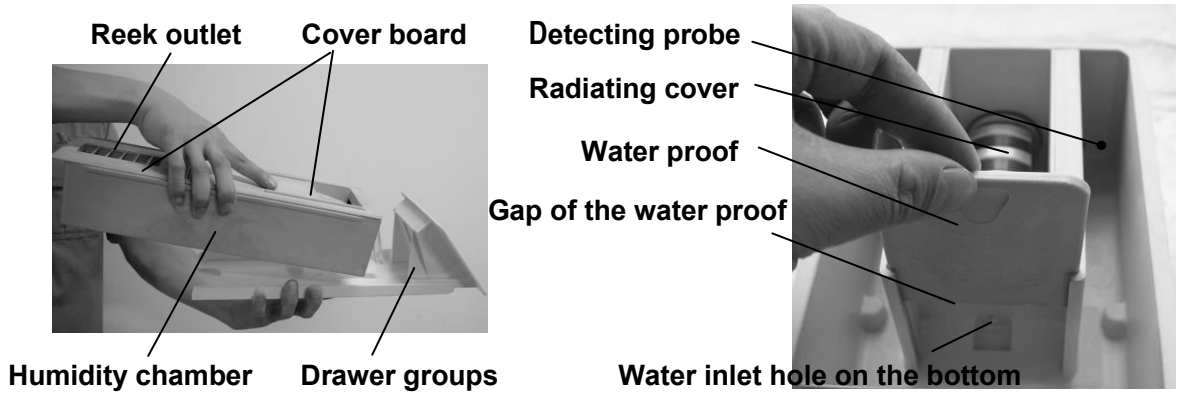
Use neutral disinfectant-detergent to thoroughly clean all surfaces, including all holes, indentations, Access Doors and Iris Ports then dry them with a clean cloth or paper towel. If the air filter is dirt or is used for more than 2 months, please replace it.

I. Clean the water tank

Take the humidifying chamber out from the drawer group as figure 5.9 shows. Open the two cover boards on the humidifying chamber and pull up the water input baffle. Use the national registered 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 that clean the inner and outter 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 detecting.

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 clear unobstructed after cleaning. Two gaps on the water proof must placed downwards.

3. If the water tank is uncleaned, especially there're 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 5.9

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 sterilize will lead to crack for some parts, will damage the water tank and will eventually need to change the water tank.

J. Clean the oxygen infusion tube

Clean the surface of oxygen infusion tube with clean cloth. Replace it when it is damaged.

K. 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.

A. Install the water tank back to tank in the reverse steps as they are moved out.

B. Install the Heater Cover.

C. Install the Main Deck.

CAUTION: Make sure the Hood is raised before attempting to install the Main Deck. Installing the Main Deck when the Hood is down may result in damage to the Main Deck and/or jamming of the Hood in place.

D. Install the Mattress Tilt Bars on the Main Deck.

E. Install the Mattress Tray and X-ray Tray.

F. Install the Mattress.

Visually and physically examine the mattress for any holes or cuts that will permit the entry of fluids onto the inner foam. If the mattress is damaged, it should be replaced.

G. Lock the inner wall back and make sure that the inner wall in a locked condition.

H. Rotating the iris entry sleeves, see figure 5.10.

Install the smaller diameter elastic band of a new Sleeve over the inner ring of the port housing.

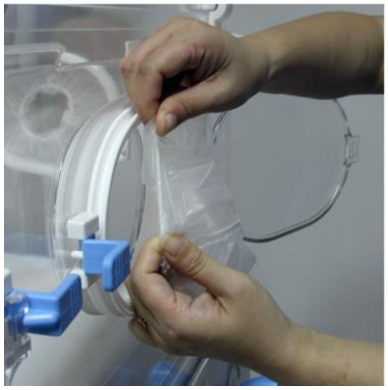
Fold back and slip elastic band over the outer ring of the port housing.

Rotate outer ring to close. If properly installed, the sleeve will open again if rotation is reversed.

FIGURE 5.10

I. See figure 5.11, install the Access door gasket, and then install the Access door cuff.

Installation of Access Door Gasket



Installation of Access Door Cuff

FIGURE 5.11

NOTE: 1. If the Incubator is to be gas sterilized, wait until after sterilization to install new cuffs.

2. If the Access Door Gasket is too hard and difficult installation, please place them into warm water before installation.

J. Install Tubing Access Ports, as shown in Figure 5.12.

NOTE: the gap of the tubing access ports should be outward.

FIGURE 5.12

K. Install an Air Intake Micro filter. Refer to the Paragraph 4.3.3, Step H, place the Air Intake Microfilter into the Cover and tighten the thumbscrews.

5.3 MAINTENANCE

WARNING: To ensure the safety of using the equipment is not affected, the modified 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 discard, so need to be recover 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 power and Power Failure Alarm is not activated	Power Switch not on	Depress Power Switch
The color of screen is abnormal	High temperature for controller	Switch off the temperature controller, restart it after cool, if the abnormal condition occurs again, Please refer to qualified service personnel
Power failure alarm light flashes, power failure alarm	No power supply	Turn off the Power Switch
	Power Cord unplugged	Make sure the Power Cord is fully inserted.
The “**Alarm**” light will flash, and the screen indicator will show “**Alarm Sensor box is placed wrong**”	The sensor box wrongly placed	The sensor box right placed

TROUBLESHOOTING TABLE (Continued)

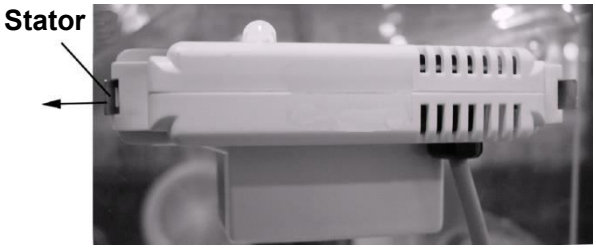
SYMPTOM	POSSIBLE CAUSE	REMEDY
The "**Alarm**" light will flash, and the screen indicator will show "**Alarm error Skin Sensor 1**"	Skin temperature sensor 1 unconnect or illconnect	Connect the Skin temperature sensor 1 correctly.
	Skin temperature sensor 1 damaged	Replace the skin temperature sensor 1
The "**Alarm**" light will flash, and the screen indicator will show "**Alarm O_2 Sensor 1 Fault**"	Oxygen sensor 1 not installed	Install the oxygen sensor 1 correctly
	Oxygen sensor 1 damaged	Replace the Oxygen sensor 1
The "**Alarm**" light will flash, and the screen indicator will show "**Alarm O_2 Sensor 2 Fault**"	Oxygen sensor 2 not installed	Install the oxygen sensor 2 correctly
	Oxygen sensor 2 damaged	Replace the Oxygen sensor 2
The "**Alarm**" light will flash, and the screen indicator will show "**Alarm Over Temperature**"	Ambient temperature overhigh	Far away from the heat source or decrease the ambient temperature
	High humidity	Decrease the humidity inside hood
The "**Alarm**" light will flash, and the screen indicator will show "**Alarm Temp. Deviation**"	Door or panel of hood is open	Close the door or panel of hood
	Ambient temperature changes a lot	Check the Ambient temperature
	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	Power cord disconnected	Connect the power cord
	Power switched off	Switch on the power

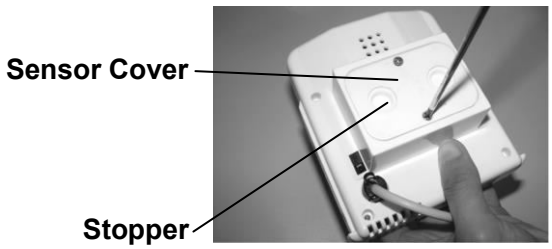
SECTION 6
OXYGEN CONCENTRATION MONITORING / CONTROL SYSTEM

6.1 GENERAL

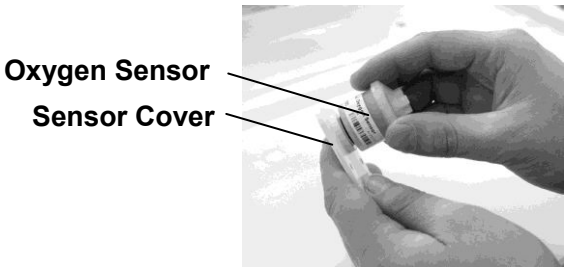
This Section provides operation checkout procedure and operation instruction for the Oxygen Control System. Oxygen concentration serve Control System is optional function.

6.2 INSTALLATION OF OXYGEN SENSOR

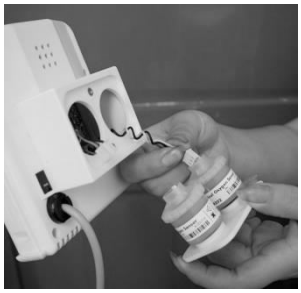




Pull out the stator on the left side of sensor box as the arrow indicates, and pull out the sensor box, unscrew 2 Cross groove countersunk head bolts, and take out the sensor cover, and then unscrew the stopper on it.



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 (if the device is equipped with oxygen control system, 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

6.3 FUNCTIONAL DESCRIPTION

The incubator has function of monitoring and servo-controlling the oxygen concentration. But "**Alarm O2 sensor 1 Fault**" is applying for both two functions, "**Alarm O2 sensor 2 Fault**", "**Alarm O_2 Sensors are differen**", "**Alarm O_2 Deviation**" are only applying for the function of servo-controlling. Please see the table 3.1 to get details of alarm message. If the above alarms are active, press the **Silence /Reset key** to stop alarming for about 115s. If the power of the heater is not cut off, the oxygen servo-control system will cut off the oxygen supplying automatically (Except for low oxygen deviation alarm).

When the indicator displays "**O_2 Module Switched off**", there's something wrong with Oxygen concentration module, it hasn't been installed or its function failure. If the indicator displays "**O_2 Module Off**", the O_2 Module is switched off by user selecting in the software.

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 inbreathed 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.**

6.4.1 CONNECTION OF MANUAL OXYGEN INPUT PORT

Connect by the oxygen transfuse tube of monitoring device and the manual oxygen input port, (refer to figure 4.3) to make sure the airproof connecting port. This port can not control the oxygen, while the oxygen flow can be adjusted by the user. The different oxygen flow can cause the different oxygen concentration, please refer to the oxygen concentration table, which is located on the back of incubator, the oxygen concentration needs a calibrated oxygen analyzer for long period monitoring.

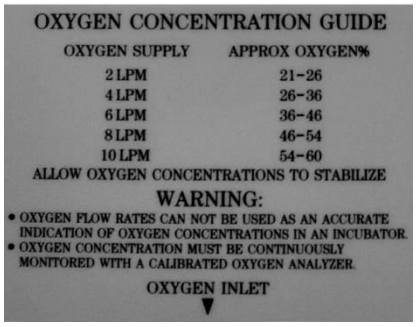


FIGURE 6.2

6.4.2 CONNECTION ABOUT THE INPUT INTERFACE OF SERVE CONTROL OXYGEN

Connect the oxygen transfering tube of serve control oxygen interface (see figure 4.3)and the oxygen-offering system equipped with the oxygen monitoring device, and make sure the seal of connecting part.

Electromagnetic valve is in servo control oxygen input interface.when the oxygen sensor in sensor box detect the oxygen is enough for user it will cut off the oxygen supply,if not enough it will continue supply oxygen.The sensor box will alarm if in wrong place and the electromagnetic will cut off oxygen supply.

NOTE: 1. To make sure the safety, when offering the oxygen, there must be a calibrated oxygen analizer that can monitor the oxygen concentration inside of hood.

2. The oxygen transfering tube offered by our company can only connect the serve control oxygen input interface, using the manual oxygen input interface is forbidden.

WARNING：Over high oxygen concentration can cause the great hurt on the baby, so please follow the advice of doctor when offering the oxygen, and use the relevant oxygen monitoring device to make it reach the setting state set by physician. Please read the indication values, the oxygen concentration table is just regarded as a reference.

6.5 OXYGEN SYSTEM OPERATIONAL CHECKOUT PROCEDURE

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 kinds of 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 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 press the second self-definite function key, turning the controller to enter the interface of oxygen concentration calibration. Press “21% Cal.” Key, see the figure 6.3. The controller can calibrate oxygen sensor automatically, and the screen indicates “**O_2 sensor calibration**”. After calibration, controller can enter into the first interface. If calibration work fails, the indicator displays the failure hint, and then users can solve problems according to the hint. If these failures can not be canceled, please ask the authorized and qualified personnel for repair.

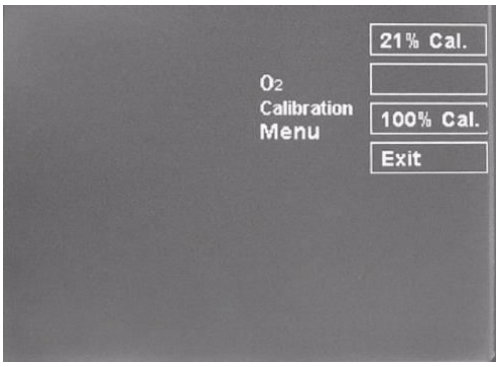


FIGURE 6.3

100% OXYGEN CALIBRATION

a. Turn off the controller, pull the sensor box out as figure 6.4 shows, connect the oxygen calibration device which equipped with oxygen connecting pipe to the sensor box, supplying the device with 100% oxygen for more than 2min.

b. After press the second self-definite function key, turning on the controller, the indicator display the interface of oxygen concentration calibration. Press “100% Cal.” Key, see the figure 6.3. The controller can calibrate oxygen sensor automatically, and the screen indicates “**O_2 sensor calibration**”. After calibration, controller can enter into the first interface. If calibration work fails, the indicator displays the failure hint, and then users can solve problems according to the hint. If these failures can not be canceled, please ask the authorized and qualified personnel for repair.

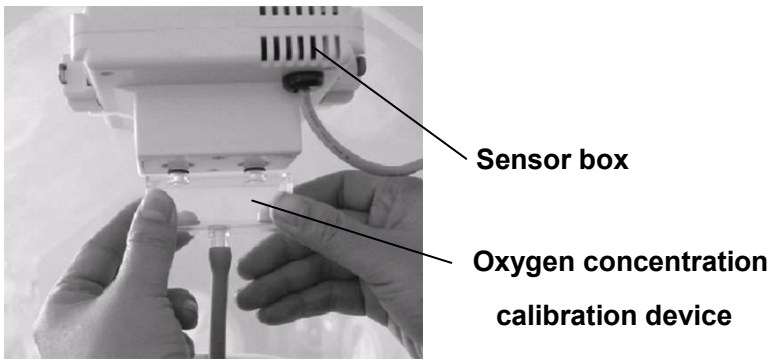


FIGURE 6.4

CHECK THE OXYGEN CONCENTRATION MONITOR FUNCTION

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

2. Input oxygen to the device, wait until the oxygen concentration displays steady, the value deviation displayed between the value displays in the Oxygen Concentration indicator and the oxygen concentration analyzer should in the range of ±3%.

CHECK FOR OXYGEN CONCENTRATION DEVIATION ALARMING FUNCTION

Connect the oxygen supply system and manual oxygen input interface, set the oxygen concentration as 30%, when the oxygen concentration reaches the setting value, increase the oxygen flow immediately, when the display value is different from the setting value +5%, the device should give a high priority alarm sound, "**Alarm O_2 Deviation"** information will replace the curve indication on the screen, the alarm character should be consistent with the description of section 3.4; set the oxygen concentration as 30%, when the oxygen concentration reachs the setting value, decrease the oxygen flow immediately, when the display value is different from the setting value -5%, the device should give a high priority alarm sound, "**Alarm O_2 Deviation"** information will replace the curve indication on the screen, the alarm character should be consistent with the description of section 3.4. When alarm occurs, press silence/reset key once, can cancel the alarm sound, but the alarm light still flashes until the display value is within ±5% of setting value.

Connect the oxygen supply system and servo control oxygen input interface, set the oxygen concentration as 30%, when the oxygen concentration reaches the setting value, increase the oxygen flow immediately, when the display value is different from the setting value +5%, the device should give a high priority alarm sound, "**Alarm O_2 Deviation"** information will replace the curve indication on the screen, the alarm character should be consistent with the description of section 3.4; set the oxygen concentration as 30%, when the oxygen concentration reachs the setting value, decrease the oxygen flow immediately, when the display value is different from the setting value -5%, the device should give a high priority alarm sound, "**Alarm O_2 Deviation"** information will replace the curve indication on the screen, the alarm character should be consistent with the description of section 3.4. When alarm occurs, press silence/reset key once, can cancel the alarm sound, but the alarm light still flashes until the display value is within ±5% of setting value.

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

6.6.2.1 According to the requirements of physician, on the first screen, press oxygen self-definite function key, please refer to the figure 6.5 to set the oxygen concentration monitoring datum mark.

NOTE: During operation, if there is information like "O_2 Module Switched off" displays on the screen, there must be something wrong with the oxygen module: not been installed or fails to work.

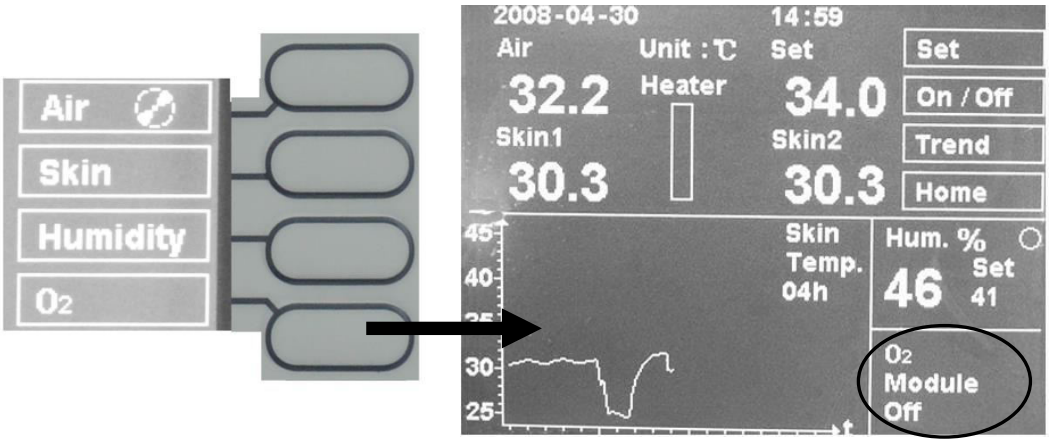
WARNING: 1. The oxygen input interface of oxygen –offering system and the one of serve control can not be used together.

2. If the artery blood oxygen pressure of patient (PaO_2) can not maintain 65% O_2 saturation; you need to change the other oxygen transfusion method.

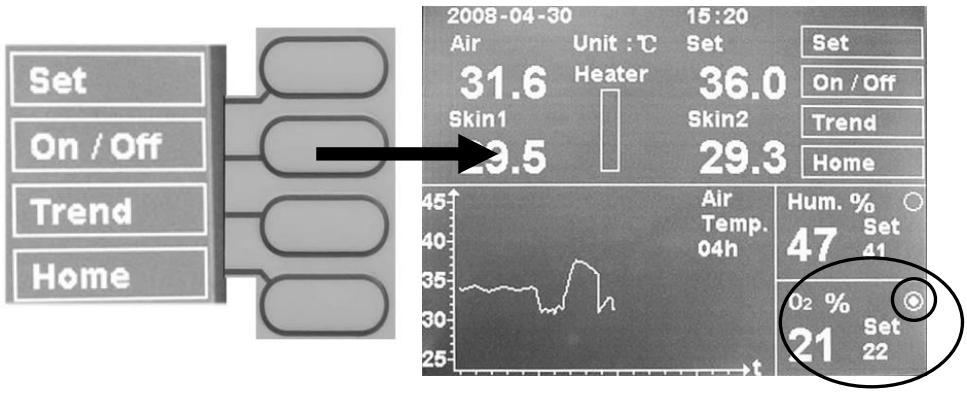
3. Do not supply wet oxygen to the oxygen port, or else the oxygen inlet port would be damaged.

SET OXYGEN MODULE WORKING MODE

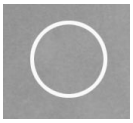
When the keypad lock indicator light is on, press O_2 Soft key to enter into the oxygen concentration operation interface.



Press On/Off key to open or close the oxygen module. In the opening state, oxygen concentration indication window can indicate the actual oxygen concentration inside of the incubator. After entering into the normal condition, if equipped with the oxygen concentration servo control system, and the oxygen concentration indication window can indicate the circular marks on the top right corner in the oxygen indicating area.



The start-up mark of oxygen inpput valve under the oxygen concentration servo control system



The closed mark of oxygen inpput valve under the oxygen concentration servo control system

FIGURE 6.5

NOTE: 1. Only when the keypad lock indicator light is on, value setting to the device can be proceed.

2. If no key is pressed within 15 seconds during the value setting procedure, the indicator will automatically revert to first indication interface and keep the latest set value.

1 Set

Press to activate Setting Oxygen Concentration datum mark set point, the Indicator "**Set**" in the area of O_2 flashes.

2 Set
20

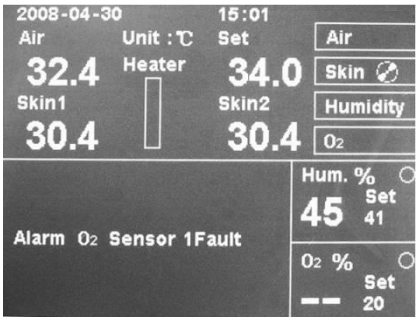
Press Up Arrow to rise set point from the current value to 60%O_2. Press one time to raise datum mark in 1% O_2 increments. Press this key without stopping to make the oxygen concentration setting increase rapidly.

3 Set
20

Press down Arrow to decrease set point from current value to 20% O_2. Press one time to decrease datum mark in 1% O_2 increments. Press this key without stopping to make the oxygen concentration setting decrease rapidly.

4 On/Off

Press this key to close or open the oxygen module. If the following indication can appear on the screen, and it means that the system is in the state of opening, and the oxygen concentration sensor is not installed or the oxygen sensor or oxygen system is failed.



5 Trend

Press to enter third indication interface A Refer to Paragraph 6.6.2.2 for detail.

6 Home

Press to acknowledge Oxygen Control Setting and return to first indication interface.

7 

Press this key, the keypad lock indicator light will shine and access controller set state. After setting back to first interface, press keypad lock to control area, and keypad lock indicator light goes out, or don't press any key it will return to control state automatically and keypad lock indicator light goes out after 15 seconds.

8 

Under the alarm condition, the alarm light will flash and sound alarm calls, the alarm message instead of the curve display(expect outage alarm). Please refer to the specific description of 3.4 chapter. Alarm mute/reset key has two functions, When occurs alarm, press this key once to stop alarm, press this key twice to reset the alarm status , the incubator will back to the set state and monitor the alarm again.

6.6.2.2 OXYGEN CONCENTRATION TREND DISPLAY

Under the condition which as Figure 6.6 indicated, press Soft key to select Oxygen Concentration Trend Display Menu.

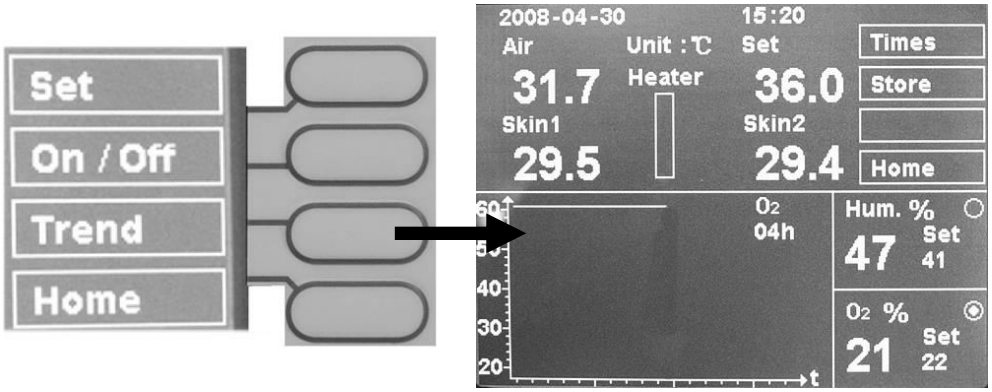
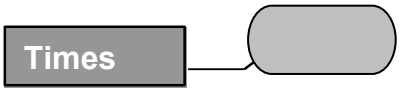


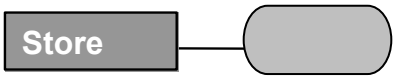
FIGURE 6.6

NOTE: 1. Only when the keypad lock indicator light is on, value setting to the device can be proceed.

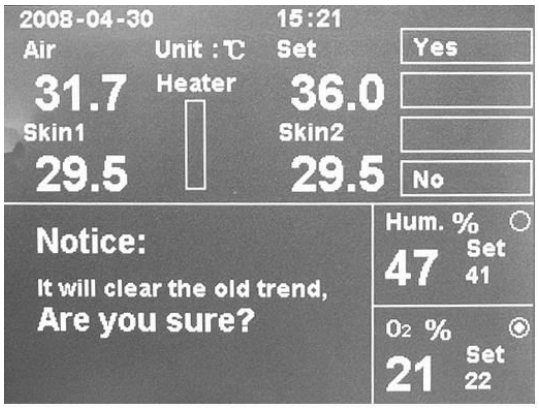
2. If no key is pressed within 15 seconds during the value setting procedure, the indicator will automatically revert to first indication interface and keep the latest set value. (But for the step 2 inquiry screen, the indicator displays the previous screen instead).

1 

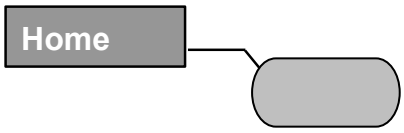
Press this key to select the time intervals of curve trend and the indication area xan indicate 2,4,8,12 and 24 hours Oxygen Concentration Trend Display.

2 

Press this key to make the trend restore fron the current state, at the same time, the operator can read the information anout notice as the following screen.



If press YES, it can return the last screen, the controller can cancel the orginal storaging data; press NO, it can return the last screen, the controller can continue to store the data on basis the orginal one.

3 

Press this key to return to first indication interface, the curve indication window can indicate the oxygen concentration curve.

4 

Press this key, the keypad lock indicator light will shine and access controller set state. After setting back to first interface, press keypad lock to control area, and keypad lock indicator light goes out, or don't press any key it will return to control state automatically and keypad lock indicator light goes out after 15 seconds.

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 screen indicator will show "**Alarm O_2 Deviation**"	Displayed oxygen concentration too high	Please calibrate the oxygen sensor again
		Adjust the proper oxygen flow
	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 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 sensor modular of the hood which adjust 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.

When the indicator displays "**Humidity Module Switched off**", there's something wrong with the humidity module.

7.3 OPERATION AND CALIBRATION PROCEDURES

Please calibrate the incubator when the incubator is used for the first time or reuse it after cleaning and installation. Before calibrating the device, please refer to section 7.4 to see how to set humidity of the incubator.

A. Fulfill the humidity chamber to the highest level with water, then place a calibrated humidity analyzer in the middle of the bassinet.

B. Heating the incubator to 36℃, set the humidity value in 50%.

C. Waiting until the value in the indicator rose to 50%RH, the **Humidity** indicator should display 50%RH±10%RH.

D. Check the humidity deviation alarm

On humidity set mode, set the value at 40%RH, when the humidity reaches the setting value, increase the humidity display value, let the display value high than set value +15%RH, the device should give a medium priority alarm, the "**Alarm Humidity Deviation**" information will replace the curve indication on the screen, the alarm character should be consistent with description of section 3.4. On humidity set mode, set the value at 40%RH, when the humidity reaches the setting value, decrease the humidity display value, let the display value lower than set value -15%RH, the device should give a medium priority alarm, the "**Alarm Humidity Deviation**" information will replace the curve indication on the screen, the alarm character should be consistent with description of section 3.4. Press silence/reset key can cancel the alarm sound, but the alarm light still flashes until the display value is within ±15%RH. If 4mins later, the alarm condition is still not cancel, alarm sound will start again.

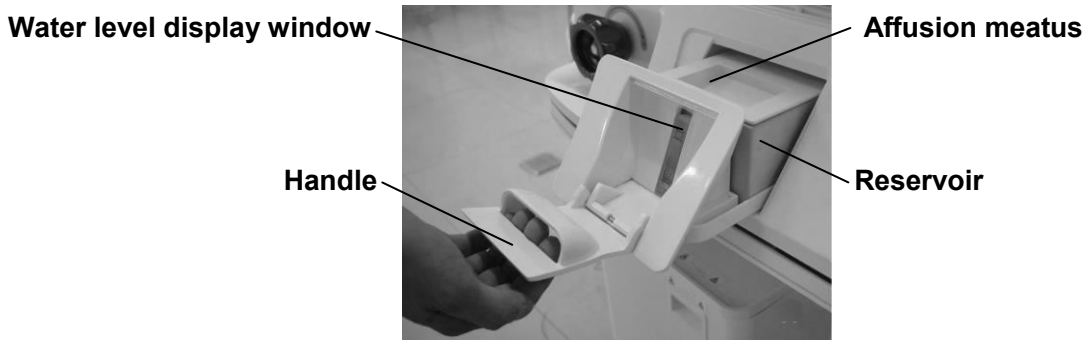
NOTE：If the displayed value won't rise anymore or can't decline to the set value in the deviation rate more than ±15%, the alarm won't occur. When checking the low-deviation alarm, please make sure that the environmental humidity is lower than the humidity in the hood so that the alarm can be active.

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 clear in the neonate. Therefore, temperature control mode, temperature value and humidity value should certified by the chief doctor. Monitor the patient's recta and armpit temperature according to the doctor's instruction.

7.4.1 Preparation

Pull the water tank out as following figure shows, adding proper distilled water into the tank. Can not over the high water level. Set the incubator in the Air control mode. It can pre-warm the air in the hood according to the set temperature which set by the main doctor or chief nurse.



NOTE: When the handle of the water tank is pulled to a vertical position, water level can be observed. When the handle is pulled to the horizontal position, water tank can be took out. (Please keep the water tank flat and stright and don't move it up towards when it been pulled out, or else it will be hard to pulled out)

1. Do not start using the humidifying function in the condition that lack water, or humidifying system will be damaged.

2. The water must be pushed in position when the incubator work in any time, or will affect the normal temperature control.

3. In order to extend the service life of humidity device, the cleaned distilled water is the only choice; the sterilized water can not take place of distilled water.

4. The water tank should be thoroughly cleaned every 24 hours and replace cleaned distilled water, to prevent the microbial propagation and the pollution of humidifying chamber. The water changing should be performed after the water tank is cooling sufficient, so as not to scald.

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

2. Please set the humidity value to 0%RH when you're not using the "humidify" function.

Under the condition of high temperature and high humidity (temp. ≥37℃, humidity ≥85%RH), some disadvantageous results may caused to the humidifier just like it may burn itself etc. Therefore, please wait no less than 45minutes when taking out the water tank or restart the humidifier.

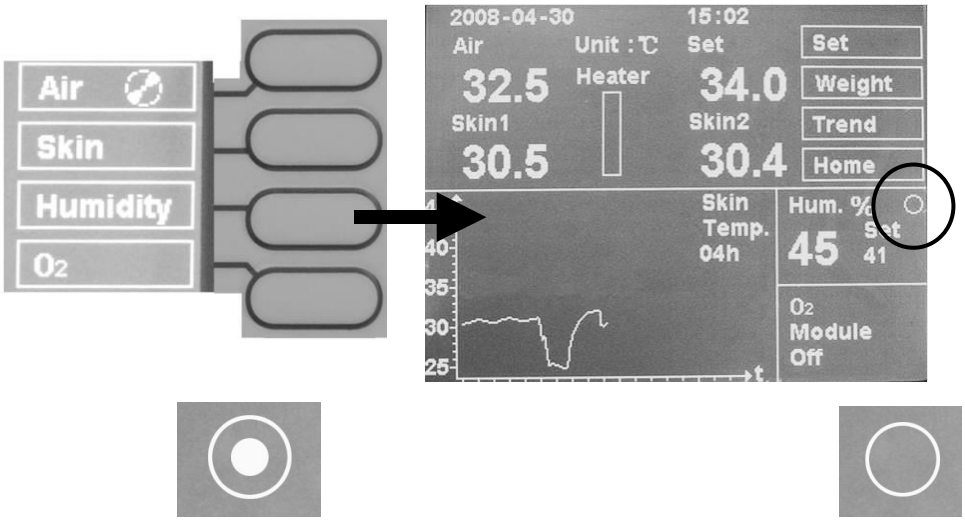
7.4.2 Operation

7.4.2.1 According to the requirements of physician, on the first screen, press humidity self-definite function key, please refer to the figure 7.1 to set the humidity value.

NOTE: The actual humidity achievable inside the system is depend on the Incubator Set Temperature and room conditions.

SELECTING HUMIDITY CONTROL AND SET POINT

When the keypad lock indicator light is on, select and press Humidity Soft key to enter Figure 7.1 on first indication interface.

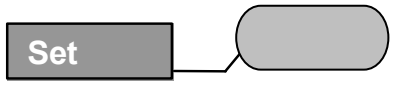


Humidity control system is in the state of adding humidity Humidity control system stops working

FIGURE 7.1

NOTE: 1. All setting should be operating under the keypad lock indicator light is on.

2. If no keys are pressed within 15 seconds of selecting this Mode or setting Humidity, it will automatically revert to first indication interface.

1 

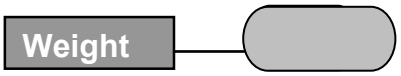
Press to activate Setting Humidity set point, the indicator "**Set**" in the area of Humidity flashes.

2 
Set
20

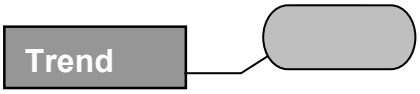
Press Up Arrow to raise set point from 0%RH to 90%RH. Press one time to raise set point setting in 1% RH increments.

3 
Set
20

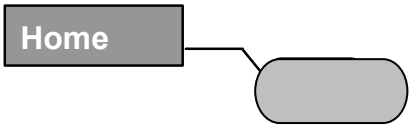
Press Down Arrow to lower set point from 90%RH to 0%RH. Press one time to lower set point setting in 1% RH increments.

4 

Press this key to enter into the weight function set.

5 

Press to enter third indication interface A. Refer to Paragraph 7.4.2.2 for detail.

6 

Press to acknowledge Humidity Control setting and return to first indication interface.

7 

Press this key, the keypad lock indicator light will shine and access controller set state. Press keypad lock to control area, and keypad lock indicator light goes out, or don't press any key it will return to control state automatically and keypad lock indicator light goes out after 15 seconds.

8 

Under the alarm condition, the alarm light will flash and sound alarm calls, the alarm message instead of the curve display(expect outage alarm). Please refer to the specific description of 3.4 chapter. Alarm mute/reset key has two functions, when occurs alarm, press this key once to stop alarm, press this key twice to reset the alarm status , the incubator will back to the set state and monitor the alarm again.

7.4.2.2 Humidity trend display

Under the condition as indicated in Figure 7.1, press Soft key to select Humidity Trend Display Menu.

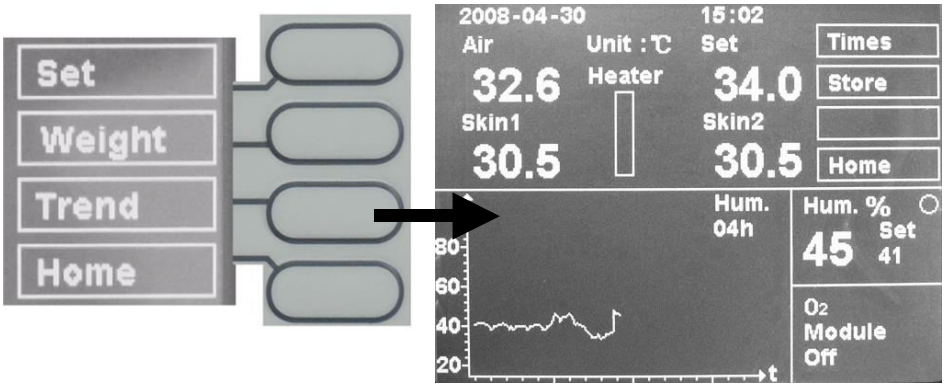
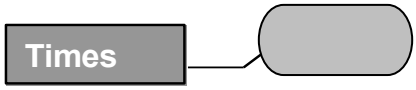


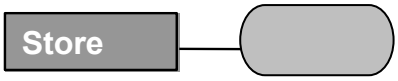
FIGURE 7.2

NOTE: 1. All setting should be operating under the keypad lock indicator light is on.

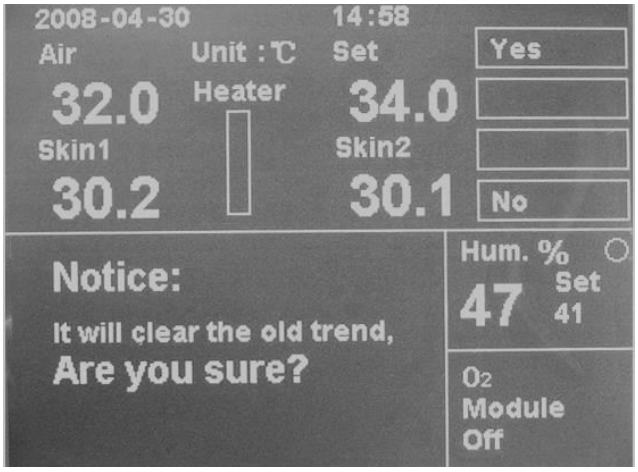
2. If no keys are pressed within 15 seconds of selecting this Mode or setting Humidity, it will automatically revert to first indication interface. (Return the last step except for the step 2)

1 

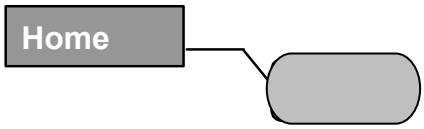
Press to select 2,4,8,12 and 24 hours Humidity Trend Display.

2 

Press this key to make the trend restore fron the current state, at the same time, the operator can read the information anout notice as the following screen.



Press YES, it can return the last screen, the controller can cancel the orginal storaging data; press NO, it can return the last screen, the controller can continue to store the data on basis the orginal one.

3 

Press to acknowledge Humidity Control setting and return to first indication interface.

4 

Press this key, the keypad lock indicator light will shine and access controller set state. After setting back to first interface, press keypad lock to control area, and keypad lock indicator light goes out, or don't press any key it will return to control state automatically and keypad lock indicator light goes out after 15 seconds.

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
Humidity deviation alarm	Environmental humidity change greatly	Check the surrounding humidity condition
	No distilled water in the tank	Add distilled water into the tank
Indication symbol 	No distilled water in the tank	Add distilled water into the tank (Wash it when there's a need)
Alarm Water Reservoir is placed incorrectly	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.
Fill the water tank with water after water lack indication, "humidify" can't be started immediately	Humidifier over-heat protection unrecovered	Waiting for about 10 minutes
Alarm not be actived 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.
Heating circuit failure alarm	Over-heat relay works because the dusts near the probe.	Clean the water tank throughly after it cool down, use the soft cloth with disinfector to wipe around the detect point

SECTION 8
WEIGHING SYSTEM

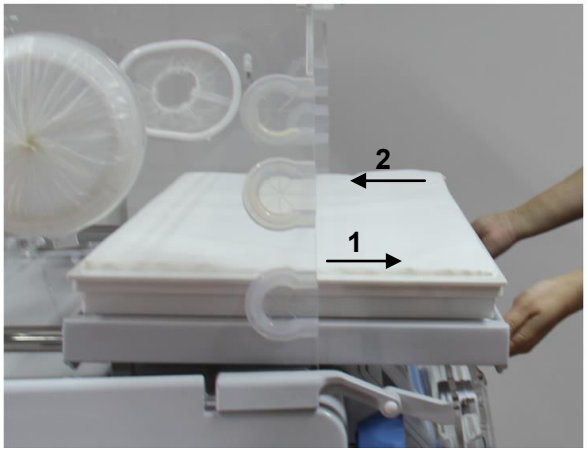
8.1 GENERAL

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

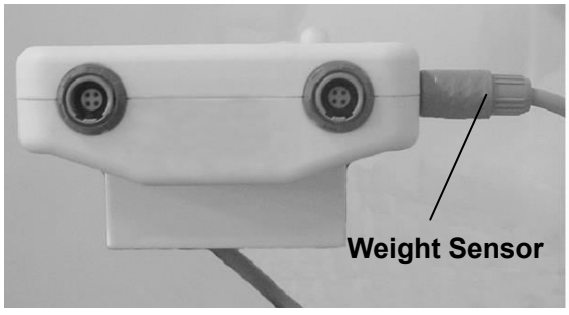
Weighing system is selectable.

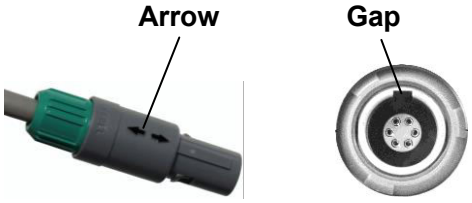
8.2 INSTALLATION

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



Please refer to the F of chapter 4.3.3, Adjust the bed to the lowest position, and open the front door, place the bed with baby scale on the wavering mechanism, and it can be pulled out and push in freely as the arrow 1 and 2 indicates.





Make the weight sensor can be inserted into The gap of socket correctly

WARNING: 1. When plug in or out the power supply cord, the plug must be taken hold and the wring should not be pulled.

2. Do not bend the connection of sensor.

Connect the plug of sensor on the baby scale with the socket on sensor box correctly.

FIGURE 8.1

8.3 FUNCTION DESCRIPTION

The weight system is equipped with the operation of calibration, and the balancer must be able to zero. User can do this operation by pressing the self-definite function key on the panel of temperature controller. 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

If need the weight indication, the user should reset the controller and make it enter into the third indication interface B. The body weight can be indicated only on the third indication screen or weight curve indicate window.

NOTE：Apply the weight sensor calibration and operation procedure when first using the incubator or reuse it after disassembly, clean, and maintain.

CALIBRATION OF WEIGHT SENSOR

When the keypad lock indicator light is on, on the second interface B, press weight self-definite function key to enter into the interface in figure 8.2 to calibrate the weight sensor.

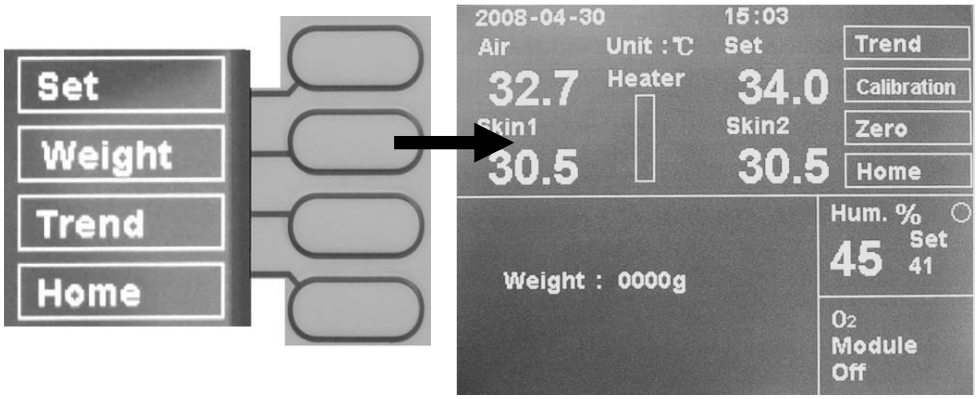


FIGURE 8.2

NOTE: 1. All setting should be done when the keypad lock indicator light is on.

2. Whichever operation, If not proceed the next step after pressing the key for 15s, and then the indication can come back to the first interface and restore the operation result of last time.

A. Take out all the things on the bed and make sure the bed cleans.

B. Press the zero self-definite function key, weight indicator can read 0000g±5g, if exceeds this range, press ZERO key again.

C. Put the weight of 5000g on the baby scale, and then press Calibration self-definite function key, the indication window can indicate the following figure 8.3, press No key or do not pressing any key within 15s, the system can exit the calibration procedure automatically. Press Yes key, the system can enter into the calibration state, the indication window can indicate the weight within 5000g±5g, when exceeds this range, repress Calibration self-definite function key until the weight is in the right range. If failed, the baby scale should be repaired by qualified personnel.

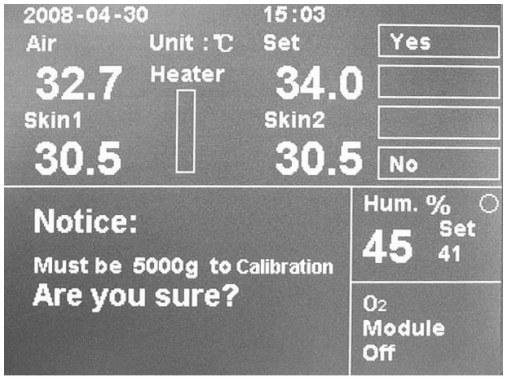


FIGURE 8.3

CHECKING THE CONNECTING OF WEIGHT SENSOR

Disconnect the connection between the weight sensor and the sensor box, enter into the interface in figure 8.2, weight indicator can hint the failure of weight sensor, the controller can cancel the failure indication information automatically and indicate the weight of sensor.

OPERATION OF ALL KEYS OF WEIGHT INTERFACE

NOTE: All operation key should be done when the keypad lock indicator light is on.

1 Trend

Press this key to enter into the weight curve indication in figure 8.4.

2 Zero

Press this key to make the weight indication come back to zero, if exceeds 2000g, press this key, the system can indicate zero error.

3 Calibration

This key is just used for calibrating the weight sensor; do not press this key in normal operation.

4 Home

Press this key to confirm the new setting value and come back the first indication interface.

INDICATION OF WEIGHT TREND

In indication interface of figure 8.2, press curve self-definite function key to select the menu the weight trend indicates.

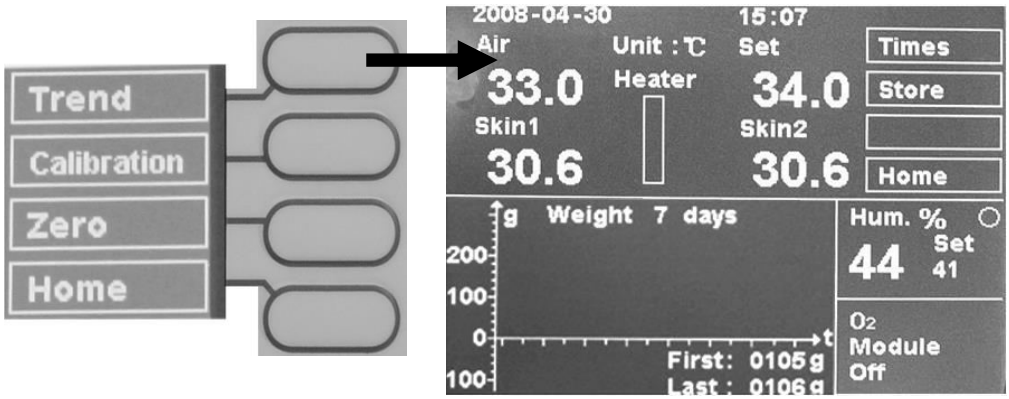
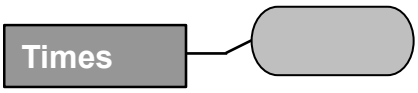


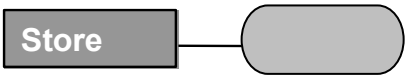
FIGURE 8.4

NOTE: 1. All setting should be done when the keypad lock indicator light is on.

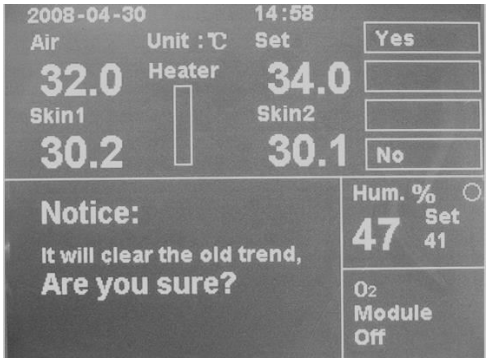
2. Whichever operation, If not proceed the next step after pressing the key for 15s, and then the indication can come back to the first interface and restore the operation result of last time.(except for step 2: inquiry interface)

1 

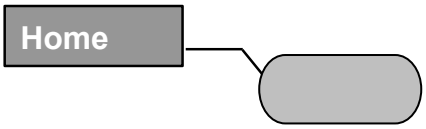
Press this key without stopping can select the time intervals of curve trend, and indicate the trend of one week, two weeks, three weeks, four weeks, five weeks, six weeks, and seven weeks.

2 

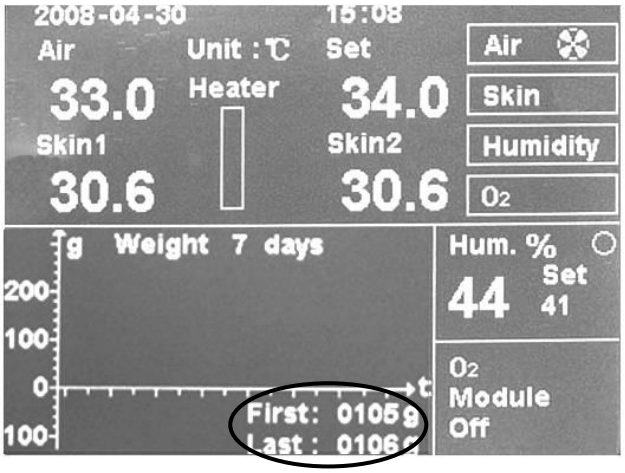
Press this key to restore the data from the current state, meanwhile, it can indicate the following interface: inquiry the operator: are you sure?



Press Yes to confirm and return the last interface, the controller can restore the original information continuously. press NO, it can return the last interface, the controller can continue to store the data on basis the orginal one.

3 

Press this key to return to the first indication interface, the following trend can be indicated.



First: indicate the recorded weight of trend, last: indicate the current weight. The trend indicates the deviation between the Last and First. If press store self-definite function key, and the result of first can be replaced by the new storage weight.

NOTE: When there is failure on the connection of weight sensor, Last indication can be replaced by Over.

8.5 OPERATION OF WEIGHING SYSTEM

After calibrating and reset 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 "Weight Senser Falut"	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 aclinic	Adjust the bassinet into aclinic
	Infant is not placed in the centre of the mattress	Lay the infant in the centre of the mattress
	Environmental temperature varies greatly	Check the environmental temperature
	Weight sensor have been incorrectly calibrated	Please calibrate it again with a 5000g standard poise

SECTION 9 PARTS LIST

This section provides the lists of accessories and removable parts of the incubator. The users only can use the matirials provided by our company, or will reduce the safety of equipment.

Number	Name of parts	Serial number
1	Skin temperature sensor	88.05.005.01
	Disposable skin temperature sensor	88.07.005.00
2	Power line	86.46.020.00
3	Air filtering	13.04.018.00
4	Plastic sleeve of elliptic access	05.02.029.00
5	Plactic sleeve of circular port for rotating	05.02.025.00
6	Water tank	13.05.002.02
7	Bassinet	13.03.007.01
8	Sensor box	13.38.026.01S
9	Seal of access door	13.02.032.02
		13.02.033.03
10	I.V. soft port	13.02.011.01
11	Oxygen sensor	86.60.093.00
12	Oxygen calibration device	12.16.004.01S
13	Oxygen therapy pipe	13.16.036.01

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

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The BABYGUARD I-1120 Infant Incubator is intended for use in the electromagnetic environment specified below. The customer of the user of the BABYGUARD I-1120 Infant Incubator should assure that it is used in such and environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The BABYGUARD I-1120 Infant Incubator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The BABYGUARD I-1120 Infant Incubator is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

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

Guidance and manufacture's declaration – electromagnetic immunity			
The BABYGUARD I-1120 Infant Incubator is intended for use in the electromagnetic environment specified below. The customer or the user of BABYGUARD I-1120 Infant Incubator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BABYGUARD I-1120 Infant Incubator requires continued operation during power mains interruptions, it is recommended that the BABYGUARD I-1120 Infant Incubator be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity

The BABYGUARD I-1120 Infant Incubator is intended for use in the electromagnetic environment specified below. The customer or the user of BABYGUARD I-1120 Infant Incubator should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the BABYGUARD I-1120 Infant Incubator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	$3V_{rms}$ 150 kHz to 80 MHz outside ISM bands [a]	3 V_{rms}	$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
	10 V_{rms} 150 kHz to 80 MHz in ISM bands	10 V_{rms}	$d = \left[\frac{12}{V_2}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = \left[\frac{12}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{23}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

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 BABYGUARD I-1120 Infant Incubator is used exceeds the applicable RF compliance level above, the BABYGUARD I-1120 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 BABYGUARD I-1120 Infant Incubator .

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the BABYGUARD I-1120 Infant Incubator

The BABYGUARD I-1120 Infant Incubator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BABYGUARD I-1120 Infant Incubator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BABYGUARD I-1120 Infant Incubator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**			
	150 kHz to 80 MHz outside ISM bands $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = \left[\frac{12}{V_2}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{12}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{23}{E_1}\right]\sqrt{P}$
0.01	**0.1167**	**0.12**	**0.12**	**0.23**
0.1	**0.3689**	**0.3795**	**0.3795**	**0.7273**
1	**1.1667**	**1.2**	**1.2**	**2.3**
10	**3.6893**	**3.7947**	**3.7947**	**7.2732**
100	**11.6667**	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 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.

NoTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could couse interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change or any other important changes of information. Contents of this manual are subject to change without prior notice.

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DIXION

DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

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