

nice Neotech Medical Systems Pvt. Ltd.

nice 3030 Baby Incubator



OPERATING/INSTALLATION MANUAL

This operating manual provides all the information necessary for the user to safely set up and operate this equipment. It is the responsibility of the user to follow the instructions and recommendations provided

Part Number - 73-00-008
Revision - 04
Date - 19/12/2017

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User Responsibility / Operator Profile

This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, nice Neotech recommends that a telephone or written request for service advice be made to the nearest dealer. This Product or any of its parts should not be repaired other than in accordance with written instructions provided by nice Neotech and by nice Neotech trained personnel. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than nice Neotech.

Warning: Before using the nice Neotech Incubator, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the benefits and risks of this type of device.

Declaration for Languages

User Manual and label will be provided in the appropriate language to ensure that the user understands. Language validation will be done for the language of the user manual, Label, Corresponding documents, when nice Neotech Medical Systems Private Limited supplies to EU countries

Model Descriptions:

All models of the nice Neotech Infant Baby Incubator provide a controlled source of Hot air with oxygen for infants and paediatric patients. The control system uses a microprocessor and provides both Servo air mode and servo skin modes of operation.

The model nice 3030 is Standard Baby Incubator.

Definitions:

Incubator Temperature: Air temperature at a point 10 Cm (3.9 in) above and centered over the mattress surface.

Control Temperature: The Temperature Controller's Set Point Selected by User.

Average Incubator Temperature: the average of the maximum and minimum Incubator Temperature achieved during **Temperature Equilibrium**.

Incubator Temperature Equilibrium: the condition reached when the average **Incubator Temperature** does not vary more than 1.0°C over the period of one hour. These measurements are taken at **control temperatures** of 32°C and 36°C.

Temperature uniformity: the amount by which the average temperature at each of four points 10 Cm (4 in.) above the mattress surface differs from the **Average Incubator temperature** at Incubator Temperature Equilibrium.

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 rise time: the time required for the Incubator Temperature to rise 11°C, when the air Control Temperature is at least 12°C above ambient.

Temperature Overshoot: the amount by which Incubator Temperature exceeds Average Incubator Temperature at Incubator Temperature Equilibrium shall be restored within 15 minutes as a result of an increase in Control Temperature Value.

Temperature Correlation- Temperature indicator Vs Incubator Temperature, the amount the air temperature Indicator at Incubator Temperature Equilibrium differs from the Incubator Temperature.

Measurement Points- Measurements are taken at five points in a plane parallel to and 10 cm above the mattress surface. One point shall be 10 Cm above the centre of the mattress; the remaining four points shall be the centers of four areas formed by lines, which divide both the width and length in two parts.

Definition of Warning indication:

Three levels of Warning indication are used throughout this manual and on the unit. They are defined as follows; A DANGER notice indicates an immediately hazardous situation which, if not avoided, will result in death or serious injury, serious damage to property such as total loss of use of equipment, and a fire.

A WARNING notice indicates an indirectly (Potentially) hazardous situation which if not avoided, will result in death or Serious injury, serious damage to property such as total loss of use of equipment, and a fire.

A CAUTION notice indicates a hazardous situation which, if not avoided can result in minor or moderate injury, partial damage to property and loss of data stored in computers.

Section A: Warnings

Warning: Incubator is intended for use by a qualified practitioner under the direction of qualified physician. Personnel operating the incubator must become thoroughly familiar with the instruction manual prior to using the baby incubator with the patients.

Warning: Only facility-authorized personnel should troubleshoot the Model nice 3030 baby incubator. Troubleshooting by unauthorized personnel could result in Personal injury or equipment damage.

Warning: Do not use the incubator if it fails to function as described. Personal injury or equipment damage could occur. Refer the unit for servicing by qualified personnel.

Warning: To prevent Personal injury or damage to the variable height adjustable pedestal stand when transporting, employ a person of sufficient strength to adequately control the incubator.

Warning: To prevent Personal injury, Particular care must be taken to ensure that the additional Equipment connected to the baby is electrically safe

Warning: A dirty air intake micro filter may affect oxygen concentrations and/or cause carbon dioxide built-up. Check the filter routinely and change it at least every 3 months or when it is visibly dirty. Failure to do so could result in infant injury.

Warning: Two people are required to lift the hood assembly. Failure to use at least two people could result in personal injury or equipment damage.

Warning: Allow 45 minutes for the heater assembly to cool. Failure to do so could result in personal injury.

Warning: Follow the product manufacturer's instructions. Failure to do so could result in personal injury or equipment damage.

Warning: Make sure that the oxygen supply to the incubator is turned off and that the incubator is disconnected from the oxygen supply when performing cleaning procedures. A fire and explosion hazard when cleaning in an oxygen-enriched environment.

Warning: nice 3030 Dose not having any additional Equipment to maintain the hood Temperature

Warning: Failure to clean the heater radiator and fan impeller could result in sufficient lint built-up to reduce airflow, which will affect temperature control and cause high oxygen concentrations. Infant injury could occur.

Warning: Only facility-authorized personnel should perform preventive maintenance on the Model nice 3030 baby incubator. Preventive maintenance performed by unauthorized personnel could result in personal injury or equipment damage.

Warning: The Hood/Shell assembly must attach to the pedestal/stand using the screws provided. Failure to do so could result in the hood/shell assembly separating from the pedestal stand when sufficiently tilted, particularly with the hood open. Personal injury or equipment damage could occur.

Warning: To keep the incubator from sliding when parked on an incline, the pedestal stand's front locking casters must be facing down the incline and locked.

Warning: Oxygen Flow rates cannot be used as an accurate indication of oxygen concentration in an incubator. Continuously monitor the oxygen concentrations with a calibrated oxygen analyzer. Failure to do so could result in Personal injury or equipment damage.

Warning: Ensure all sensor leads are properly routed. Use cable management clips to avoid entanglement and possible infant injury.

Warning: The use of oxygen increases the danger of fire and the auxiliary equipment producing spark shall not be placed in the equipment

Warning: Even Small quantity of flammable agents such as ether and alcohol, left in the incubator it can cause fire in connection with oxygen

Warning: The direct sun light or other radiant heat sources can cause an increase an incubator temperature to dangerous levels

Warning: The warm up time of the incubator is less than 45 minutes to attain the temperature of 32°C in the baby compartment

Warning: The administration of oxygen may increase the noise level for the baby within the incubator

Warning: There is a possibility of electromagnetic interference or other interference causes from other external equipment, the Incubator may get in operation. Use EMC compliance Equipment to avoid the interference

Warning: Don't misaligned the EMI Shielding and the beads it may cause the EMI interference to the equipment

Warning: The Incubator may cause radio interference, in which case adequate measure may be required to prevent interference

Warning: nice 3030 Baby Incubator compliance with EN/IEC 60601-1-2, 2004, the use of accessories, sensors and cables other than specified may result in increased emission/or create invalid output of nice 3030

Shock Hazard: Ensure that the building power source is compatible with the electrical specifications shown on the right side of the incubator and the variable height adjustable pedestal stand. For proper grounding reliability, connect the power cord only to a properly marked, three-wire, hospital-grade or hospital-use receptacle. Do not use extension cords.

Shock Hazard: Unplug the power cord from the controller assembly. Failure to do so could result in Personal injury or equipment damage.

Shock Hazard: Do not expose the unit to extensive moisture. Personal injury or equipment damage may occur.

Section B: Cautions

Caution: When using Variable Height adjustable pedestal stand, always lower the incubator to its lowest position prior to transport for optimum stability. Failure to do so could result in Personal injury or equipment damage.

Caution: When reconnecting the rear panel connectors, connect the sensor cable to the corresponding sensor cable connector only. Do not connect the sensor cable to any other connector.

Caution: Use caution when lowering the shell assembly in place on the shell bottom. Ensure that no cables are pinched and that the extrusion bumper fits properly. Failure to do so could result in equipment damage.

Caution: Do not use harsh cleansers, such as scouring pads or heavy-duty grease removers or solvents, such as acetone. Equipment damage could occur.

Caution: Some chemical cleaning agents may be conductive and/or leave a residue that may enable a built-up of conductive dust or dirt. Do not permit cleaning agents to contact electrical components. Do not spray cleaning solutions onto any of these surfaces. Equipment damage could occur.

Caution: Do not use alcohol for cleaning. Alcohol can cause crazing of the clear acrylic hood.

Caution: Do not expose the hood assembly to direct radiation from germicidal lamps. Ultraviolet radiation from these sources can cause cracking of gaskets, fading of paint, and crazing of the clear acrylic hood.

Caution: To prevent Component damage, ensure that your hands are clean, and only handle the P.C.board by its edges.

Caution: When handling electronic components wear an antistatic strap Failure to do so could result in component damage.

Caution: For shipping and Storage Place the removed P.C.board in an antistatic protective bag Equipment damage could occur.

Caution: Do not use silicone-based lubricants. Equipment damage could occur.

Caution: When removing the equipment from the cartons, take care not to scratch or otherwise damage unprotected surfaces.

Caution: Before lifting the incubator hood for cleaning, ensure that all mounted accessories have been removed to prevent possible interference with the raised hood.

Caution: To avoid Equipment damage, use only distilled or sterile water. Sterile water alone is not an acceptable substitute for distilled water.

Caution: Isolation from the supply mains is Detachable Power cord provided

Caution: The equipment may shows incorrect reading while using the defebulator

Caution: Periodically clean and disinfect the incubator it fails cause cross infection

Caution: Use of nonstandard components: Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance

Attention: nice 3030 baby Incubator is not indented to Produce X Radiation for diagnostic and therapeutics purposes.

Section C: Symbols

Mark	Indication
	Caution
	Caution, electric shock
	Caution, ignition (Indicates possible ignition under certain condition)
	Caution, Hot surface
	Caution, Pinched finger or hand
	Warning
	Warning, Do not touch
	Warning, Don't use fire
	Protective Earth (ground)
	Alternating current
	Off (Power: disconnection from main)
	On (Power: connection to the main)

	Type BF
	"Off" (only for a part of Equipment)
	"On" (only for a part of Equipment)
	Audio Indicator
	Audio Silence
	Consult Instruction for Use.
	Serial Number
	Authorised Representative in European Community
	Date of Manufacture
	Manufacturer
	Model Number
	Refer Instruction for use

Section 1: Description

- 1.1 Intended Use
- 1.2 General
- 1.3 Hood Assembly Area
- 1.4 Air circulation
- 1.5 Shell unit
- 1.6 Control System
- 1.7 Cabinet (RH/LH) with Pedestal Stand.
- 1.8 IV Stand
- 1.9 Mattress Tray

1.1 Intended Use

The 3030 intensive care incubator is used for therapy, the care of premature babies and new-born babies with impairment of vital functions. Regulation of heating, humidification of the inside air provide a favorable environment, protected from infection, for the care of even small new-born babies.

Using the skin temperature regulation, it is also possible to regulate the temperature of the inside air according to the skin temperature.

1.2 General

The nice Neonatal Intensive care Incubator provides an optimum thermal environment for the infant who's are low weight, high risk and less the gestation period of 36 weeks. The incubator helps to stabilize the infant's body temperature at the normal level by minimizing the infant's heat loss. The incubator directs the heated air through the air ducts in it and monitors the inside temperature in it with temperature sensors. The air speed in the incubator is limited to less than 25 cm/Sec, thus minimizing the convective heat loss. Fresh heated air is introduced into the incubator along with reticulated air. A built in humidifier minimizes the evaporative heat loss by humidifying the infant compartment air.

The Incubator is used in various hospital locations such as NICU, Labor Ward, Operation Theaters, and Nursery.

1.3 Hood Assembly Area

The Intensive care incubator consists of an infant Compartment (Canopy), Lower unit and cabinet. The incubator Control panel is located at the lower unit. The microprocessor based control system provides a controlled temperature environment for the infant. The display panel visually indicates Audio and Visual Indication conditions on a display while an audible Audio and Visual Indication sounds to alert the operator to check the Audio and Visual Indication condition. The unit also features an over temperature safety system. The patient temperature, the control temperature and the air temperature are continuously displayed on the displays.

The infant Compartment consists of a single walled, transparent or double walled (optional) transparent acrylic hood. The hood has a large front door to aid in placing or removing the baby from the incubator. It has five elbow operated ports for better access of the infant during small procedures.

The hood has inlet for IV tube, Probes and Ventilator tubes. The canopy itself can be removed so that the internal parts can be cleaned and accessed.

The control panel is modular, that is the entire control panel with heater blower and the electronics can be easily replaced in case of repair. This ensures the minimum down time for the equipment.

1.4 Air Circulation

Air is circulated inside the incubator using a centrifugal blower. Fresh air enters the incubator air circulation system through the air filters located at the rear end of the incubator. The fresh air mixes with the circulated air in the incubator canopy which is passed over the heater and the humidifier.

The temperature inside the incubator is maintained by a sensor placed on the hood. Thus the heated air flow maintains the surrounding of the infant at the desired temperature. A slight positive pressure is maintained inside the incubator to prevent any pathogen to enter the incubator through the access ports.

Warning: Do not cover or block the air filter through which fresh air is circulated into the incubator. The blockage of fresh air input can cause carbon dioxide built up inside the canopy.

The canopy, the baby tray and the mattress are all X-ray transparent enabling X-ray taken without removing the infant from the incubator.

1.5 Shell Unit

The lower unit houses the control box, the touch key front panel with display, Humidifier chamber and the air filter. A wet sponge has to be placed in the Humidifier chamber by disassembling the mattress tray. The control panel located at the front of the lower unit features touch switch controls on a smooth surface for ease of cleaning and resistance to liquid penetration. The digital display indicates air temperature, Patient temperature and Set Control temperature with a light touch to the increase or decrease touch switch. Air or patient modes of operation can be selected by the touch switch controls and indicated by the respective indicator lamps. A separate display gives out visual message in case of an Audio and Visual Indication.

1.6 Micro Controller Control System

The Micro controller monitors the canopy temperature with temperature sensor placed inside the incubator attached to the wall of the canopy. The patient sensor attaches to the lower unit with a flexible lead which minimizes sensor detachment caused by the infant movement.

The Air temperature is measured by the sensor mounted inside the incubator. When the Air Mode of operation is selected the heater is proportionately controlled to maintain the air temperature at the selected control temperature. The patient sensor may be used to monitor patient skin temperature, but does not control the air temperature in the Air Mode.

The Patient Mode of Operation maintains the infant's skin temperature at the selected control, which should be the desired skin temperature. The patient mode uses feedback information provided by the patient temperature probe to determine the proper Air temperature based on the Comparison of the patient temperature and the control temperature. An Audio and Visual Indication sounds if the patient temperature differs from the control temperature by more than 0.5°C. An Electronic air temperature safety System monitors the infant Compartment and Deactivates the Heater. This safety System activates at the temperature of 39.0°C.

The Audio and Visual Indication section of the Control panel features a visual of Audio and Visual Indication condition, an audible Audio and Visual Indication and the Audio and Visual Indication silence touch switch. The Audio and Visual Indication silence touch switch deactivates the audible Audio and Visual Indication for approximately 18 minutes. The visual display still remains ON until the Audio and Visual Indication condition no longer exists.

A memory back up system holds the data of Control temperature and the mode of operation even if the power goes OFF and turns ON again.

A battery operated power failure Audio and Visual Indication activates when the external power source fails or is disconnected.

1.7 Cabinet (RH/LH) with Pedestal stand

The two individual cabinets with a horizontal separation are provided with wide storage space to keep essential nursing kits. The Main power inlet connector and the power switch are placed at the front bottom side of the shell area. The fixed pedestal stand is placed in center of the two cabinets.

1.8 IV Stand

IV Stand is mounted on the left rear side of the incubator. The IV pole mounted on the stand can support two bottles simultaneously.

1.9 Mattress Tray

The incubator Mattress tray includes a mattress. The X-ray cassette can be placed beneath the Mattress. The tilt-able Mattress tray platform allows Trendelenburg and Fowler positioning. The system for the tiltable Mattress tray provides a one step motion to avoid disturbing the patient.

Section 2: Installation

- 2.1 Set-up
- 2.2 Installation of Hood, shell and the Pedestal Stand.
- 2.3 Installation of Accessories
- 2.4 Installation of Probes
- 2.5 Mechanical Checkout Procedure
- 2.6 Controller Checkout Procedure

2.1 Set-up

This section provides assembly procedures for the hood, shell and the pedestal/stand along with procedures for the accessories of IV stand, Monitor stand and Observation light.

When removing the equipment from the cartons, take care not to scratch or otherwise damage unprotected surfaces.

After removal from the shipping containers, inspect the nice Neotech baby incubator and all accessory items for any signs of damage which may have occurred during shipment. File a damage claim with the shipping carrier if damage has occurred. Also confirm the presence of all accessory items or factory installed options as listed on the packing slip.

2.2 Installation of shell and the Pedestal Stand.

- 2.2.1 Assembling the Hood on the Shell
- 2.2.2 Assembling the Hood/Shell on the Pedestal Stand

2.2.1 Assembling the shell on the Pedestal stand. (See the Picture 1)



Picture 1

i. Mount the shell on the pedestal as shown in the picture and fix it using the four 8X15mm hex bolts and 8mm washer provided with the equipment.

2.2.2 Assembling the Hood on the shell and pedestal/stand. (See the Picture 2 & 3)

The hood consists of single walled (Standard) and Double walled (Optional), transparent shaped acrylic Sheet, Access port, Access panel, lead grommet and air probe. Lift this hood and place it on the shell and place the back plate of hood hinge as shown in the picture 2 and Fix the hood with the shell using the 5X15mm Screw provided as shown in the picture 3.

Important: The Hood/shell and the pedestal/stand are keyed such that the Hood/shell can only be mounted on the pedestal when the Hood/shell faces the direction in which the wheels with brake are placed. The wheels with brake are placed on the front side of the equipment.

Warning: The incubator must be attached to the pedestal/stand using the bolts provided. Failure to do so could result in the incubator separating from the pedestal/stand if sufficiently tilted, particularly with the hood open.



Picture 2



Picture 3

Connect the Main Power Cord: Take out the Power cord and connect to the bottom side of the shell socket.

2.3 Installation of Accessories

2.3.1 Installation of the Mattress tray

2.3.2 Installation of Humidity System

2.3.3 Installation of IV Stand.

2.3.1 Installation of the Mattress tray (See Picture 4)



Picture 4

- Lift the hood from the front side and place it securely. Open the Mattress tray stand (if required) and place it on the deck. After locating the mattress tray put the mattress and place the hood in normal position.
- **Caution:** when the mattress is in the tilted position, ensure an additional support is provided to minimize the baby falling.

2.3.2 Installation of Humidity System (see the Picture 5)

Important: To prolong the useful life of the Humidity module, use only distilled water. Sterile water is not an acceptable substitute for distilled water.



Picture 5

- Remove the mattress tray and deck from the shell after opening the hood.
- Take off the sponge from the humidifier chamber and make it wet and place it on the same place for humidification.
- After placing the wet sponge, place the deck and mattress tray and close the hood.

2.3.3 Installation of IV Stand (See Picture 6)



Picture 6

- Place the IV pole holder on the IV stand which is on the left side bumper.
- Place the IV pole on the IV stand as shown in the picture.
- Put the IV knob to hold the IV pole firmly with the IV stand.

2.4 Installation of Probes

2.4.1 Installation of air probe

2.4.2 Installation of Skin probe

2.4.1 Installation of air probe (See the Picture 7)



Picture 7

- Connect the air probe with an air probe socket which is placed on the right side of the shell

2.4.2 Installation of Skin probe (See Picture 8)



Picture 8

- Connect the skin probe with a skin probe socket which is placed on the right side of the control display and put the probe into the hood through the lead grommet.

2.5 Mechanical Checkout Procedure

2.5.1 Overall Appearance

2.5.2 Mechanical Checks

2.5.3 Accessory checks

Warning: Before using the nice Neotech Baby incubator, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury.

Warning: Do not perform the Checkout Procedures (Mechanical and Control Unit) while a patient occupies the incubator.

Warning: Complete the “Checkout Procedures” section of this manual before putting the unit into operation. If the incubator fails any portion of the checkout procedures it must be removed from use and repaired.

2.5.1 Overall Appearance

- Disconnect the power cord from the AC power source for the mechanical checks portion of this procedure.
- Check the overall appearance of the incubator. There should be no obvious damage.

Setup and Checkout Procedures

- For units with castors, check that all castors are in firm contact with the floor and that the incubator is stable and moves freely.
- Lock the two front castors and check that the incubator is held in place.
- Examine the power cord for damage. Replace the power cord if damage is evident.

Warning: Do not place any accessories or other objects directly over the bed surface. This may block heat energy and lead to cooling of the infant.

Warning: Do not place items on top of the Hood assembly. Items placed on top of the Hood assembly can fall and injure the patient and may pose a fire hazard.

2.5.2 Mechanical Checks

1. Hood operation (see Picture 9)



Picture 9

- Pull the blue color knob which is on the right side rear end of the canopy and lift the canopy from the front side and place it securely.
- The blue color knob is used as a lock system.
- The hood operation is displayed on the picture.

2. Access panel Operation (see Picture 10)



Picture 10

- Rotate the locks and open the access panel.
- Pivot the access panel to the full open position.
- Close the access panel and check the locks are properly secured to avoid accidental opening of the panel.

3. Access Door, Latches and Gaskets (see Picture 11)



Picture 11

- Press the door release of each access door. The access door should swing open. Close the door and check for proper latching and quietness. Check the access ports are placed properly on the wall.

4. Inner Walls are properly latched (Optional):

- Open the access panel and check that the front and rear inner walls are properly latched.

5. Iris Entry Ports (Optional):

- Rotate the outer ring of the Iris port(s), the Iris should open and close as the rotation is continued through 360 degree.

6. Air intake Micro filter (see Picture 12)

Warning: A Dirty air intake micro filter may affect oxygen concentrations and/or cause carbon dioxide build-up. Check filter on a routine basis and change at least every 3 Months.



Picture 12

- Loosen the two thumb screws of the air intake filter cover and remove the cover. Inspect the micro filter; if visibly dirty, replace it.

Warning: A Dirty air intake micro filter may affect oxygen concentrations and/or cause carbon dioxide build-up. Check filter on a routine basis and change at least every 3 Months.

2.5.3 Accessories Checks

Perform these checks if they are applicable.

Warning: Limit the load of accessories to 5 Kg per side on the Incubator to ensure stability. Accessories should not be mounted more than 56 inches (142 cm) above the floor.

Warning: Due to the increased height of units with height adjustment, a tipping hazard may exist. Limit the total accessory load to 5 Kg.

Caution: Check that all accessories are mounted securely and that the load limits are not exceeded. Check that all gas accessories are installed and operating properly. Where applicable, perform the checkout procedures detailed in the Operation and Maintenance Manuals for the accessories.

1: IV Stand: (see Picture 13)



- Using the knob, to fix the IV firmly on the IV stand. The maximum Load of the IV pole is 5 Kg.

2.6 Controller Checkout Procedures

- 2.6.1 Air Flow Fail Audio and Visual Indication.
- 2.6.2 Air Control Mode Operation.
- 2.6.3 High/Low Air Temperature Audio and Visual Indication.
- 2.6.4 Skin Control Mode Operation.
- 2.6.5 High/Low Skin Temperature Audio and Visual Indication.
- 2.6.6 Maximum Air Temperature.
- 2.6.7 Skin probe Fail Audio and Visual Indication.
- 2.6.8 Air probe Fail Audio and Visual Indication.
- 2.6.9 Check the Programmable Mute Time.
- 2.6.10 Check Memory Back-Up, power fails.

2.6.1 Air Flow Fail Audio and Visual Indication.

Warning: The Incubator should not be used, if it fails to function as described. Service should be referred to qualified personnel.

Warning: The Heater can be sufficiently hot to cause burns. Permit the heater to cool for at least 20 minutes before attempting this procedure.

- Set the Power Switch to OFF. Remove the mattress tray and remove the cover from the heater and the fan. Remove the impeller from the fan motor shaft. Replace the cover and the Mattress tray. Place the power switch to the ON position and wait for the end of the self cycle. Wait for 20-30 minutes. The low air flow fail Audio and Visual Indication message will occur. Replace the impeller and restore the incubator for normal Operation before proceeding to the next step.

2.6.2 Air Control Mode Operation

- With all Access openings closed, allow the incubator to warm up to the air set temperature of 35°C. It should take less than 45 minutes depends upon the Environment Temperature. When the air temperature display has stabilized, the digital display should remain within 0.5°C of the set temperature for 15 minutes.

Note: Check the Air Temperature Display window Shows 25.5°C when connect the calibrated test probe.

2.6.3 High/Low Air Temperature Audio and Visual Indication

- Open the Access panel. In approximately 5 minutes the Audio and Visual Indication indicators should activate, the low air temperature visual and audio Audio and Visual Indication should sound. Close the Access panel.
- Rub the Air temperature probe with hand to raise the temperature 0.5°C greater than the set temperature, the high air temperature visual and audio Audio and Visual Indication should Sound.

2.6.4 Skin Control Mode Operation

- With all Access openings closed, Place the skin probe 4 inches above the mattress center. Allow the incubator to warm up to the Skin set temperature of 35°C. It should take less than 45 minutes depends upon the Environment Temperature. When the Skin temperature display has stabilized, the digital display should remain within 0.5°C of the set temperature for 15 minutes.

Note: Check the Skin Temperature Display window Shows 25.5°C when connect the calibrated test probe.

2.6.5 High/Low Skin Temperature Audio and Visual Indication

- Set the Skin set temperature to 35°C. When the temperature Stabilizes, open the access panel. In approximately 5 minutes, the low Skin temperature visual and audio Audio and Visual Indication should Sound.
- Rub the skin temperature probe with hand to raise the temperature 0.5°C greater than the set temperature, the high Skin temperature visual and audio Audio and Visual Indication should Sound.

2.6.6 Maximum Air Temperature

- Select the skin temperature mode and set temperature is greater 37°C. Place the skin probe outside the incubator. Allow the incubator to heat. If the skin temperature low Audio and Visual Indication sounds, press the mute key. The incubator should not heat above 39.9°C as indicated by the air temperature display. When reaching the air temperature at 39°C over temperature Audio and Visual Indication should sound and the heater should be OFF.

2.6.7 Skin probe Fail Audio and Visual Indication

- Disconnect the skin probe from the socket. The audio Audio and Visual Indication Sound activates and the display shows "S.O" (Sensor Open) and the heater should be OFF. Reconnect the skin probe, the incubator should return to normal operation.

2.6.8 Air probe Fail Audio and Visual Indication

- Disconnect the air probe from the socket. The audio Audio and Visual Indication Sound activates and the display shows "S.O" (Sensor Open) and the heater should be OFF. Reconnect the air probe, the incubator should return to normal operation.

2.6.9 Programmable Mute Time

- Press the Mute Key and switch ON the equipment. The Air temperature Display window shows the mute time. It can vary between 2 & 20 minutes by using increase / decrease keys. Set at 15 minutes. Press mode key, it comes to normal operation.

2.6.10 Memory Back up, power Fail

- **Memory Back** Switch to the Skin Mode. Set the skin set temperature at 36.5°C. Switch OFF the equipment. Switch On the equipment again. The mode and the set value should remain the same.
- **Power Fail:** Remove the power cord and then switch on the equipment. Power Fail LED is glow.

Section 3: Operation

- 3.1 Control Panel Operation
- 3.2 Operating Modes
- 3.3 Mattress Platform Operation
- 3.4 Front Access Panel Operation
- 3.5 Patient environment
- 3.6 X-ray Procedures
- 3.7 Humidifier operation

3.1 Control Panel Operation:

- 3.1.1 Displays
- 3.1.2 Indicator Lights
- 3.1.3 Switches
- 3.1.4 Audio and Visual Indication

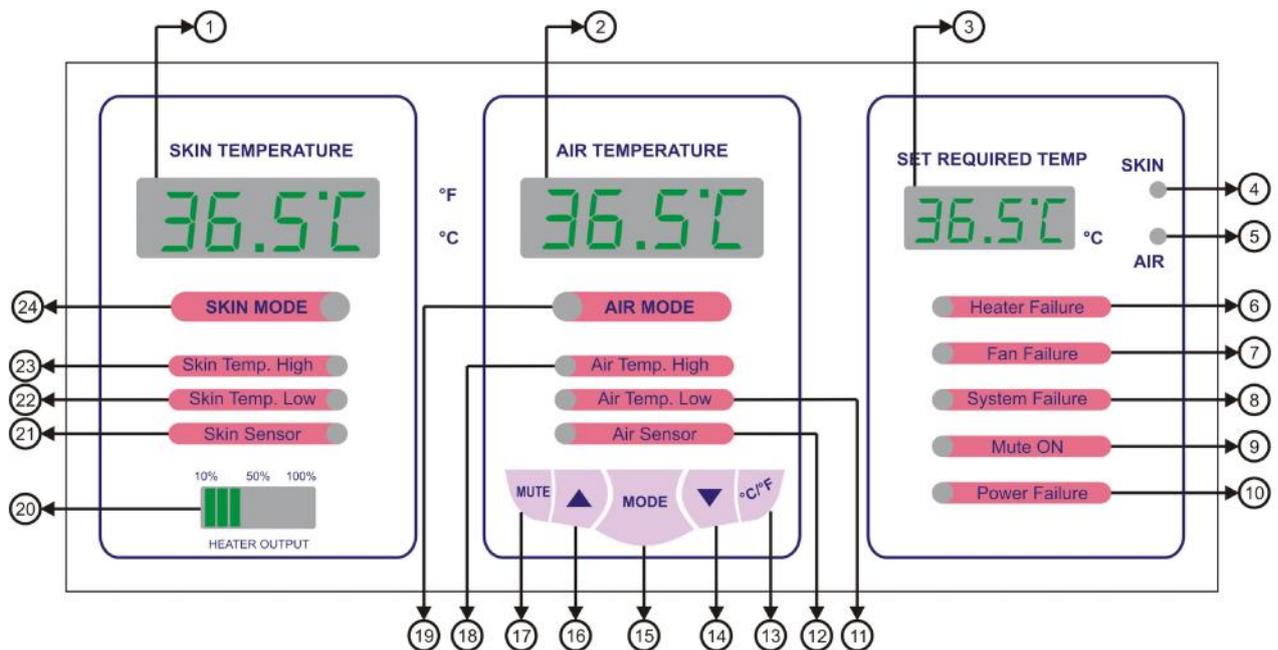


Figure 1

Front Panel Buttons

1	Skin Temperature Display	13	°C/°F Conversion Key
2	Air Temperature Display	14	Decrease Key
3	Skin/Air Set Temperature Display	15	Mode Key
4	Skin Set Temperature Indicator	16	Increase Key
5	Air Set Temperature Indicator	17	Mute Key
6	Heater Failure Indicator	18	Air Temperature High Indicator
7	Fan Failure Indicator	19	Air Mode Indicator
8	System Failure Indicator	20	Heater Output Indicator

9	Mute ON Indicator	21	Skin Sensor Failure Indicator
10	Power Failure Indicator	22	Skin Temperature Low Indicator
11	Air Temperature Low Indicator	23	Skin Temperature High Indicator
12	Air Sensor Failure Indicator	24	Skin Mode Indicator

3.1.1 Displays

- ❖ **Skin Temperature:** The patient temperature display indicates the temperature sensed at the skin temperature probe tip. The skin temperature probe must be properly connected to the baby incubator and the infant for an accurate patient temperature measurement. The range of temperature measurement is from 30.0 to 38.0°C, with a resolution of 0.1°C.
- ❖ **Air Temperature:** The air temperature display indicates the temperature sensed at the air temperature probe tip. The air temperature probe must be properly connected to the Baby incubator and the infant for an accurate air temperature measurement. The range of temperature measurement is from 20.0 to 30.0°C, with a resolution of 0.1°C.
- ❖ **Skin Set Temperature:** The Set temperature display indicates the control temperature selected in the skin mode. The skin control temperature range is from 35.0 to 38.0°C.
- ❖ **Air Set Temperature:** The Air Set temperature display indicates the control temperature selected in the Air mode. The air control temperature range is from 30.0 to 39.0°C.
- ❖ **% of Heater Output Power:** The % power display indicates the percentage of maximum power that is being supplied to the radiant heater in 10% increments.
- ❖ **Memory Back-up:** Switch to the Skin Mode. Set the skin set temperature at 36.5°C. Switch off the equipment. Switch On the equipment again. The mode and the set value remains the same.

3.1.2. Indicator Lights

- ❖ **Skin Mode Indicator:** The skin mode indicator lights when the Baby incubator is in the skin mode of operation.
- ❖ **Air Mode Indicator:** The air mode indicator lights when the Baby incubator is in the air mode of operation.

3.1.3. Switches

- ❖ **Mode Switch:** This switch is used to select either the Manual or Skin or Air mode of operation. An audio tone sounds momentarily when the mode switch is depressed.
- ❖ **Increase () and Decrease () Switches:** These switches are used to set the radiant power level (% power) in the manual mode and to set the control temperature in the skin & air mode.
- ❖ **Mute:** This switch is used to silence the audible Audio and Visual Indication. It silences all Audio and Visual Indication except the system failure Audio and Visual Indication and temperature > 39.0 C, Probe Fail.
- ❖ **Centigrade/Fahrenheit Key:** This switch is used to select temperature reading from Centigrade to Fahrenheit or vice versa.
- ❖ **Observation Light On/Off:** This switch activates the observation light located in the right side of the shell

Warning: Prolonged exposure to the light emitted by the observation lamp in this unit may harm the unprotected eyes of the infant. For safety, cover the infant's eyes.

Warning: There is a possibility of electromagnetic interference or other interference causes from other external equipment, the Incubator may get in operation. Use EMC compliance Equipment to avoid the interference

Warning: The Incubator may cause radio interference, in which case adequate measure may be required to prevent interference

Caution: Isolation from the supply mains is Detachable Power cord provided

3.1.4. Audio and Visual Indication

- ❖ **Air Probe Failure Audio and Visual Indication:** The air probe failure Audio and Visual Indication is only active in the air mode of operation. The Audio and Visual Indication activates when the air temperature probe fails electrically due to an open or short circuit, or is disconnected from the Baby incubator. The heater deactivates and the patient temperature displays “S.O”.
- ❖ **Skin Probe Failure Audio and Visual Indication:** The skin probe failure Audio and Visual Indication is only active in the skin mode of operation. The Audio and Visual Indication activates when the skin temperature probe fails electrically due to an open or short circuit, or is disconnected from the Baby incubator. The heater deactivates and the patient temperature displays “S.O”.
- ❖ **Air Temperature High:** The Temperature High Audio and Visual Indication is only active in the air mode of operation. The Audio and Visual Indication activates when the difference between the environment temperature and the control temperature is greater than 1°C. When the air temperature returns to within 0.1°C of the control temperature, this Audio and Visual Indication is automatically reset.
- ❖ **Air Temperature Low:** The Temperature Low Audio and Visual Indication is only active in the air mode of operation. The Audio and Visual Indication activates when the difference between the air temperature and the control temperature is lesser than 3°C. When the air temperature returns to within 0.1°C of the control temperature, this Audio and Visual Indication is automatically reset.

Warning: In the air mode, verify that the air temperature probe is securely attached to the side panel at least once every half hour. A dislodged probe may not trigger an Audio and Visual Indication. If the probe becomes dislodged, the Baby incubator can over or under heat the infant.

Warning: The air temperature probe should be located on the back panel of the baby incubator in an area which is directly in the path of the radiant heat. It should not be attached to an area which is shielded from the radiant heat. Large temperature gradients and very long air response times will result from improper probe placement.

- ❖ **Skin Temperature High:** The Temperature High Audio and Visual Indication is only active in the skin mode of operation. The Audio and Visual Indication activates when the difference between the patient temperature and the control temperature is greater than 1°C. When the patient temperature returns to within 0.1°C of the control temperature, this Audio and Visual Indication is automatically reset.
- ❖ **Skin Temperature Low:** The Temperature Low Audio and Visual Indication is only active in the skin mode of operation. The Audio and Visual Indication activates when the difference between the patient temperature and the control temperature is lesser than 1°C. When the patient temperature returns to within 0.1°C of the control temperature, this Audio and Visual Indication is automatically reset.

Warning: In the skin mode, verify that the patient temperature probe is securely attached to the patient at least once every half hour. A dislodged probe may not trigger an Audio and Visual Indication. If the probe becomes dislodged, the Baby incubator can over or under heat the infant.

Warning: The skin temperature probe should be located on the patient’s skin in an area which is directly in the path of the radiant heat. It should not be attached to an area which is shielded from the radiant heat or between the patient and the mattress. Large temperature gradients and very long skin response times will result from improper probe placement.

- ❖ **System Failure Audio and Visual Indication:** The system failure Audio and Visual Indication activates in any mode of operation, if any components are defect.

- ❖ **Power Failure Audio and Visual Indication:** The power failure Audio and Visual Indication activates in any mode of operation if the power cord gets disconnected or when there is no AC main power.
- ❖ **Over Temperature Audio and Visual Indication greater than 39°C Skin/Air mode:** The over temperature Audio and Visual Indication activates and displays 'OT' when anyone of the sensor senses the temperature as 39°C in either mode and the heater deactivates.
- ❖ **Fan Fail Audio and Visual Indication:** The Fan Fail Audio and Visual Indication activates in any mode of operation, if the impeller gets struck or electrically defect (without operation of fan).
- ❖ **Heater Failure Audio and Visual Indication:** The Heater Failure Audio and Visual Indication activates in any mode of operation, if the Heater gets electrically defect.
- ❖ **Fan Failure Audio and Visual Indication:** The Fan Failure Audio and Visual Indication activates in any mode of operation, if the fan gets electrically defect.

3.2 Operating Modes

3.2.1 Skin Mode

3.2.2 Air Mode

Warning: Before using the nice Neotech Incubator, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the benefits and risks of this type of device.

Warning: Do not leave the patient unattended when using the Baby incubator. Check the patient's temperature periodically to ensure the comfort and the safety of the patient. If the Baby incubator is used for an extended time, it is recommended that the Skin mode of operation be used. When an Audio and Visual Indication is silenced, close monitoring of the patient's condition is required.

Warning: Use of electrosurgical units or other electrical field radiating equipment can affect the operation of the Baby incubator. Keep the patient probe lead as far away as possible from electrosurgical cables. Do not allow excess electrical cables to be laid on the bed platform. Use of electrosurgical units or other instruments which radiate electrical fields can cause indirect heating, by several tenths of a degree of the skin temperature probe due to absorbed electrical energy. When using these devices near the Baby incubator, operate the Baby incubator in manual mode for maximum safety.

Warning: Baby incubator increase an infant's insensible water loss. Take appropriate measures to maintain the patient's fluid balance while caring for them in a Baby incubator.

Warning: Do not use the Baby incubator in the presence of flammable anesthetics; a possible explosion hazard exists under these conditions.

Warning: When using a Baby incubator, change the patient's diapers frequently. Radiant energy causes more rapid urine evaporation, and may lead to inaccurate urine diagnosis test analysis and inaccurate weight measurements.

- ❖ Connect the power cord to a properly grounded AC power source. Place the power switch in the ON position. During the first seconds of operation, the Baby incubator performs a self check of the control system. The software is verified, calibration is checked and operation of the solid state relay controlling the heater is verified. All displays and indicators are lit and the audible Audio and Visual Indication is sounded. If the self check detects a failure, the Audio and Visual Indication stays on and service is required.

Note: When the Power is ON, the incubator begins operation in the mode last used.

3.2.1 Skin Mode Operation

Note: The skin temperature probe must be properly attached before starting Skin mode operation.

- ❖ User must select a Skin control temperature (Set required Temperature) setting when the Baby incubator is used in the Skin mode for the first time. Users are prompted to make this setting with an operator prompt tone and the changing of the control temperature display.

Setting of Skin Control Temperature

- ❖ The Skin control temperature is adjusted by pressing the increase () and decrease () touch switches. The control temperature can be adjusted from 35 to 37°C. In the Skin mode, the temperature sensed by the skin temperature probe is used by the control system to modulate the radiant heat and maintain the patient's skin temperature at the selected control temperature.

Note: To over ride the skin control temperature range from 37.1 to 38°C, Press Mute key and increase ()/decrease () Key simultaneously

Note: The Baby incubator cannot differentiate between an increase in core temperature with cold skin (fever), and low core and skin temperature (hypothermia). Patient temperature should be verified with an ancillary thermometer.

Warning: In the Skin mode, verify that the patient temperature probe is securely attached to the patient at least every half hour. A dislodged probe does not always trigger an Audio and Visual Indication. If the probe becomes dislodged, the Baby incubator can over or under heat the infant.

Note: A patient placed in any Baby incubator will normally develop temperature gradients with hotter and cooler areas. This is due to radiant heat being applied above the infant, the unequal skin cooling effect from evaporative water loss, unequal heat generation within the patient, and the environmental variables of room temperature, room air movement, incidental sunlight, etc.

WARNING: The use of Halogen based phototherapy equipment may raise the patient's temperature.

3.2.2.1 Skin Temperature Probe Attachment.

Warning: Use only the Reusable nice Neotech skin temperature probe to monitor the patient's skin temperature. Use of other manufacturer's probes may affect the accuracy of Baby incubator operation and the electrical safety of the patient.

Warning: The skin temperature probe should be located on the patient's skin. It should not be attached to an area which is shielded from the radiant heat or between the patient and the mattress. Large temperature gradients and very long skin response times will result from improper probe placement.

Warning: Rectal temperatures must never be used to skin control patient's temperature.

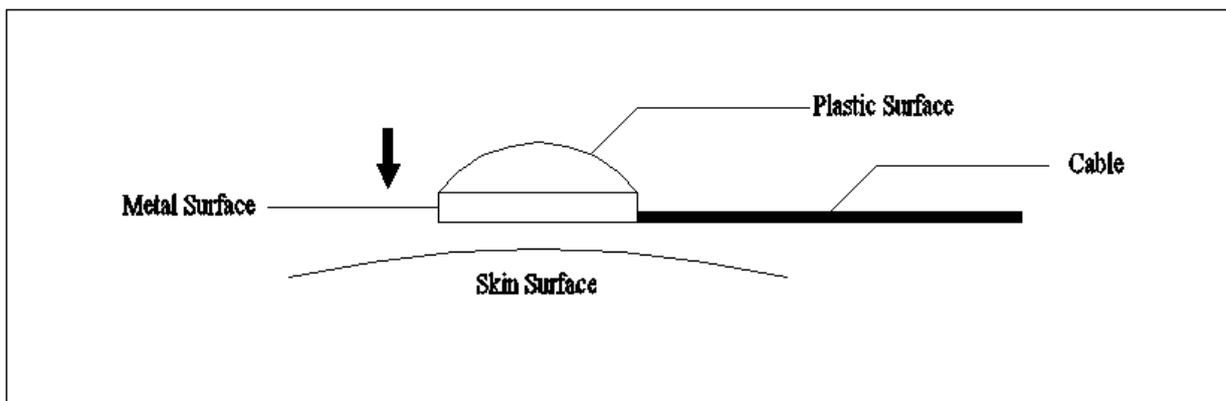


Figure 2

- ❖ Place the metal side of the skin temperature probe on the skin over the liver area of the infant's abdomen. Remove the paper protecting the hypoallergenic adhesive on the Heat Reflective Patch. Secure the skin temperature probe to the patient's skin with the adhesive side of the patch.

- ❖ Connect the skin temperature probe to the Baby incubator by plugging the probe connector into the right side of the Connector as viewed from the front.

Note: The nice Neotech Patient probe lead is made from low mass wire that helps prevent probe detachment while reducing pulling on the neonate's skin

Note: The probe jack is attached at a specific torque value. Loosening or tightening the jack may break the electrical connector.

Note: If the patient is prone, place the skin temperature probe on the back, where it will not be against the mattress. If the probe is between the patient and the mattress, it will produce false readings.

Note: Avoid placing excessive strain on the skin temperature probe lead. Always remove the probe by grasping the plug at the panel. Do not pull on the probe lead.

Warning: Intimate contact between the skin temperature probe tip and the patient's skin must be maintained for accurate skin temperature measurement. Under heating or overheating may result from poor contact between the skin temperature probe and the patient. Verify that the skin temperature probe is securely attached to the patient at least once every half hour.

Warning: Periodically monitor the infant Temperature Probe it may remove from the Skin due to poor affixing, poor adhesive of the tape. It may cause over heating of the baby.

Caution: Always remove the probe from the patient by grasping and removing the heat reflective patch first, and then remove the probe from the patient or the patch. Always remove the probe from the Baby incubator by grasping the plug at the panel. Placing excessive strain on the skin temperature probe lead can damage the probe.

3.2.2 Air Mode Operation

Note: The Air temperature probe must be properly attached on the rear side of the Baby incubator hood, before starting air mode operation.

- ❖ User must select an air control temperature (Set required Temperature) setting when the Baby incubator is used in the air mode for the first time. You are prompted to make this setting with an operator prompt tone and the changing of the control temperature display.

Setting of Skin Control Temperature

- ❖ The air control temperature is adjusted by pressing the increase () and Decrease () touch switches. The control temperature can be adjusted from 30 to 37°C. In the air mode, the temperature sensed by the air temperature probe is used by the control system to modulate the radiant heat and maintain the Environment temperature at the selected control temperature.

Note: To over ride the Air control temperature range from 37.1 to 39°C, Press Mute key and increase ()/decrease () Key simultaneously

Note: The Baby incubator cannot differentiate between an increase in core temperature with cold skin (fever), and low core and skin temperature (hypothermia). Patient temperature should be verified with an ancillary thermometer.

Warning: In the air mode, verify that the air probe is securely attached to the rear side of the hood. A dislodged probe does not always trigger an Audio and Visual Indication. If the probe becomes dislodged, the Baby incubator can over or under heat the infant.

Note: The Air mode is used when the baby skin is very delicate from attaching the skin probe.

Warning: The use of phototherapy equipment may raise the patient's temperature.

3.3 Mattress Platform Operation

- ❖ The Mattress platform tilts for Trendelenburg and Fowler positioning capabilities. Rotate the knobs (left and right side) placed on the front side of the shell to position the bed (up or down).

Warning: Inspect all patient connected tubes or wires before and after moving or tilting the bed. Tilting or moving the Baby incubator bed up or down can pull on tubing or leads connected to the patient. This may disconnect tubes or leads, restrict gas or liquid flow, or move sensors out of position.

3.4 Front Access Panel Operation

- ❖ Rotate the locks and open the access panel. Pivot the access panel to the full open position. After completion of the procedure close the access panel and lock it.

3.5 Patient environment

- ❖ Open front flap by turning the left and right-hand locks towards one another. The front flap should only be left open for as short a time as possible. Withdraw bed from pre- warmed incubator and place patient on it. Replace bed in original position.

Important: Never place patient in cold incubator. Reclose front flap (front door)

- ❖ Handle the flaps open automatically by pushing the operating knob. The bed can be tilted up to 8° to either side as required with the adjusted mechanism. To do this, loosen the associated adjusting handle by 1/4 rotation, set handle vertical and retighten with a 1/4 turn.

3.6 X-ray Procedures

- ❖ The X-ray cassette may be placed in the slot under the bed platform or in the X-ray cassette tray, if installed.
- ❖ The X-ray cassette tray facilitates X-ray procedures while patients occupy the Incubator mattress. An X-ray cassette can be placed on the tray and slid into the cavity beneath the bed without disturbing the patient (optional).
- ❖ X-rays may be taken directly through the Hood. Position the X-rays cassette directly under the infant Mattress tray (Standard).

3.7 Humidifier operation (Conventional)



Picture 14

- ❖ The initial step is to remove the mattress tray and the deck al which is placed over the shell.
- ❖ After removing it, you can see the humidifier chamber with sponge like shown in the picture.
- ❖ Take off the sponge provided from the humidifier chamber and immerse it in water. Make sure that the sponge is not too wet and not too dry.
- ❖ Place the sponge back in the humidifier chamber and place the deck al and mattress tray above it and lock the hood. When the fan is turned on the air inside the canopy will gain humidity from the wet sponge.

Warning: nice 3030 have Conventional Humidity System and hence humidity of inside hood is not controlled by the equipment.

Section 4: Cleaning and Maintenance

4.1 General

4.2 Cleaning

4.1 General:

- This Section Provides Cleaning and Maintenance Instructions. Where necessary, disassembly instructions are provided.
- Routinely inspect patient compartment for signs of breakage and replace assemblies before placing Incubator into service.

Warning: Make sure that the Oxygen supply to the Incubator is turned OFF and that the Incubator is disconnected from the oxygen supply when performing cleaning and Maintenance procedures; a fire and explosion hazard exists when performing cleaning and/or Maintenance procedures in an oxygen-enriched environment.

Warning: Switch off the equipment and disconnect the Power cord from the mains before take in to cleaning

Warning: Don't pour the water for cleaning it may enter into the electronics circuits it cause short circuit and get shock.

Warning: Don't use flammable agents for cleaning even Small quantity of flammable agents such as ether and alcohol, left in the incubator it can cause fire in connection with oxygen

4.2 Cleaning

4.2.1 Disassembly for cleaning

4.2.2 Cleaning Agents

4.2.3 Reassembly after cleaning

- It is recommended that when an infant is discharged, or at least once a week, to thoroughly clean and disinfect the incubator. The most effective way to clean is to first disassemblies in categories according to the method of cleaning required.

Caution: Periodically clean and disinfect the incubator it fails cause cross infection

4.2.1 Disassembly for cleaning

Note: For routine cleaning there is no need to separate the hood/Base assembly from the pedestal/Stand. If Separation is necessary, refer to the installation section 2.

- Refer to Para 2.5.2 (3) and disconnect the Sensor cables from the Shell 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.

1: Removal of Mattress Tray



Picture 15

2: Removal of Main Deck (Main Cover).

- ❑ Refer to Para 2.3.1 and remove the Mattress tray.



Picture 16

- ❑ After removing the Mattress Tray, take off the Deck al as shown in the picture 16.

3: Removal of Heater/impeller covers

Warning: The Heater can be sufficiently hot to cause burns; remove or touch the heater if the unit has been switched off for at least 45 minutes.



Picture 17

- Pull the heater fins as shown in the picture 17.



Picture 18

- Remove the spring which holds the impeller and take off the impeller as shown in the picture 18.

7: Removal of Micro Filters



Picture 19

- ❑ Remove the Air intake Micro filter Cover by loosening the two thumbscrews.

- ❑ Remove Disposable Iris Entry Port Sleeves by pulling each Sleeve off the retainer rings. Wipe clean.
- ❑ Remove Disposable Access door cuff from each Access door Gasket by pulling it off from the outside; discard the cuffs.

4.2.2 Cleaning Agents

- ❑ Use an Adopter or Quaternary Disinfectant Registered by the Environment Protection Agency, but only after the Incubator is empty and disassembled as described in Para 4.2.1. Cleansers such as Kleenaseptic®* Germicidal Surface Cleanser may be used. When using any cleaning agent, follow the manufacturer's directions for use. After removing all solid wastes and contaminants from the disassembled parts, clean them as follows,
- ❑ **Skin Temperature Probe:** Use a disinfectant-detergent to thoroughly clean all surfaces, then dry with a clean cloth or paper towel.
- ❑ **Access Door Gaskets and Tubing access Ports:** Place the Access door gaskets and Tubing Access Ports into a Suitable container filled with a Disinfectant-detergent.
- ❑ Allow them to soak as recommended by the cleaning Solution's Manufacturer, then remove them and dry completely with a clean cloth or Paper towel.
- ❑ Wipe these Portions clean with a cloth dampened with a disinfectant-detergent.

Caution: Some Chemicals cleaning agents may be Conductive and/or leave a residue which may permit a built-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 these Surfaces.

Caution: Don't keep the metal surface in wet condition it may cause corrosion and damage the part

- ❑ **Humidity chamber:** Fill with water at 80°C and leave for 10 minutes and wash the chamber, clean with a cloth dampened with a disinfectant-detergent.
- ❑ **Controller, shell and Pedestal Stand:** Use a disinfectant-detergent to clean all surfaces thoroughly, and then dry with a clean cloth or paper towel.

Caution: When cleaning the interior of the incubator shell, care must be taken to prevent liquids from entering the motor shaft opening.

- ❑ **Hood, air Sensor and Inner walls:** The Inner walls are hinged on the access Panel(s) or rear Wall of the incubator. Refer to figure and release the inner Wall by pressing on the catches located at the top of the inner wall (optional)
- ❑ Use a disinfectant-detergent to clean all surfaces thoroughly, including the air Sensor, inner walls and access door(s). Make sure to clean all holes and indentations; then dry with a clean cloth or paper.

Caution: Alcohol can cause crazing of the Clear Acrylic hood. Do not Use alcohol for Cleaning.

Caution: Do not expose the Hood assembly to direct radiation from germicidal lamps. Ultra violet radiation from these sources can cause cracking of gaskets, fading of paint, and crazing of the Clear Acrylic hood.

- ❑ **Heater Radiator and Fan Impeller:** Remove any lint built-up on the Heater Radiator and Fan Impeller.

Caution: Failure to clean could result in sufficient lint built-up to reduce air flow, which will affect temperature control and cause high oxygen concentrations.

- ❑ **Mattress Tray, Main deck, Heater/Impeller Cover:** Use a disinfectant-detergent to clean all surfaces thoroughly, and then dry with a clean cloth or paper towel.
- ❑ A dirty Inlet filter may affect oxygen Concentration and/or cause carbon dioxide built-up. Be sure the filter is checked on a routine basis commensurate with local conditions. Particularly, if the incubator is used in an unusually dusty environment, more frequent replacements may be necessary.

4.2.3 Reassembly after cleaning

Note: Inspect all cleaned components for any breakage or cracks before reassembling into the incubator. Harsh cleaning agents may attack some of the plastics used in the Patient Compartment.

- ❑ Install the Heater fins and Fan Impeller.
- ❑ Install the Heater/Impeller Cover.
- ❑ Install the Main Deck.
- ❑ Install the Mattress Tray.
- ❑ Install the Disposable Mattress cover. Place a new disposable mattress cover over the mattress, and then place the mattress onto the tray.
- ❑ Install Disposable Iris Entry Port Sleeves (Optional)
- ❑ Install tubing access Ports into the front and rear edges of each side of the hood. Replace if distorted or torn.
- ❑ Install a New Access Door Cuff onto each Access Door gasket by stretching the larger diameter elastic band into the groove in the gasket. When installed correctly, the cuff has a small opening at its center. The Access door latch with slight pressure and should open when the latch lever is de-pressed (Optional).
- ❑ Install a new Air Intake Micro filter if necessary (Discolored or dirty). Replace the Air Intake Micro filter Cover and tightens the two thumbscrews

Note: If the incubator is to be gas Sterilized, wait until after Sterilization to install new cuffs..

Important: Perform a complete functional checkout (Refer 2.5) before returning the unit to service.

Caution: Use of nonstandard components: Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance

4.3 Life time of product

Since the product is classified under programmable medical electrical system and incase of unavailability of microcontroller the life time of the product can be considered as minimum five years.

Section 5: Specification

Voltage supply	:	~230V/50Hz /2A
Power Rating	:	370W Max
Heater Power Rating	:	300W Max
Electronics	:	Micro Controller based
Memory back-up	:	To Store the previous data of set temperature and the mode of operation
Programmable Mute time	:	2 min to 20 min
Incubator control	:	Servo Air and Servo Skin mode
Carbon Dioxide (CO ₂) Level within the Hood	:	Less than 0.8% when a mixture of CO ₂ in air is delivered at 750ml/min at a point 10cm above the centre of mattress

Temperature Accuracy

Air mode	:	Accuracy $\pm 0.2^{\circ}\text{C}$
Skin mode	:	Accuracy $\pm 0.2^{\circ}\text{C}$
Max. Temperature	:	39°C
Air Mode Control	:	30°C -37°C 37.1°C - 39°C Temperature Override Mode
Skin Mode control	:	35°C -37°C 37.1°C - 38°C Temperature Override Mode
Initial Temp Overshoot	:	< 0.5°C
Temperature uniformity (Level Mattress)	:	<0.8°C
Temperature Variability	:	<0.5°C
Temperature Rise Time	:	<35 minutes (Typical @ 23°C ambient)
Sensor	:	Thermistor

Probe Interchangeability	:	Accuracy $\pm 0.2^{\circ}\text{C}$ (Calibration not required)
Over temperature cutoff	:	Activated if incubator temperature exceeds 39°C In any skin/air mode
Bed tilting	:	$\pm 8^{\circ}$
Noise level within Hood environment	:	<50 db
Air Velocity Over the mattress	:	<0.25 m/s
Air Filter capacity	:	99% (0.5 microns)
Air Intake volume without filter	:	250 liter/min
Air Intake volume with filter	:	25 Liter/min

Audio and Visual Indication

Skin Temperature High	:	If skin temperature is $> 0.5^{\circ}\text{C}$ from set temperature.
Skin Temperature Low	:	If skin temperature is $< 1^{\circ}\text{C}$ from set temperature.
Air Temperature High	:	If air temperature is $> 0.5^{\circ}\text{C}$ from set temperature.
Air Temperature Low	:	If air temperature is $< 3^{\circ}\text{C}$ from set temperature.
Air Probe Fail	:	If air probe is removed or damaged.
Skin Probe Fail	:	If skin probe is removed or damaged.
System Fail	:	If any component is defective.
Over Temperature	:	If skin/air temperature is $> 39^{\circ}\text{C}$ in any mode
Heater Fail	:	If the heater is disconnected or fails
Fan Fail	:	If the fan is disconnected or fails
Air Flow Fail	:	If the impeller or fan gets defect
Power Fail	:	If the power supply is disconnected or fails

IEC 60601-1 Specifications

Type of Protection against electric Shock	:	Class 1
Degree of Protection against electric Shock	:	Type B
Mode of Operation	:	Continuous
Protection against hazardous of explosion	:	Not protected
Protection against increase of liquid	:	Not protected
Product Classification	:	Class II b.

Environment

Operating Temperature	:	15°C to 35°C
Operating Relative Humidity	:	15 – 90% RH, non condensing

Storage Ambient Temperature	:	-10°C to 60°C
Storage Relative Humidity	:	50% - 90% RH, non-condensing
Altitude	:	Sea level to 1.9 miles 3 Km.

Physical Dimensions

Overall width	:	99 cm
Overall height	:	139 cm
Height of bed	:	90 cm
Overall depth	:	72 cm
Dimensions of bed	:	70 cm x 40 cm x 5 cm
Weight	:	85 Kg with cabinet and 60 Kg without cabinet
Castors	:	4" diameter antistatic (2 lock & 2 non-locks)
IV Pole Max. Load	:	5 Kg.

Quality Test Approval

Quality	:	ISO 9001:2008
	:	ISO 13485:2003
Electrical Safety	:	IEC 60601-1:2005, Amd 1:2012
	:	IEC 60601-2-19:2009, Amd 1:2016
EMC Safety	:	IEC 60601-1-2:2014

Section 6: Warranty

6.1 Conditions

1. The warranty is confined to the first purchaser of the product only and is not transferrable.
2. Repairs under warranty period shall be carried out by the company authorized personnel only
3. In the event of repairs of any part/s of the unit, this warranty will thereafter continue and remain in force only for the unexpired period of the warranty. The time taken for repair and in transit whether under the warranty or otherwise shall not be excluded from the warranty period.
4. In case of any damage to the product/misuse detected by the Authorized service personnel the warranty conditions are not applicable and repairs will be done subject to availability of parts and on a chargeable basis only
5. Wear and Tear, and defects caused by manipulation or unsuitable treatment are not included under the warranty.
6. Temperature Probe & Battery carry only 3 months warranty. Lamps do not carry any warranty.
7. We warranty this unit for 12 months from the date of Installation. Warranty includes the repair and replacement of faulty components.
8. Defects caused by improper use, and defects due to causes beyond control like lightning, abnormal voltage, acts of god, and also defects caused by rats, cockroaches or any other insects will not be covered under warranty.
9. Warranty is not applicable if the equipment is not purchased from Neotech/authorized Neotech Dealer
10. Warranty is not applicable if the warranty card is not filled and sent back to Neotech.
11. Equipment has an expected shelf life of 5 years and service life of 6 years.

Customer Details cum Warranty Card

Date: _____

Hospital Name & Address: _____

Contact Person & Telephone/Fax No _____

Email _____

Department: NICU / PICU / OT / Gynecology / Causality / Others _____

Equipment Name: _____

Model No: _____ Sl. No. _____

Date of Purchase: _____ Date of Installation _____

Name of Authorized Dealer: _____

Customer Signature & Date
(I accept the terms & conditions of Warranty)

Dealer Signature with seal

Kindly fill the above and sent the same

From _____

To:
The Service In-charge
nice Neotech Medical Systems Pvt. Ltd.
No, 85. Krishna Industrial Estate,
Vannagaram, Mettukuppam,
Chennai-600095. Tamil Nadu,INDIA
Ph: 91-44-24762594, 24764608
Tele Fax: 91-44-24766920 – Ext: 203
Email: service@niceneotech.com, info@niceneotech.com
Web: www.niceneotech.com
Toll Free No. 1800-425-2594 (India only)

Section 7: Trouble Shooting

- 7.1 General System Failure
- 7.2 System Fault Baby Incubator
- 7.3 Maintenance interval
- 7.4 Disposing of the equipment

7.1 General System Failure

Sl. No.	Problem	Cause	Remedy
1.	Power failure LED is ON with audio Audio and Visual Indication	Power Failure	Check the unit is Plugged in to Main supply
			Check the mains are switched ON.
			Otherwise Contact nice Neotech
2.	System Failure LED is ON with audio Audio and Visual Indication	System Failure	Contact nice Neotech.

7.2 System Fault Baby Incubator

Sl. No.	Problems	Possible Causes and Remedy
1	No Display on the Control Panel	Check A/C Supply Voltage
		Check if Power Cord is disconnected
		Check Fuse in the Rear side of Pillar
		Otherwise, Contact nice Neotech
2	No Heater Output	Check the relay and fuse.
		Set Temperature may be less than Actual Temperature
		Check Heater Connection
		Otherwise Contact nice Neotech
3	Equipment Working But Fan & Heater output not working	Check the Fan connection
		Check Fuse in the PCB.
		Check Transformer Voltage
		Replace Fan. Otherwise Contact nice Neotech.
4	Equipment not give the Audio Audio and Visual Indication	Check the Temperature it may near to the Set temperature
		Check Mute ON.
		Otherwise Contact nice Neotech
5	Patient Temperature Display shows "S-O" with Continuous Audio and Visual Indication (S-O: Sensor Open)	Check if skin Probe is Disconnected from the equipment.
		If skin probe is defective, replace new probe
		Otherwise Contact nice Neotech

6	Air Temperature Display shows "S-O" with Continuous Audio and Visual Indication (S-O: Sensor Open)	Check if air Probe is Disconnected from the equipment.
		If air probe is defective, replace new probe
		Otherwise Contact nice Neotech
7	Display shows Heater Fail	Check the relay and fuse.
		Check Heater Connection
		Otherwise Contact nice Neotech
8	Over temperature Audio and Visual Indication i.e. Temperature > 39 ° C Display shows 'O-T'	Check incubator Temperature above 39° C
		Check the infant's skin.
		Check the skin probe intact.
		Check Infant Fever
9	Continuous Skin Temperature High Audio and Visual Indication	Check Patient Temperature is 0.5°C above Set Temperature
		Check the incubator temperature
		Otherwise Contact nice Neotech
10	Continuous Skin Temperature Low Audio and Visual Indication	Check Patient Temperature is 1°C below Set Temperature
		Probe may be wet.
		Otherwise Contact nice Neotech
11	Continuous Air Temperature High Audio and Visual Indication	Check Hood Temperature is 0.5°C above Set Temperature
		Otherwise Contact nice Neotech

Sl. No.	Problems	Possible Causes and Remedy
12	Continuous Air Temperature Low Audio and Visual Indication	Check incubator Temperature is 3°C below Set Temperature
		Probe may be wet.
		Otherwise Contact nice Neotech
13	Incubator Temperature over Mattress does not rise	Check Low incubator Temperature it should be approximately (22-30°C)
		Check draft around air conditioning outlet
		Check Percentage Heater Output is Set at low in Air Mode
		Low Supply Voltage
14	Incubator Temperature over Mattress rises excessively	Check direct Sun light, Heating Device or other Heat Source
		Percentage Heater Output is Set at High in air Mode
15	Incubator Temperature over Mattress dose not stabilize	Check unstable ambient temperature (should be 22-30°C)
		Check Strong Air conditioning draft
16	Temperature Display does not display Infant's Temperature accurately	Probe Thermal Sensitive Portion attached improperly
		Check Thermal Sensitive Portion of Probe covered improperly
17	Baby skin Temperature not correlate with display Temperature	Check sensitive portion of the Probe is fixed with baby skin properly.
		Check Probe is fixed to the lower abdomen of baby
18	In Skin Mode Baby getting over heat but equipment gives Low Temperature Audio and Visual Indication	Check the probe is intact with lower abdomen of baby
		Check the probe is removed and keep away
		Check the Set Temperature is high
19	Incubator temperature is not maintained	Check the Access panel, it should be closed
		Check the Access Port, it should be closed
		Check the Iris Port, it should be closed
		Check the environment temperature , it should be >22°C

7.3 Maintenance Intervals:

- Always disinfect and clean the unit and accessories before any maintenance – even when returning the unit to the supplier for repair.
- Always disconnect power supply before any maintenance.
- Use only nice Neotech's original parts for maintenance.

Warning: Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.

Warning: Don't misaligned the EMI Shielding and the beads it may cause the EMI interference to the equipment.

- **Access Panel:** To visually inspect the panels every day, whether it is properly fixed or breakages or lose.
- **Temperature measuring system:** Measuring system should be checked by trained service personnel with calibrated test probe every year.

Measurements Specific to units:

- Place Measuring stand with calibrated precision thermometer at the centre of mattress and clamp skin sensor under the holding spring on the top of the Measurement Stand at above 10 cm of the Mattress
- Set the set-temperature of 32°C (Air mode).
- Place the wet sponge in the Humidifier Chamber, After approximately 45 minutes note the indicated ACTUAL air temperature and the ACTUAL temperature.
- Raise set-temperature to 36°C and after at least 30 min. Again note the indicated ACTUAL air temperature and the ACTUAL temperature.
- The ACTUAL VALUE indicated may deviate by $\pm 0.2^\circ\text{C}$ from the set -temperature. If this deviation is exceeded, the dynamic adjustment must be performed by a qualified technician according to the service Instructions.
- On the nice 3030 over-temperature of the monitoring temperature sensor is detected. The Audio and Visual Indication threshold for this is defined by the software at 39°C. No adjustment is therefore necessary if the conditions in points 2 and 4 are satisfied.
- Fan fails Audio and Visual Indication: Incubator with setting 36°C. Remove the fan impeller and wait for 30 minutes. The fan fail Audio and Visual Indication must be given.
- The safety check results should be recorded.
- If the unit is not functionally and/or operationally reliable, it must be repaired or the operator informed of the danger arising from the use of the unit.

Note: No need of calibration if a new temperature probe is replaced.

- **Bed Up/Down Tilting:** To be inspected once in every three months by the trained technical personnel.
- **Inspection & Maintenance:** Yearly by trained Service Personnel.

Safety Checks:

Note: The following must be performed on this unit at least every 6 months by persons who are capable of carrying out these safety tests in a proper way on the basis of their training. Knowledge and practical experience and who do not have to be instructed in this work.

- Visual checks of the unit and accessories for mechanical damage affecting functions
- **Acrylic Hood** Check secure Access port by pressing from inside. In the event of wear, replace the Access port. Re-adjust turn bolt of hinge if play, present.
- **Control:** Check Water inlet tube which should be very smooth.
- Check Blower (fan), heater, air flow Sensor, air sensor and skin Sensor.
- **Fan Motor:** Noise must be Barely Audible on the bed (noise level<50 db) Replace motor if bearings damaged.
- **Skin Temperature Sensor:** Check line for damage and loose contacts.

- Check Safety Warning notices for 'Legibility'.
- Check equipment fuse links for rated current and fusing characteristic.
- Perform functional check according to operating instructions (section 3)

Replacement of Power failure Battery

- Remove the controller panel located in the front side of the shell by removing the knob. Then remove the 9V Dry Battery from the battery connector by pulling. Replace new battery by pressing the cap. Always use Hi Watt branded battery to minimize the down time.

Note: Do not use rechargeable battery. Ensure there is no wrong polarity when battery is connected to the cap.

7.4 Disposing of the Unit

- At the end of its Service life Dispose of the equipment in accordance with National waste Disposal Regulation or ask a suitable Disposal contractor to dispose of the unit. The local Environmental agency can supply further details.

Caution: Use of nonstandard components: Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance

Section 8. Spare Parts List

Sl. No.	Part No.	Part Name	Qty	UOM
3	30-05-034	Controller Assembly, 3030	1	No
7	30-05-037	Air Probe Assembly, 3030	1	No
8	30-05-039	Skin Probe Assembly, 3030	1	No
9	30-05-041	Mattress Tray Assembly, 3030	1	No
10	30-05-042	Hood Assembly, 3030	1	No
11	30-05-043	Access Panel Assembly, 3030	1	No
	30-05-044	Access port assembly, 3030	1	No
12	30-10-067	Deck	1	No
	30-10-075	IV pole	1	No
15	30-05-033	Transformer Assembly, 3030	1	No
16	30-05-036	PCB Control Assembly, 3010	1	No
17	99-00-060	Grommet	4	No
18	91-00-051	Battery 9V	1	No
19	91-00-068	Heater	1	No
20	99-00-115	Impeller	1	No
22	30-05-056	Shell Assembly, 3030	1	No
24	87-00-009	Mattress 271/2"x151/2"x2"WOP 3010	1	No
25	87-00-047	Air Filter	10	No
26	88-00-021	3726 High Pressure Tube ID6mm OD3mm	0.50	Mtr.
27	89-16-007	5A Fuse Small	2	Nos
28	90-00-029	Power Cord 3Pin M/C 24/.2 3mtr CPU	1	No
29	91-00-003	Switch IRS 16	1	No
30	91-00-013	Connector FM 14	1	No
31	91-00-090	EMI Filter 230V 3A	1	No
32	93-00-015	Castor 4" Jainsons JM - 1 Break	2	Nos
33	93-00-016	Castor 4" Jainsons JM - 1 WO Break	2	Nos

Service contact:

nice Neotech Medical Systems Pvt. Ltd.
 85. Krishna Industrial Estate, Vannagaram,
 Mettukuppam Chennai-600095. Tamil Nadu, INDIA.
 Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594
 E-mail: service@niceneotech.com / info@niceneotech.com
 Web: www.niceneotech.com/

EU Authorised Representative

CMC Medical Devices
 C/Horacio Lengo N° 18
 P 29006, Malaga – Spain
 Mr. Manuel Mateos
 Manager – Regulatory Affairs
 Tel: +34951214054

Section 9: Manufacturer’s EMC Declaration.

Guidance and manufacturer’s declaration – electromagnetic emissions		
The Baby Incubator is intended for use in the electromagnetic environment specified below. The customer or the user of the Baby Incubator should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Class A	The Baby Incubator is suitable for use in professional hospital environment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer’s declaration – electromagnetic immunity			
The Baby Incubator is intended for use in the electromagnetic environment specified below. The customer or the user of the Baby 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	± 8 kV contact ± 15 kV air	Criteria B	Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient. IEC 61000-4-4	± 2 kV for power supply lines	Criteria A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Criteria A	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	70% dips for 25 cycles 0% of dips for 0.5 & 1.0 cycle 0% short interruption for 250 cycles	Criteria A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Baby Incubator requires continued operation during power

			mains interruptions, it is recommended that the baby incubator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Criteria A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Baby Incubator is intended for use in the electromagnetic environment specified below. The customer or the user of the Baby Incubator should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands 10 Vrms 150 kHz to 80 MHz in ISM bands	Criteria A	Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

For Complaints/Comments/Suggestions or Feedbacks

Date: _____

Hospital Name & Address: _____

Contact Person & Telephone/Fax No _____

Email _____

Department: NICU / PICU / OT / Gynecology / Causality / Others _____

Equipment Name: _____

Model No: _____ Sl. No. _____

Date of Purchase: _____ Date of Installation _____

Complaints _____

Comments: _____

Suggestions: _____

Feed back: _____

Kindly fill the above and sent the same

From: _____

To:
The Marketing In-charge
nice Neotech Medical Systems Pvt. Ltd.
No, 85. Krishna Industrial Estate,

Vannagaram, Mettukuppam,
Chennai-600095. Tamil Nadu,
INDIA.

Ph: 91-44-24762594, 24764608

Tele Fax: 91-44-24766920 – Ext: 203

Email: marketing@niceneotech.com

Toll Free No. 1800-425-2594 (India only)