nice Neötech Medical Systems Pvt. Ltd.

nice 2000 B

Infant Radiant Warmer

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

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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 Neötech recommends that a telephone or written request for service advice be made to the nearest nice Neötech Regional Service Center.

This product or any of its parts should not be repaired other than in accordance with written instructions provided by nice Neötech and by nice Neötech trained personnel. The product must not be altered without the prior written approval of nice Neötech's Quality Assurance Department. 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 Neötech.

- Before using the nice Neötech Infant Radiant Warmer, 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 Neötech medical systems private limited supplies to EU countries

Declaration for RoHS

RoHS electronic components are used for production of the devices and complies with Annex I categories of the RoHS Directive 2011 65 EU.

Declaration for Biocompatibility

The skin contact part - mattress, skin temperature sensor are biocompatible, complies with ISO 10993-1, ISO 10993-5, ISO 10993-10 requirements.

Model Description

nice Neötech Infant Radiant Warmer provides a controlled source of radiant heat for infants and pediatric patients. The control system uses a microprocessor and provides both manual and servo modes of operation. The model nice 2000 B is a servo control Infant Radiant Warmer having integral bed, storage cabinet and storage tray.

Definitions

a. **Mattress Temperature**: Environment temperature at a center point of the mattress surface.

b. **Control Temperature**: The temperature controller's set point selected by the user.

c. **Baby temperature**: The temperature measured from the skin surface by a temperature sensor.

d. **Air* Temperature**: The temperature measured from the environment temperature by an air* temperature sensor.

e. **Temperature uniformity**: It refers to the consistency of the temperature between four points on the mattress surface.

f. **Temperature rise time:** The time required for the Infant Radiant Warmer to rise required control temperature.

g. **Temperature Overshoot:** The amount of temperature is increased from the control temperature at a constant environment temperature.

h. **Measurement Points**- Measurements are taken at five points in a plane mattress surface. One point shall be center 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.

i. **Hypoxic ischemic encephalopathy (HIE)** - It is a type of brain dysfunction that occurs when the brain doesn't receive enough oxygen or blood flow for a period of time. 'Hypoxic' means not enough oxygen; 'ischemic' means not enough blood flow; and 'encephalopathy' means brain disorder.

*Air – Optional mode

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

- Before using the nice Neötech Infant Radiant Warmer, 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 risks and benefits of this type of device.
- Overloading the shelves can affect the stability of the unit. Limit the load to 3 kg per instrument shelf.
- Limit the load of accessories to 50 pounds (23 kg) per side on the Warmer to ensure stability. Accessories should not be mounted more than 56 inches (142 cm) above the floor.
- Limit the load placed on the x-ray cassette tray to 5 lbs. (2.2 kg) to avoid a tipping hazard.
- Overloading the cabin can affect the stability of the unit. Limit the load to 10 lbs. (4.6 kg) per cabin.
- Do not use the Warmer in the presence of flammable anesthetics; a possible explosion hazard exists under these conditions.
- Do not touch the protective grill under the radiant heater or the top of the Heater assembly. These surfaces may be hot and a burn could result.
- Disconnect power to the Infant Radiant Warmer and allow the heater rod to cool before cleaning to avoid the possibility of a burn.
- Never oil or grease oxygen equipment. Oils and grease oxidize readily, and in the presence of oxygen, will burn violently.
- Disconnect power to the Infant Radiant Warmer and allow the unit to cool before replacing the observation lights.
- In a dust free area, keep hands clean and then install the equipment.
- Proper installation of the nice 2000 B Infant Radiant Warmer may require two people.
- Power supply cord should be replaced by trained service personnel.
- Bed-to-heater spacing which differs from the specified 85 cms will result in incorrect operation and may affect the patient's condition.
- Do not place any accessories or any other objects directly over the bed surface. This may block radiant heat and lead to cooling of the infant.
- Do not place items on top of the heater assembly. Items placed on top of the heater assembly can fall and injure the patient, prevent adequate ventilation of the heater assembly, and may pose a fire hazard.
- Do not perform the checkout procedures (Mechanical and Control Unit) while a patient occupies the Infant Radiant Warmer.
- Complete the "Checkout Procedures" section of this manual before putting the unit into operation. If the Infant Radiant Warmer fails any portion of the checkout procedures it must be removed from use and repaired.
- Regularly inspect the bed side panel latching mechanism, and the bedside locking mechanism on the model, to ensure proper operation.
- Inspect all patient connected tubes or wires before and after moving or tilting the bed. Tilting or moving the warmer 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.

- 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.
- Do not use the Infant Radiant Warmer if the system failure indication is activated. Remove the unit from use and refer to qualified personnel for repair.
- Radiant energy can adversely affect blood components. When using intravenous tubing systems for delivery of blood components to patients occupying a warmer, shield any tubing with aluminum foil
- When using an Infant Radiant Warmer, change the patient's diapers frequently. Radiant energy causes more rapid urine evaporation, and may lead to inaccurate urine diagnostic test/ analysis and inaccurate weight measurements.
- Do not move the Infant Radiant Warmer by pushing or pulling on the bed side panels. This action may lead to the deterioration and breakage of the components which form a safety barrier around the infant.
- Ensure that the bedside panels are locked in position when a patient occupies the bed. Blankets or other foreign objects may prevent the latches from fully engaging.
- Do not leave the patient unattended when the side panels are lowered.
- Never place an infant on the X-ray cassette tray.
- Do not place any foreign objects on the warmer bed or in the under bed cavity while performing X-ray procedures. Incompatible materials in the path of the X-ray may adversely affect the quality of the X-ray image. Use of mattress or bedding materials other than those supplied by nice Neötech should be evaluated by a Neonatologist or Radiologist.
- Independent monitoring of the temperature of the infant by the operator is essential, Do not leave the patient unattended when using the Infant Radiant Warmer. Check the patient's temperature regularly to ensure the comfort and the safety of the patient, patient temperature may increase or decrease.
- If the Infant Radiant Warmer is used for an extended time, it is recommended that the servo mode of operation be used. When an indication is silenced, close monitoring of the patient's condition is required.
- Use the baby mode unless the manual or air* mode is specifically prescribed. While all three modes require patient monitoring, the manual mode requires constant attention.
- In the manual mode, the user should ensure changes in the environment (drafts, direct sunlight, phototherapy lamp usage, etc.) or the patient condition requiring heater adjustments in response to these changes.
- In the air* mode, user can set the required environmental temperature; indirectly maintain the baby temperature automatically as required when the baby's skin is very delicate to fix the temperature sensor.
- In the baby mode, the infant warmer automatically adjusts heater output to maintain the desired baby temperature, reducing (but not eliminating) the need to monitor the patient and make adjustments to the equipment.
- Use of electrosurgical units or other electrical field radiating equipment can affect the operation of the Infant Radiant Warmer.
- Keep the patient sensor 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 baby temperature sensor due to absorbed electrical energy.
- When using these devices near the Infant Radiant Warmer, operate the Infant Radiant Warmer in manual mode for maximum safety.
- The use of phototherapy equipment may raise the patient's temperature.

- Infant Radiant Warmer increases an infant's insensible water loss. Take appropriate measures to maintain the patient's fluid balance while caring for them in a radiant warmer.

- Use only the nice Neötech skin temperature sensor to monitor the patient's baby temperature. Use of other manufacturer's sensors may affect the accuracy of Infant Radiant Warmer's operation and the electrical safety of the patient.

- The skin temperature sensor 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 servo response times will result from improper sensor placement.

- Rectal temperatures must never be used to servo control a patient's temperature.

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

- In the baby mode, verify that the patient temperature sensor is securely attached to the patient at least once every half an hour. A dislodged sensor may not trigger an indication. If the sensor becomes dislodged, the Infant Radiant Warmer can over or under heat the infant.

- Oxygen concentrations higher than 40% can increase the risk of retrolental fibroplasia (premature retinopathy). It is probable that even concentrations of 40% or less oxygen (formerly considered safe) could be dangerous to some infants. Therefore, arterial blood gas measurements are extremely important for regulation of the concentration of inspired oxygen when an oxygen-enriched environment is considered necessary. (See current edition of "Standards and Recommendations for Hospital Care of Newborn Infants" prepared by the Committee of Fetus and Newborn of the Academy of Pediatrics.)

- The patient sensor is not isolated from earth ground. Any additional equipment used with the nice Neötech Infant Radiant Warmer must comply IEC Standard.

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

- The warmer may cause radio interference, in which case adequate measure may be required to prevent interference

- The oxygen Concentration must be monitored with a calibrated oxygen measuring unit the head of the patient.

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

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

- Even Small quantity of flammable agents such as ether and alcohol, left in the Radiant warmer it can cause fire in connection with oxygen

- The administration of oxygen may increase the noise level for the baby while using Head box (oxygen hood)

*Air - Optional mode

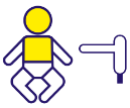
Section B: Cautions

- Keep the patient in the effective area, monitor periodically on failing which patient falling off from the effective area.
- Use cleaning solution sparingly on a cloth when cleaning the Infant Radiant Warmer. Do not saturate the unit - excessive solution causes damage to internal components.
- Do not autoclave or gas sterilize the skin temperature sensor. Do not immerse the sensor in liquid cleaner. Avoid placing excessive strain on the sensor lead. Always remove the sensor by grasping the plug at the panel. Do not pull on the sensor lead. These precautions will help avoid damage to the sensor.
- Do not autoclave or gas sterilize the mattress.
- Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area. Control measures are taken to control the heat by Heater cutoff when the temperature goes above 39°C, and Enclosure do not go beyond 42°C as heater control is provided. Additionally thermostat is provided for heater cut off when the temperature of the parabola reaches above 90°C.
- Only competent individuals trained in the repair of this equipment should attempt to service it as detailed in the service manual. The service manual provides detailed information solely for use by individuals having proper knowledge, tools and test equipment, and for service representatives trained by nice Neötech.
- The equipment may show incorrect reading while using the defibrillator.
- **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
- The maximum load on

IV Pole	: maximum load: 1.5 Kg.
Mayo tray	: maximum load: 3 Kgs. (per tray)
Storage cabinet	: maximum load: 3 Kgs (per cabin)

Section C: Symbols & Labels

Mark	Description
	Caution
	Caution, ignition (Indicates possible ignition under certain condition)
	Caution, electric shock
	Warning
	Warning - Hot Surface area – Protective grill
	Baby temperature
	Set Temperature
	Air* Temperature
	Heater output
	Audio paused
	Increase
	Decrease
	Power failure
	Mode selection
	Baby mode
	Safe mode

	Air* mode
	Manual mode
	Prewarm mode
	HIE mode
	APGAR Timer
	Lock
	Observation lamp
	ECO function
	Celsius / Fahrenheit conversion key
	Skin temperature sensor
	Air* temperature sensor
	General prohibition sign
	Warning, Do not touch
	Warning, Don’t use fire
	General mandatory action
	Warning, Don’t disassemble
	Protective earth (ground)

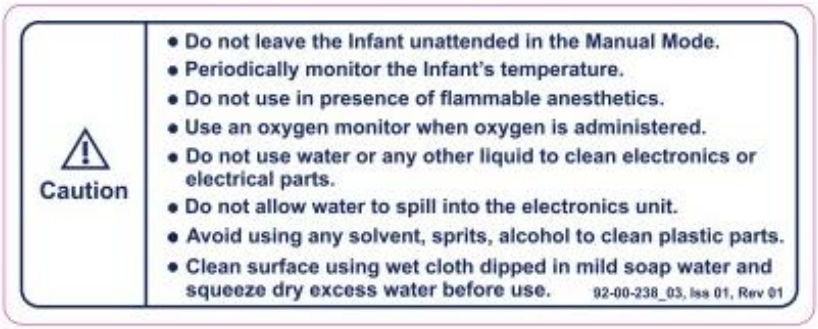
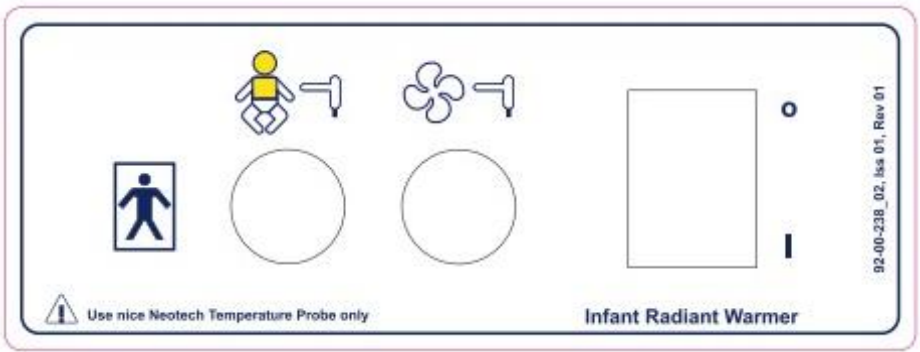
	Alternating current
	Direct Current
	Off (Power: disconnection from main)
	On/off Push switch
	“Off” (only for a part of Equipment)
	“On” (only for a part of Equipment)
	Type B (Mattress)
	Type BF (Skin temperature sensor)
	Serial Number
	Authorized Representative in European Community
	Date of Manufacture
	Manufacturer
	Model Number
	Refer Instruction for use
	Do not step on surface
	Do not lean on the device

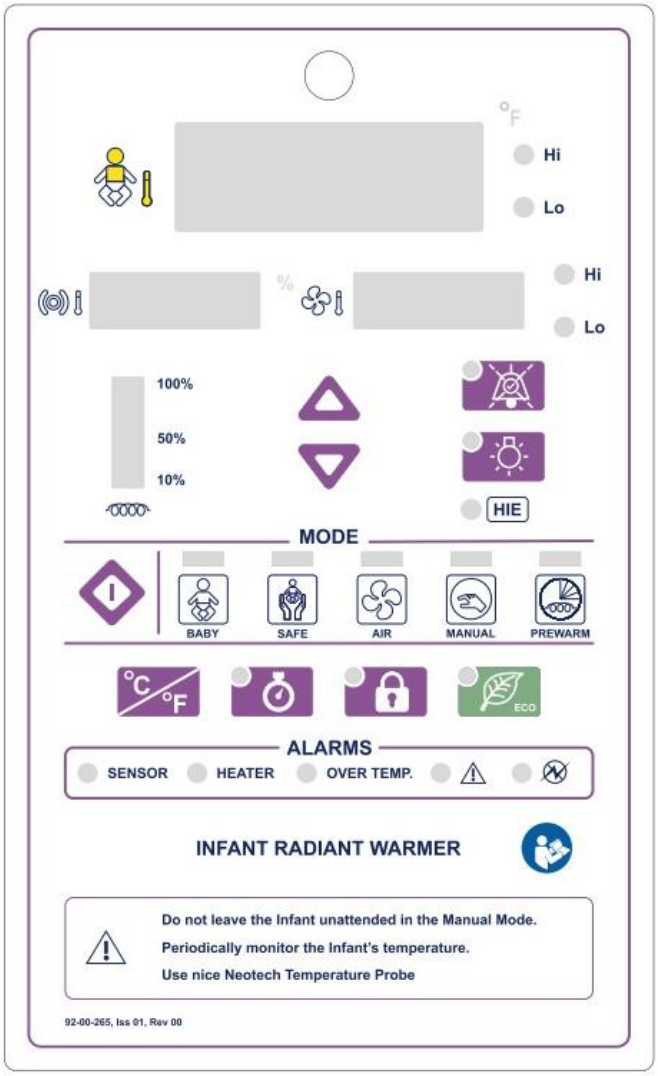
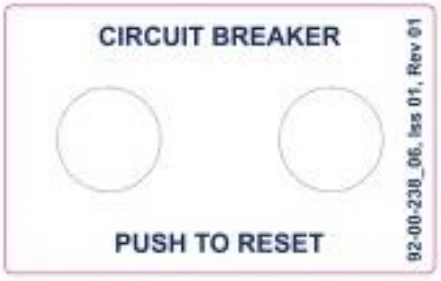
	RoHS compliant
	Non-sterile

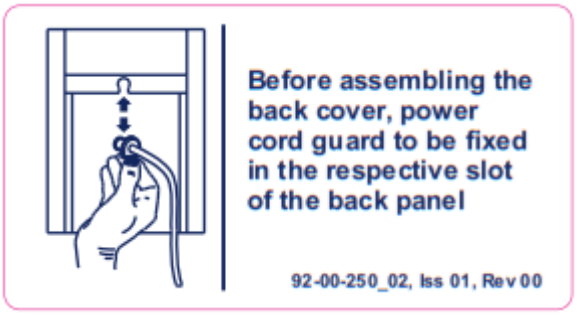
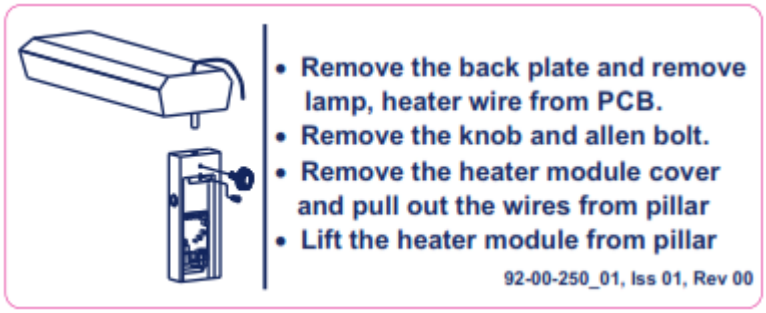
*Air – Optional mode

Labels

Label	Description
	Label, Max weight 1.5kg- IV Pole
	Label, Max weight 3kg – Mayo Tray
	Label, Storage cabinet, Max weight 3kg- Cabinet
	Label, Safety sign, Hot surface
	Label, Safety sign, Do not step on surface
	Label, Safety sign, Do not lean on the device
	Label, skin temperature sensor tag

	Label, caution
	Label, Marking Plate
	Label, Toll free
	Label, Heater module
	Label, Switch and Sensor connector

	Label, nice 2000 B
	Label, Circuit breaker
	Label, Mattress

	Label, Pillar plate (back side)
	Label, Heater module back side
	Label, Power Rating
	Label, Reference and serial no. (Front side Pillar)
	nice Neötech – Brand Logo

Section 1: Description

1.1 Intended Use

- The model **nice 2000 B** is an Infant Radiant warmer for warming pre-mature babies, neonates and infant with a body weight of up to 10 kg to maintain the body temperature at the desired level.

1.2 Indication

- Infant Radiant Warmer is used for Pre-mature babies to maintain the baby skin temperature.

1.3 Contraindication

- Infant Radiant Warmer is contraindicated for HIE patient. (Hypoxic Ischemic Neonatal Encephalopathy)

1.4 Side-effects

- Infant Radiant Warmer may affect insensible water loss and can also induce rapid drying of the skin surface.

1.5 Target Population

- Pre-mature, Neonates and Infants up to 10 kg.

1.6 Working Principle

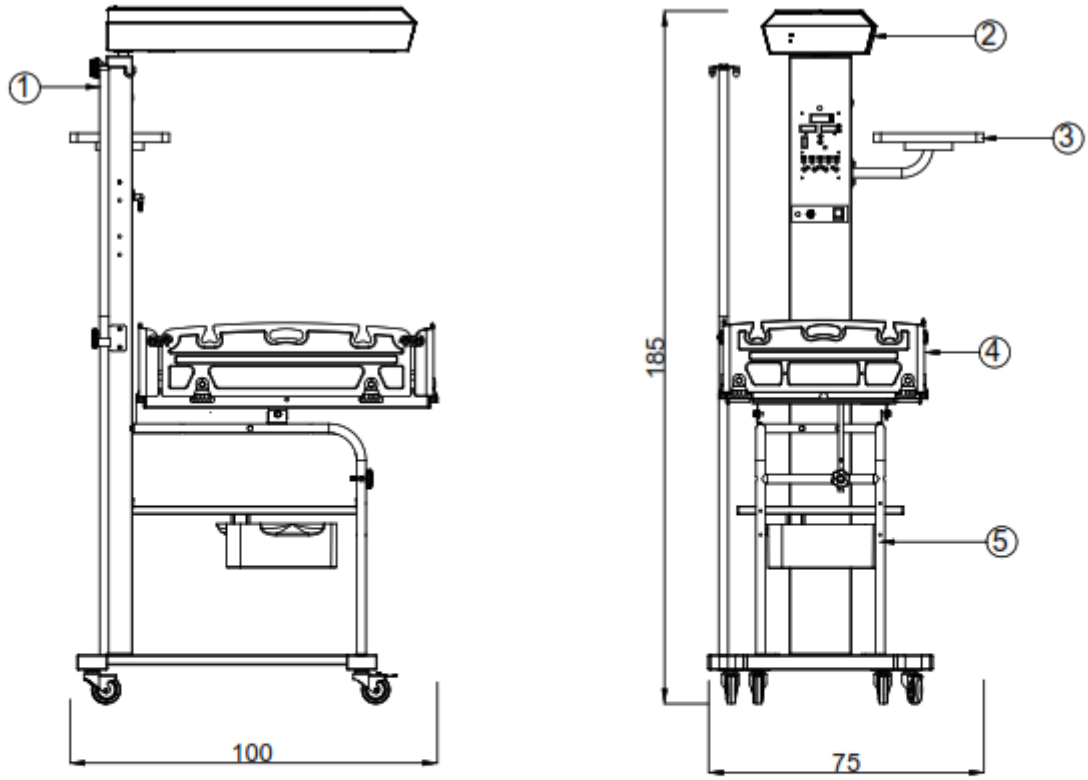
Heat has a tendency to flow in the heat gradient direction that is from high temperature to low temperature. The heat loss in some newborn babies is rapid; hence baby warmers provide an artificial support to keep the baby temperature constant. In certain areas with very cold climate, babies are kept on Radiant Warmer for couple of hours immediately after birth to ensure the baby is stabilized after birth.

Radiant Warmers consists of an open tray (where the baby is kept) and the artificial heating is provided by a heating mechanism mounted overhead. The heating mechanism consists of quartz heater which produces the desired heat and a reflecting mechanism to divert the heat at the baby bed to achieve uniformity. The baby temperature can be monitored by a temperature sensor attached to the skin. The variation in the baby temperature can be seen on the display panel which continuously shows the baby temperature and set temperature. Radiant warmers are equipped with alarm to indicate the change in temperature and hence attract attention of medical professional attending the baby. The heat generated can be controlled manually in Manual mode as well as automatically depending on the Servo mode (Baby mode) Radiant Heat Warmer.

Radiant Warmers can be manual or automatic (servo system – heater output is determined automatically based on baby temperature. The baby temperature is set at 36.5°C). The heat generated and the temperature of the skin can be individually seen. The servo control mode increases the heat output in small predetermined steps to reach at the desired temperature of the baby.

1.7 Product Description

1.7.1 Mechanical Layout



Weight-52Kgs

Sl.No	Material Description
01.	IV Pole
02.	Heater Module Assembly
03.	Mayotray
04.	Bed Assembly
05.	Single Cabin Assembly

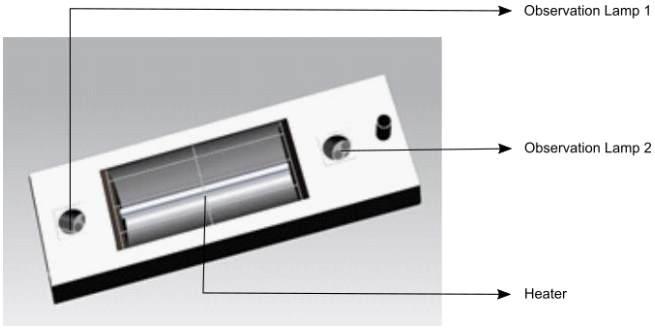
Infant Radiant Warmers provide a controlled source of radiant heat for infants. The control system uses a microprocessor and provides modes i.e. baby, air*, manual, prewarm, safe, HIE modes of operation. The patient temperature and set temperature are digital for ease of viewing. A complete audio and visual indication is included in the control panel.

Air* – Optional mode

1.7.2 Support Structure

The support structure provides excellent stability for the radiant heater and optional accessories.

1.7.3 Heater Assembly



The Infant Radiant Warmer is designed to warm infants on a bed surface located 84-87 cm beneath the heater assembly.

Warning

- Bed-to-heater spacing which differs from the specified 84-87 cm will result in incorrect operation and may affect the patient's condition.

The heater assembly consists of a radiant heater, parabolic reflector and two observation light. The parabolic reflector focuses radiant energy on the bed surface, minimizing energy loss due to scattering and providing an even field of radiant heat over the bed surface. The dual lamp observation light provides intense light for medical procedures. The entire heater assembly rotates to the side for X-ray procedures and for observation lamp replacement.

There are two observation lights present in Warmer, which are used to provide light at the centre where the baby is placed. While observing the baby, the physicians hand does not interfere or cast shadow on the baby which is why dual lamps are provided.

1.7.4 Control Unit

The control unit contains the electronic circuits and controls used to operate the radiant heater. The control unit performs regular self-checks during its operation including failure diagnostics. The radiant heater is controlled by the control unit through six modes of operation: baby mode, air* mode, manual mode, safe mode, pre-warm mode and HIE mode. Power consumption by the equipment can be optimized by enabling the ECO function.

Baby mode:

Baby mode is a servo controlled operation which automatically controls the radiant heater based on the set required temperature and actual temperature of the baby. Actual temperature of the baby will be recorded by the skin temperature sensor and displayed in the control unit, the information from the sensor is supplied to the heater control unit, which proportions the heater output to maintain the baby set temperature. In baby mode, the control unit enables the user to control the baby temperature between 32 to 38°C.

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

i-sense technology:

When the skin temperature probe is detached from the baby and the skin temperature suddenly drops to 3 ˚C, the device can automatically sense the temperature reduction and reduce the heater output to 50% with the help of i-sense technology. The necessity of i-Sense Technology is to protect the baby from the occurrence of hyperthermia (body temperature above 37.5°C).

Note: When the heater output is greater than 60% for 10 minutes, it displays "check sensor" on the screen, and the heater output will be reduced to 25% for 5 minutes, or until the physician attends to the patient. If the physician doesn't check the sensor, the cycle will continue.

Safe mode:

In safe mode of operation, the heater output power is increases to only 40% thus making it a very safe mode of operation and the actual baby temperature is displayed. It does not cause hypothermia or

chances of hyperthermia as it delivers optimal servo controlled heater output. This mode is generally used when the baby left unattended or at night, but continuous monitoring of baby is recommended.

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

Air mode (optional):

Air mode is a servo controlled operation which automatically controls the radiant heater based on the set required temperature and actual ambient temperature. Actual ambient temperature will be recorded by the air temperature sensor and displayed in the control unit, the information from the sensor is supplied to the heater control unit, which proportions the heater output to maintain the set temperature. In air mode, the control unit enables the user to control the baby temperature between 20 to 38°C.

Note: In the air mode, verify that the air probe is securely attached to the front panel at least every half an hour.

Manual mode:

In manual mode of operation, the control unit enables the user to manually control the radiant heater by selecting the heater output percentage. The heater output can be set from 0% to 100% in the control panel with 5% increment. Actual baby temperature will still be displayed when skin temperature sensor is attached with baby. If the heater output level is selected more than or equal to 50%, after 15 minutes a manual mode alert activates and heater will reduced to 30% to avoid the risk of overheating.

Note: In the manual mode, the user must take the responsibility for detecting changes in the environment (drafts, direct sunlight, phototherapy lamp usage, etc.,) or the patient condition requiring heater adjustments in response to these changes.

Prewarm mode:

Prewarm mode enables the user to warm the bed platform before the baby is placed on the bed for treatment. In pre-warm mode, the control unit provides 100% heater output for the first 5 minutes and then it reduces to 30% heater output after 5 minutes.

Note: Do not place the patient when the warmer is in pre-warm mode, may cause hyperthermia.

HIE mode:

In HIE mode, which is a no-warm mode, i.e., there is a zero percent heater output, the control unit enables the user to only monitor the baby's skin temperature.

The control unit of nice 2000 B infant radiant warmer also enables the user to switch ON/OFF the observations lamps, audio pausing and APGAR timer operation. The control unit alerts the user with prioritized audio and visual indications for failures and when attention is required by the clinician/doctor.

*Air – Optional mode

1.7.5 Bed Platform

Infant Radiant Warmer with bed includes a mattress and transparent side panels. The side panels fold down for easy access to the patient and can be removed for cleaning. The X-ray cassette tray (located beneath the bed) pulls out for insertion of X-ray cassettes and allows X-rays to be taken without moving the patient.

1. Markings located along the side panels allow easy location of the cassette in the X-ray tray relative to the position of the patient on the Infant Radiant Warmer bed.
2. The tilting bed platform allows Trendelenburg and Reverse Trendelenburg positioning.
3. The system for the tilting bed provides a smooth motion to avoid disturbing the patient.

Section 2: Installation

2.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of Infant Radiant Warmer.
- After removal from the shipping containers, inspect the nice Neötech Infant Radiant Warmer and all accessory items for any signs of damage which may have occurred during shipment.
- Also confirm the presence of all accessory items or factory installed options as listed on the packing slip.

Note: File a damage claim with the shipping carrier if damage is found in any of the assemblies or accessories in the container.

- Do not use the equipment, if damage is found.

2.2 Installation of Pillar

Picture 1

Picture 2

Picture 1: Place the pillar on the base vertically in such a way that the control panel faces the front side. Six bolt provisions are given on the bottom side of the pillar which is to be fixed.

Picture 2: Fix the pillar with base using the 6x15 Allen bolts with 6mm washer.

2.3 Installation of Heater module

Picture 3

Unbolt the 6x10 Allen bolt of the heater module pipe using Allen key.

Picture 4

Remove the heater assembly plate screws to take out the wires.

Picture 5

Remove the back cover from the pillar assembly to connect the wires from heater assembly.

Picture 6

The wires should be insert through the small opening to the pillar assembly (Refer Section 10 - Wiring drawing)

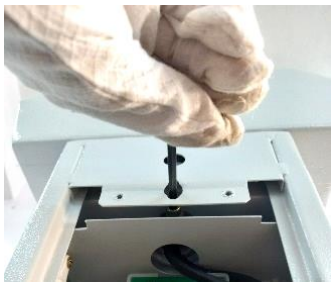
Picture 7

Place the plastic washer (spacer) on top of the pillar.

Now hold the knob down to fix the heater box firmly.

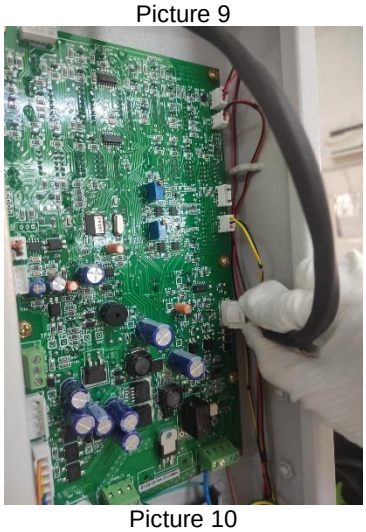
Picture 8

Fix the heater box top cover to heater module assembly using screws



Picture 9

Tighten the 6 x 10 Allen bolt heater module pipe using Allen key.



Picture 10

Perform lamp wiring connection by lock type 4 pin Molex female connector is connected with 4 pin male connector as per wiring diagram. (LAMP mentioned in the PCB)

Picture 11

Perform heater wiring connection with 4 x 8 PNPLWH as per the wiring diagram. (HEATER mentioned in the PCB)

Picture 12

Fix the ring type ground leg from the heater module mounting with pillar using 4X8 PNPL screw.

Picture 13

Fix the back cover to the pillar assembly.

2.4 Installation of Power cord from the Pillar Assembly

Picture 14

Picture 15

Picture 16

Picture 17

Picture 14: Remove the bottom back cover.

Picture 15: Take the power cord out of the pillar assembly.

Picture 16: Before fixing the power cord in the socket, fix the power cord grip to be connected with pillar assembly.

Picture 17: Close the bottom back cover with 4 x 8 PNPLWH.

2.5 Installation of Tilting Rod

Picture 18

LH and RH holder frame are attached with the pillar assembly using 8 x 15 hex bolt with 8mm tooth washer & 8mm washer.

Picture 19

Fix the LH and RH frame with the base assembly using 6 x 50 hex bolt and nut with 6mm washer at the given provision.

Picture 20

Fix LH and RH frame with the holder frame using 6 x 25 Allen bolt with washer

Picture 21

Tilting link pole is linked with LH and RH frame using 6 x 30 Allen bolt. Ensure the shorter length/side of the knob provision in the tilting link pole is placed on the right.

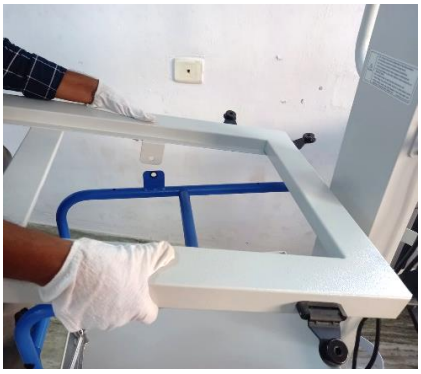
Picture 22

For the bed to be placed, a link pole is placed across the frames facing towards the bed.

Picture 23

Tilting link pole is fixed in the middle of frames facing the front side where the bolt will be placed.

2.6 Installation of Bed Assembly



Picture 24

Picture 25

Picture 26

Picture 24: Place the Bed frame on top of the tilting assembly in such a way that the tilting pole is fixed on the bed assembly holder.

Picture 25: Use special bolt and 8mm nut with washer to fix the bed frame on the trolley frames.

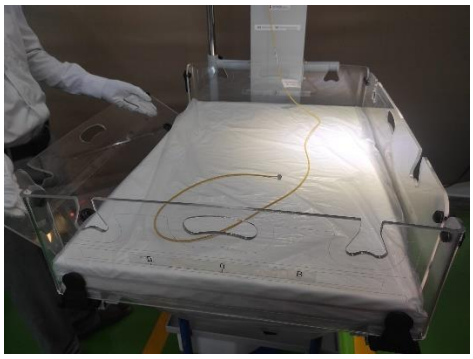
Picture 26: A tilting pole with 6mm nut is used to fix the tilting link pole with the bed frame.

2.7 Installation of X-ray Cassette tray

Picture 27

- The X-Ray tray can be stored below the bed as shown in the picture.
- Push the tray fully inside the bed frame for storing it.

2.8 Installation of Side Panels



Picture 28

- Take out the access panel hinge nut and place the side panel door on it to fix the side panel. The same action is repeated to fix the rest of the side panels.
- 8mm Allen key is used to remove the access panel hinge nut.
- With the panel on the long side, ensure that the blue strip line marking points outwards. Position the panel, semi upright.
- Press the panel down firmly until the pins lock into position at the bottom of the slots. Fold the panel up into the vertical position and allow it to drop into the locking position. Fix all four panels in this way.

Caution

Make sure that the panels are seated correctly. To open: Lift the panel all the way until the upper pins come out of their slots, and then fold the panel down.

2.9 Installation of Mattress

Picture 29

- Lay the mattress flat in the bed frame and cover it with a cotton sheet (cotton sheet from the hospital).

2.10 Installation of Mayo tray

Picture 30

- The fixed mayo tray is fixed with the Pillar on right side using 6x15 Allen bolt for placing monitors, small articles and parts.
- The maximum load applicable is 3 Kg.

2.11 Installation of IV Stand

Picture 31

Picture 32

Picture 33

Picture 31 & 32: Place the holder column IV Pole (fixed) in the base assembly as shown in picture 31 and insert the IV Pole in the holder.

Picture 33: Place the pillar handle and IV pole on the slot using 6 x 10 Allen bolt with 6 mm washer present in the pillar assembly like shown in the picture.

2.12 Installation of Storage Tray

Picture 34

- Place the storage tray below the bed frame, where the provisions are given.
- Use 6x35 Allen bolt and 6mm nut with 6mm washer to fix the tray on the LH and RH frame and use 6x15 Allen bolt and 6mm washer to fix the tray with the pillar assembly.

2.13 Installation of Cabinet

Picture 35

Picture 36

Picture 35 & 36: Place the Cabinet below the storage tray, where the provisions are given. Use 6x15 Allen bolt and 6mm washer to fix the cabinet with the storage tray.

2.14 Pre-use check instructions

2.14.1 Mechanical Pre-use check instructions

- Before using the nice Neötech Infant Radiant Warmer, read this entire manual. Attempting to use this device without a thorough Understanding of its operation may result in patient or user injury.
- Do not perform the checkout procedures (Mechanical and Control Unit) while a patient occupies the Infant Radiant Warmer.
- Complete the “Checkout Procedures” section of this manual before putting the unit into operation. If the Infant Radiant Warmer fails any portion of the checkout procedures it must be removed from use and repaired.

2.14.1.1 Overall Appearance

- Disconnect the AC power source to the unit for the mechanical checks portion of this procedure.

- Check the overall appearance of the Infant Radiant Warmer. 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 Infant Radiant Warmer is stable and moves freely.
- Lock the two front castors and check that the Infant Radiant Warmer is held in place.
- Examine the power cord for damage. Replace the power cord if damage is evident.
- Examine the unit for objects placed on top of the heater assembly.

Warning

- Power cord should be replaced only by the trained service personnel.
- Do not place any accessories or other objects directly over the bed surface. This may block radiant heat energy and lead to cooling of the infant.
- Do not place items on top of the heater assembly. Items placed on top of the heater assembly can fall and injure the patient, prevent adequate ventilation of the heater assembly, and may cause a fire hazard.

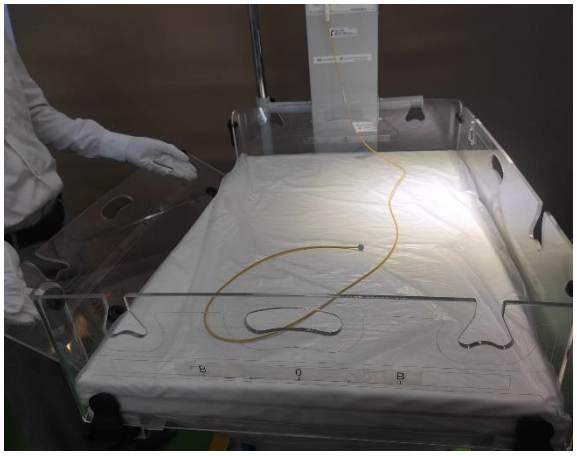
2.14.1.2 Heater Assembly Rotation

Picture 37

- Hold the knob down and swing the heater box to its sides.
- The heater box can be rotated on both sides and check for smooth movement of heater box.

2.14.1.3 Mechanical Checks

I. Side Panels



- Lift the side panels and show its way out from the hook.
- The panel must swing freely after removing from its hook; all panels can be operated on the same way.

Warning

- Regularly inspect the bed side panel latching mechanism, and the bedside locking mechanism, to ensure proper operation.

Picture 38

II. Tilting Mechanism

Picture 39

- Rotate the black round knob clockwise or anti-clockwise on the tilting rod to adjust the height of the bed frame.
- Check the operation of the tilting mechanism. Verify that the bed platform operates smoothly and locks in normal, Trendelenburg and Reverse Trendelenburg positions.

Caution

- When the mattress is in the tilted position, ensure an additional support is provided to minimize the baby falling.

2.14.1.4 Accessory Checks

List of Items supplied with the Product

- IV pole
- Mayo tray
- X-ray Cassette tray

List of Items used with Product to perform its intended use

- Air temperature sensor (optional)
- Skin temperature sensor

- Perform these checks if they are applicable.
- 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.

Warning

- Limit the load of accessories in the Mayo tray to 3 Kgs per side on the Infant Radiant Warmer to ensure stability. Accessories should not be mounted more than 56 inches (142 cm) above the floor.
- Due to the increased height of units with height adjustment, a tipping hazard may exist. Limit the total accessory load to 3 Kgs.

2.14.2 Control Unit Pre-use check instructions

Warning

- Do not perform the checkout procedures (Mechanical and Control Unit) while a patient occupies the Infant Radiant Warmer.
- Complete the “Checkout Procedures” section of this manual before putting the unit into operation. If the Infant Radiant Warmer fails any portion of the checkout procedures it must be removed from use and repaired.

2.14.2.1 Control Unit Check

- ❖ Connect the Infant Radiant Warmer power cord to an appropriate power source. Refer to the rating label on the Infant Radiant Warmer for the proper voltage needed. Switch the power on and verify the following on the Control Panel (Fig 1)

- ❖ The audible indication and all displays and indicators are lit for approximately two seconds.

Note: During this time the controller also performs self-check functions. If the controller detects a failure, the Indication stays on and service is required.

- ➢ The previous mode indicator is lit whether it is manual or baby mode. Operator prompt tones sound and the % power display lit.

- ➢ Adjust the heater output with the increase ▲ and decrease ▼ touch switches to attain the high and low limits as indicated by the % power display (% of heater output)

- ➢ Connect the skin temperature sensor to the Infant Radiant Warmer.

a. Press the mode touch switch to place the Infant Radiant Warmer in the servo mode and verify the following:

- ➢ The baby mode indicator is lit.

- ➢ The temperature low indication will sound if set temperature is lower than the actual temperature by 1°C. Warm the sensor with your fingers or silence the indication. The temperature high indication will sound if the set temperature is greater than the actual temperature by 1°C.

- ➢ Press the increase ▲ touch switch and verify that the maximum skin control temperature attainable is 38.0°C.

- ➢ Press the decrease ▼ touch switch and verify that the minimum skin control temperature attainable is 32.0°C.

b. Disconnect the skin temperature sensor. Verify the following:

- ➢ The sensor failure indicator light is lit (S-O).

c. Press the Audio paused switch and verify the following:

- ➢ Audible indications are silenced for low temperature.

- ➢ Audio paused function is enabled and the audio paused indicator light is lit.

- ➢ The audio paused function is disabled automatically after 15 minutes.

- ➢ If the actual temperature reaches the range within 1 degree from the skin set temperature, the audio and visual indication is immediately disabled.

- ➢ If the audio indications are audio paused for low temperature and when the second audio indication is triggered, the audio paused function is disabled and the audio indication is activated.

2.14.2.2 APGAR Timer

- ➢ Switch to the APGAR timer.

- ➢ The APGAR timer indicator is lit.

- ➢ The APGAR timer is lit.

- ➢ Adjust the APGAR timer between 1 – 59 minutes with the increase ▲ and decrease ▼ touch switches to attain the high and low limits

2.14.2.4 Observation Light Check

- Press the light ON/OFF touch switch in the control panel. Verify the observation light functions.

2.14.2.5 Power Fail, Memory Back up

- **Power Fail:**
  - Switch OFF the main power to the equipment while the equipment is running.
  - Power Fail LED is lit (9V non-rechargeable battery is provided).
- **Memory Back up:**
  - Switch to the baby mode.
  - Set the baby set temperature at 36.5^{o}C.
  - Switch Off the equipment. Switch On the equipment again.
  - The mode and the set value remains the same.

Section 3: Operation

3.1 Control Panel Operation

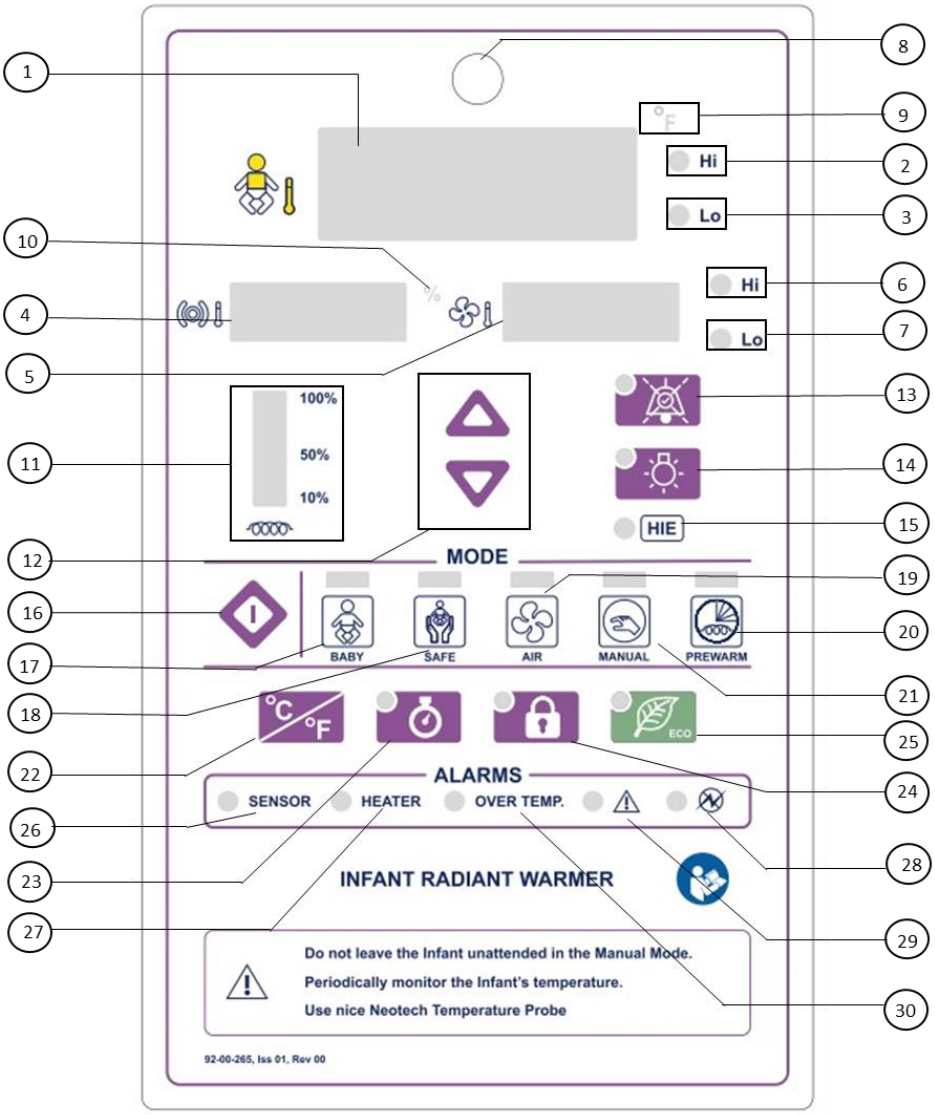


Figure 1

2000 B Control panel

1	Baby Temperature display	16	Mode selection key
2	Baby Temperature High	17	Baby mode
3	Baby Temperature Low	18	Safe mode
4	Set Temperature display	19	Air* mode
5	Air* Temperature display	20	Prewarm mode
6	Air* Temperature High	21	Manual mode
7	Air* Temperature Low	22	Celsius / Fahrenheit key
8	Pilot lamp visual indicator	23	APGAR timer
9	Fahrenheit indicator	24	Lock / Unlock key
10	% of heater output	25	Eco mode
11	% of barcode heater output	26	Sensor failure
12	Increase and Decrease key	27	Heater failure
13	Audio Paused key	28	Power failure
14	Observation lamp key	29	System failure – See manual
15	HIE mode	30	Over temperature >39˚C

Air* - Optional mode

3.1.1 Displays

	Baby Temperature	The baby temperature display indicates the temperature sensed at the skin temperature sensor tip. The range of temperature measurement is from 10.0 to 50.0°C, with a resolution of 0.1°C.
	Air* Temperature (optional)	The air temperature display indicates the temperature sensed at the air temperature sensor tip. The range of temperature display is from 10.0 to 50.0°C, with a resolution of 0.1°C
	Baby Set temperature	The Set temperature display indicates the set temperature selected in the baby mode. The baby set temperature range is from 32.0 to 38.0 C.
	Air Set temperature	The Air Set temperature display indicates the set temperature select in the Air mode. The air set temperature range is from 20.0 to 38.0 C.
	APGAR Timer	The APGAR timer indicates the APGAR timer selected in the APGAR timer. The APGAR timer is displayed in the set temperature display.
	% of heater output	The % power display indicates the percentage of maximum power that is being supplied to the radiant heater in 5% increments.

3.1.2. Indicator Lights

	Device Status indicator	A Device Status Indicator is placed on the pillar, which indicates the medium and high priority alarms. It glows in pink for self-test, amber for medium priority and red for high priority. It is further explained in section 3.7.2.
	Baby temperature high	The baby temperature high indicator lit when the baby set temperature is increased by 1°C.
	Baby temperature low	The baby temperature low indicator lit when the baby set temperature is decreased by 1°C.

	Air temperature high (optional)	The air temperature high indicator lit when the air set temperature is increased by 1°C.
	Air temperature low (optional)	The air temperature low indicator lit when the air set temperature is decreased by 3°C.
	Baby mode indicator	The baby mode indicator lit when the Infant Radiant Warmer is in the baby mode of operation.
	Safe mode indicator	The safe mode indicator lit when the Infant Radiant Warmer is in the baby mode of operation.
	Air mode indicator (optional)	The air mode indicator lit when the Infant Radiant Warmer is in the air mode of operation.
	Manual mode indicator	The manual mode indicator lit when the Infant Radiant Warmer is in the manual mode of operation.
	Prewarm mode indicator	The prewarm mode indicator lit when the Infant Radiant Warmer is in the prewarm mode of operation.
	HIE mode indicator	The HIE mode indicator lit when the Infant Radiant Warmer is in the HIE mode of operation.
	APGAR timer indicator	The APGAR timer indicator lit when the APGAR timer is activated and the Apgar timer is running.
	Lamp indicator	The lamp indicator lit when the observation lamp is switched on.
	Lock indicator	The lock indicator lit when lock feature is enabled in the control panel.

	ECO function indicator	The eco function indicator lit when ECO function is enabled in the control panel.
	Audio paused key Indicator	The audio pause indicator LED lit when there is an audible indication.
	Sensor failure indicator	The sensor failure indicator lit when the skin temperature sensor detached from the equipment or if the sensor is faulty. The audio paused key disables the indicator.
	Heater failure indicator	The heater failure indicator lit when the heater is not working. The audio paused key is used to disable the indicator.
	Over temperature indicator	The over temperature indicator lit when the temperature of the baby exceeds >39.0°C. The audio paused key is used to disable the indicator.
	System failure indicator	The system failure-see manual indicator lit when the temperature of the baby exceeds >45.0°C. The audio paused key is used to disable the indicator.
	Power failure Indicator	The power failure indicator LED lit when there is a power failure.

- Use the Baby mode unless the manual mode is specifically prescribed. While both modes require patient monitoring, the manual mode requires constant attention. In the manual mode, the user should ensure changes in the environment (drafts, direct sunlight, phototherapy lamp usage, etc.) or the patient condition requiring heater adjustments in response to these changes. In the Baby mode, the Infant Radiant Warmer automatically adjusts heater output to maintain the desired baby temperature, reducing (but not eliminating) the need to monitor the patient and make adjustments to the equipment.

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

- The Warmer may cause radio interference, in which case adequate measure may be required to prevent interference.

3.1.3. Switches

	Main switch	This switch is used to switch ON/OFF the device which is placed on the left side of the machine
	Mode selection switch	This switch is used to switch to different modes such as baby, safe, air*, manual and prewarm modes.
	Increase (▲) and Decrease (▼) Switches	These switches are used to set the radiant power level (% power) in the manual mode and to set the set temperature in the skin & air mode. It is also used to set the observation lamp percentage and to set the APGAR timer.
	Audio paused switch	This key is used to silence the audible indication. It silences all indications except the power failure indication. The audio pause indication glows when in use.
	APGAR timer switch	This switch is used to select the APGAR timer. When the APGAR timer is activated, the APGAR timer countdown begins.
	Lock/Unlock switch	This switch locks the switches in the control panel. Further inputs are not taken. Press the Lock key again to Unlock. Other switches does not work except lamp switch, APGAR timer switch and Audio paused switch.
	Observation lamp ON/OFF switch	This switch activates both the observation light located in the heater assembly. The brightness of the lamp can be adjusted using increase and decrease key from 25%, 50%, 75% and 100% within few minutes after pressing ON the lamp switch when the brightness levels flashes on the display.  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.
	Eco function switch	This switch is enabled for low power consumption of the equipment in any mode **Note:** Only used during the observation period; not used when the infant is in a critical condition.
	Celsius/Fahrenheit conversion switch	This switch is used for switching temperature units.

3.1.4. Audio & Visual Indication

Description

The Infant Radiant Warmer unit distinguishes following Audio & Visual Indication:

High Priority	Baby/Air* temperature sensor failure
	Heater failure
	Over temperature above 39°C
	System failure
	Power failure
Medium Priority	Baby temperature high
	Baby temperature low
	Air* temperature high
	Air* temperature low
	Manual mode alert

Note: Above mentioned alarm conditions causes an audible and visual alarm without any delay.

Note: Audio paused switch can be used to silence all indications except Power failure.

*Air – Optional mode

If a second indication is triggered while the audible indication is Audio paused, the audible indication will be reactivated.

- **Air temperature sensor Failure (optional):**

  The air temperature sensor failure indication is only active in the air mode of operation. The indication activates when the air temperature sensor fails electrically due to an open or short circuit, or is disconnected from the Infant Radiant Warmer. The heater deactivates and the patient temperature displays “S-O” (Sensor Open) or displays “S-S” (Sensor short).

- **Skin temperature sensor Failure:**

  The skin temperature sensor failure indication is only active in the Baby and safe mode of operation. The indication activates when the skin temperature sensor fails electrically due to an open or short circuit, or is disconnected from the Infant Radiant Warmer. The heater deactivates and the patient temperature displays “S-O” (Sensor Open) or displays “S-S” (Sensor short).

- **Air Temperature High (optional):**

  The temperature high indication is only active in the air mode of operation. The indication activates when the difference between the environment temperature and the set temperature is greater than 1°C.

- **Air Temperature Low (optional):**

  The temperature low indication is only active in the air mode of operation. The indication activates when the difference between the air temperature and the set temperature is lesser than 3°C.

- In the air mode, verify that the air temperature sensor is securely attached to the side panel at least once every half hour. A dislodged sensor may not trigger an indication. If the sensor becomes dislodged, the Infant Radiant Warmer can over or under heat the infant.
- The air temperature sensor should be located on the back panel of the Infant Radiant Warmer 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 sensor placement.

❖ **Baby temperature High:**

The temperature high indication is only active in the baby mode of operation. The indication activates when the difference between the patient temperature and the set temperature is greater than 1°C.

❖ **Baby temperature Low:**

The temperature low indication is only active in the baby mode of operation. The indication activates when the difference between the patient temperature and the control temperature is lesser than 1°C.

- In the Baby mode, verify that the patient temperature sensor is securely attached to the patient at least once every half an hour. A dislodged sensor may not trigger an indication. If the sensor becomes dislodged, the Infant Radiant Warmer can over or under heat the infant.
- The skin temperature sensor 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 sensor placement.

❖ **Heater Fail:**

The Heater failure indication activates if the heater is defected in any mode of operation.

❖ **System Failure:**

The system failure indication activates in any mode of operation, if any components are defect.

❖ **Power Failure:**

The power failure indication activates in any mode of operation if the power cord gets disconnected or when there is no AC main power.

❖ **Over Temperature:**

The over temperature indication activates when the temperature sensed by the skin temperature sensor / air* temperature sensor exceeds 39°C and the heater will deactivates in any mode of operation.

*Air – Optional mode

3.1.4.1 Visual alarm indicator

A Visual alarm indicator is fixed in the pillar control panel to produce different audio and visual indications for medium and high priority alarms other than the control panel. It produces visual indications based on colors such as pink for self-test, green for normal condition, amber for medium priority alarms and red for high priority alarms. The color codes for Visual alarm indicator are explained here:

Indicator color	Description
	Self-test
	Normal operation
	Medium priority alarm
	High priority alarm

3.2 Operating Modes

- Before using the nice Neötech Infant Radiant Warmer, 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.

- Do not leave the patient unattended when using the Infant Radiant Warmer. Check the patient's temperature periodically to ensure the comfort and the safety of the patient. If the Infant Radiant Warmer is used for an extended time, it is recommended that the Baby mode of operation be used. When an indication is silenced, close monitoring of the patient's condition is required.

- Use of electrosurgical units or other electrical field radiating equipment can affect the operation of the Infant Radiant Warmer. Keep the patient sensor 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 sensor due to absorbed electrical energy. When using these devices near the Infant Radiant Warmer, operate the Infant Radiant Warmer in manual mode for maximum safety.

- The use of LED based phototherapy equipment may raise the patient's temperature.

- Infant Radiant Warmer increase an infant's insensible water loss. Take appropriate measures to maintain the patient's fluid balance while caring for them in an Infant Radiant Warmer.

- Do not use the Infant Radiant Warmer in the presence of flammable anesthetics; a possible explosion hazard exists under these conditions.

- Radiant energy can adversely affect blood components. When using intravenous tubing systems for delivery of blood components to patients occupying Infant Radiant Warmer, shield any tubing with aluminum foil.

- When using an Infant Radiant Warmer, 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.

- Do not touch the protective grill under the radiant heater or the top of the heater assembly. These surfaces may be hot and a burn could result.

❖ 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 Infant Radiant Warmer 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 indication is sounded. If the self-check detects a failure, the indication stays on and service is required.

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

3.2.1 Baby Mode Operation

Note: The skin temperature sensor must be properly attached before starting Baby mode operation.

❖ The skin control temperature (Set required Temperature) enables the user to select the required settings when the Infant Radiant Warmer is used in the baby mode for the first time. The control panel enables the user to make this setting with an operator prompt tone and the changing of the control temperature display.

❖ The skin control temperature is adjusted by pressing the increase (▲) and decrease (▼) touch switches. The control temperature can be adjusted from 32 to 38°C. In the baby mode, the temperature sensed by

the skin temperature sensor is used by the control system to modulate the radiant heat and maintain the baby temperature at the selected control temperature.

- ❖ The default skin temperature alarm limit is 1°C. In this case, when the temperature range is the same for 6 minutes between 37.2°C and 37.5°C, the heater output goes to 10% and stays for 1 minute, then goes to 0% for 1 minute, and the cycle will continue until there are any changes in the temperature range. This is pulse-type heating output to avoid chilliness in the peripheral region of the baby.

Note: If the skin temperature alarm limit change to 0.5°C. In this case, when the temperature range is the same for 6 minutes between 36.7°C and 37.0°C, the heater output goes to 10% and stays for 1 minute, then goes to 0% for 1 minute, and the cycle will continue until there are any changes in the temperature range.

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

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

- In the baby mode, verify that the patient temperature sensor is securely attached to the patient at least every half an hour. A dislodged sensor does not always trigger an indication. If the sensor becomes dislodged, the Infant Radiant Warmer can over or under heat the infant.

Note: A patient placed in any Infant Radiant Warmer 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.

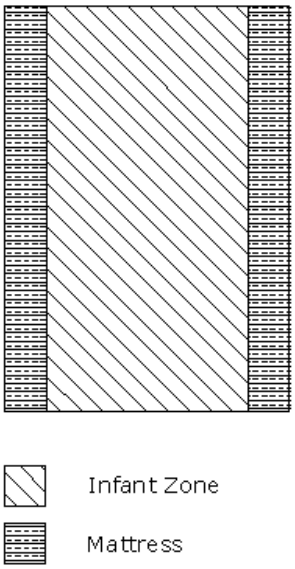
- The use of LED based phototherapy equipment may raise the patient's temperature.

Note: If the actual temperature reaches the range within 1 degree from the Skin/ Air* set temperature, the audio and visual indication is immediately disabled. (*Air – Optional mode)

If the audio indications are Audio paused for low temperature and when the second audio indication is triggered, the Audio paused function is disabled and the audio indication is activated.

3.2.3.1 Radiant Energy Distribution (See Figure 2)

This Average radiant energy distribution across the patient bed surface for informational purpose only.



- ❖ Infant Zone – 400mm wide
- ❖ Irradiance Level – 6 mW/cm²

Figure 2

3.2.3.2 Skin temperature Sensor Attachment.

Warning

- Use only the reusable nice Neötech skin temperature sensor to monitor the baby temperature. Use of other manufacturer's sensors may affect the accuracy of Infant Radiant Warmer operation and the electrical safety of the patient.

- The skin temperature sensor 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 sensor placement.

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

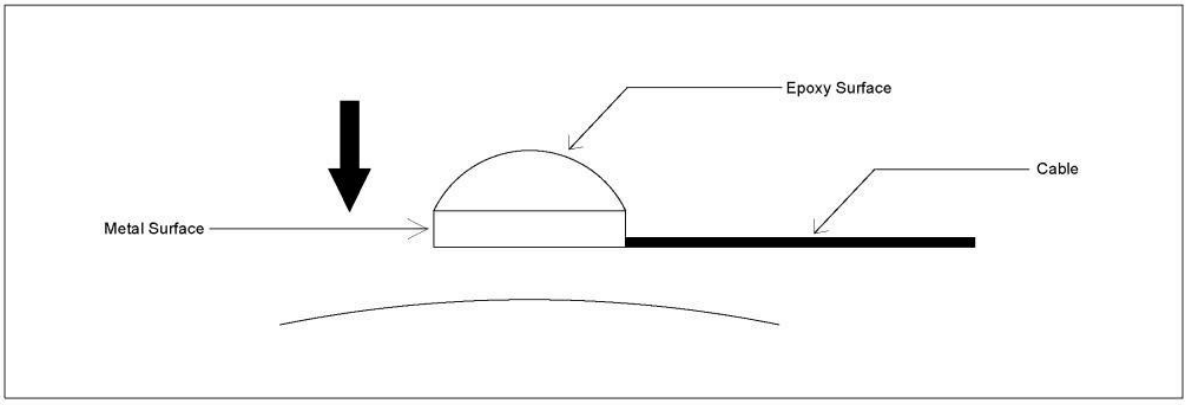


Figure 3

❖ The nice Neötech patient sensor lead is made from low mass wire that helps prevent sensor detachment while reducing pulling on the neonate's skin.

❖ Place the metal side of the skin temperature sensor on the skin over the liver area of the infant's abdomen.

❖ Fix the skin temperature sensor tip on the skin with the soft surgical tape available in hospitals and cautiously remove. (Figure 3)

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

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

❖ Connect the skin temperature sensor to the Infant Radiant Warmer by plugging the sensor connector into the left side of the Connector as viewed from the front.

Warning

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

- Periodically monitor the skin temperature sensor 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 sensor from the patient by grasping and removing the heat reflective patch first, and then remove the sensor from the patient or the patch. Always remove the sensor from the Infant Radiant Warmer by grasping the plug at the panel. Placing excessive strain on the skin temperature sensor lead can damage the sensor.

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

3.2.2 Air Mode Operation (Optional)

Note: The Air temperature sensor must be properly attached on the rear Panel of the Infant Radiant Warmer before starting air mode operation.

- ❖ The air control temperature (set required temperature) enables the user to select the required settings when the Infant Radiant Warmer is used in the Air mode for the first time. The control panel enables the user to make this setting with an operator prompt tone and the changing of the control temperature display.

- ❖ The air set temperature is adjusted by pressing the increase (▲) and Decrease (▼) touch switches. The control temperature can be adjusted from 20 to 38°C. In the air mode, the temperature sensed by the air temperature sensor is used by the control system to modulate the radiant heat and maintain the Environment temperature at the selected control temperature.

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

- In the air mode, verify that the air temperature sensor is securely attached to the rear panel at least every half an hour. A dislodged sensor does not always trigger an indication. If the sensor becomes dislodged, the Infant Radiant Warmer can over or under heat the infant.

Note: A patient placed in any Infant Radiant Warmer 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.

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

3.2.3 Manual Mode Operation

- ❖ The environment temperature in bed platform area is manually control by varying the percentage of heater output.

- Use the baby mode or air* mode unless the manual mode is specifically prescribed. While all modes require patient monitoring, the manual mode requires constant attention. In the manual mode, the user should ensure changes in the environment (drafts, direct sunlight, phototherapy lamp usage, etc.) or the patient condition requiring heater adjustments in response to these changes. In the Baby mode, the Infant Radiant Warmer automatically adjusts heater output to maintain the desired baby temperature, reducing (but not eliminating) the need to monitor the patient and make adjustments to the equipment. . In the Air* mode, the Infant Radiant Warmer automatically adjusts heater output to maintain the desired Environment temperature, reducing (but not eliminating) the need to monitor the patient and make adjustments to the equipment.

- Periodically monitor the Infant Body Temperature when the equipment in Manual Mode operation.

  Manual Timer – 15 minutes preset time

- **% of Heater output Setting** - Use the increase (▲) and decrease (▼) touch switch to adjust the % power in 5% increments. The Heater Output LED display indicates the power level selected. Select a % Heater output level each time the Infant Radiant Warmer is switched to the manual mode.

- If the heater output level is set to equal or more than 50%, and if it continues for 15 minutes, the heater output will reduce to 30%, and a manual mode alert will activate to avoid the risk of overheating. This indication can be audio paused by pressing the audio paused key, and it is triggered every 15 minutes until the heater output is less than 50%. If the heater output level selected is less than or equal to 45%, then it maintains the same temperature till the end.

Note: The set manual timer and % heater output is in the memory the values will not change unless otherwise change the settings even power goes OFF and ON again or switch of the equipment for long period

Note: The Infant Radiant Warmer bed surface may be preheated using 10 to 30% heater output level

Note: The skin temperature sensor may be used to monitor the patient's temperature in the manual mode but it does not control the radiant heat energy level.

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

*Air – Optional mode

3.2.4 Pre-warm mode Operation

- The environment temperature in bed platform area is heated or warmed before placing the baby.

- The heater output level will be 100% by default and after 5 minutes the equipment automatically reduces the heater power to 30% output.

Note: The Infant Radiant Warmer bed surface may be preheated using pre-warm mode

Note: Do not place the patient when the warmer is in pre warm mode, may cause hyperthermia.

3.2.5 HIE Mode Operation

- The HIE mode switch is enabled when ECO mode is long pressed for 4 seconds.

- To change from HIE mode to another mode, press the mode selection key.

Note: In this mode, the temperature cannot be set or controlled, only the temperature of the baby can be viewed.

- This mode is used when the baby gets Hypoxic Ischemia Encephalopathy (HIE) or hyperthermia, and when heat cannot be provided to the baby.

3.2.6 ECO mode

- nice 2000 B control unit enables the user activate ECO mode in any of the five modes of operation.

- In ECO function, the total power consumption of infant radiant warmer is optimized up to 350W.

3.2.7 Apgar Timer in any Mode of Operation

- In APGAR timer, an Apgar timer can be set between 1 – 59 minutes (Count up/Count down).

- If APGAR key is pressed once it will enable count up and if pressed again it will change to count down or vice-versa.

- APGAR timer set duration can be set by using increase or decrease key in the control unit.

- ❖ In APGAR timer, when the set time duration is 20 Minutes, the Infant Radiant Warmer will give an audio indication at 1st, 5th, 10th, 15th and 20th Minutes, to make APGAR Scores.
- ❖ Supposing, the APGAR Timer is set for a lesser duration, for e.g. 13 minutes, the Infant Radiant Warmer activates audio indication at 1st, 5th, 10th and the 13th Minute.
- ❖ After the final audio indication, the Infant Radiant Warmer automatically resumes the previous Mode of operation i.e. Baby/Air*/Manual/HIE to set the APGAR Timer again, uses the APGAR key again.

*Air – Optional mode

3.3 Bed Platform Operation

Picture 40

- ❖ The bed platform tilts for Trendelenburg and Reverse Trendelenburg positioning capabilities.
- ❖ Rotate the knob placed on the median of the tilting rod of the machine to position the bed (up or down).

Caution

- ❖ When the mattress is in the tilted position, ensure an additional support is provided to minimize the baby falling.

Warning

- Inspect all patient connected tubes or wires before and after moving or tilting the bed. Tilting or moving the Infant Radiant Warmer 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.

Note: Tilting the bed mattress can affect the operation and performance of the Infant Radiant Warmer.

3.4 X-ray Cassette Tray

Picture 41

- The X-ray cassette may be placed in the slot under the bed platform or in the X-ray cassette tray, if installed.
- The heater housing rotates to the left for X-ray procedures. To place the heater housing in the X-ray position rotates the heater to the left or right.
- The X-ray cassette tray facilitates X-ray procedures while patients occupy the Infant Radiant Warmer bed. An X-ray cassette can be placed on the tray and slid into the cavity beneath the bed without disturbing the patient.
- Rotate the heater housing out of the way, position the X-ray machine and take the X-ray.
- The tray should not be used as a writing surface or as work space during procedures.

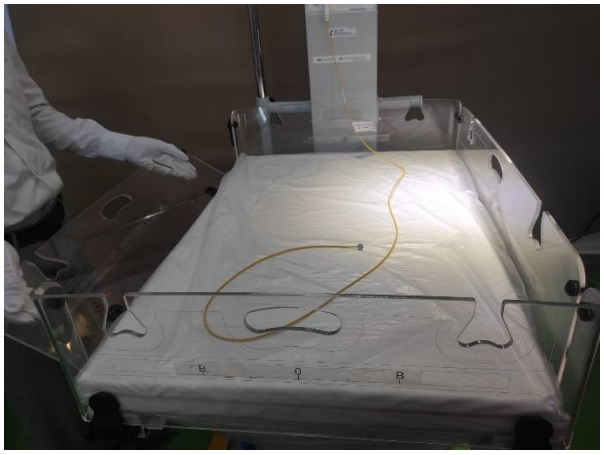
Warning

- Limit the load placed on X-ray tray 5 lbs. (2.3 Kg) to avoid a tipping hazard.
- Never place an infant on the X-ray cassette tray.
- Do not place any foreign objects on the Infant Radiant Warmer bed or in the under bed cavity while performing X-ray procedures. Incompatible materials in the path of the X-ray may adversely affect the quality of the X-ray image. Use of mattress or bedding materials other than those supplied by nice Neötech should be evaluated by a Neonatologist or Radiologist.

Caution

- The tray can be removed for cleaning by simply sliding it all the way out of the slides. The tray should be cleaned between patients according to the hospital protocol.

3.5 Side Panel operation



Picture 42

- To lower a side panel, pull it up and then pull the top edge away from the bed.
- To raise a side panel, swing it to the upright position; then allow it to engage in the latched position.

Warning

- Do not leave the patient unattended when the side panels are lowered.
- Do not move the Infant Radiant Warmer by pushing or pulling on the bedside panels. This action may lead to the deterioration and breakage of the components which form a safety barrier around the infant.
- Ensure that the bedside panels are locked in position when a patient occupies the bed. Blankets or other foreign objects may prevent the latches from fully engaging.

3.6 Heater rotation

Picture 43

- ❖ Rotate the knob (at the back side of the pillar) and swing the heater box to its sides.
- ❖ The heater box can be rotated on both sides and check for smooth movement of heater box.

3.7 Shut down Procedure

- ❖ Remove the baby from the mattress of Infant Radiant Warmer.
- ❖ Switch OFF the main switch at the front side (on pillar) of the Infant Radiant Warmer.

3.8 Transport/Movement details

- ➢ Check that all castors are in fine contact with the floor and that the Infant radiant warmer unit is stable & moves freely.
- ➢ Lock the brakes in antistatic castors to hold the base unit of Infant radiant warmer unit in static position.
- ➢ Unlock the brakes in antistatic castors to the Infant radiant warmer unit again.

3.9 Accessories

S.No	Accessory Name	Type of use	Part no.	Intended use	Picture
1.	Skin temperature sensor	Reusable	50-05-239	Intended to measure the baby temperature	

2.	Air temperature sensor (optional)	Reusable	20-05-160	Intended to measure the ambient temperature	
3.	Mattress	Reusable	87-00-139	Intended for the placement of patient (baby) under Infant radiant warmer during treatment.	
4.	X-ray Cassette Tray	Reusable	96-00-089	Intended to facilitate X-ray procedures while patients occupy the Infant Radiant Warmer bed.	

Section 4: Cleaning & Maintenance

4.1 General

- ❑ Always switch off the equipment while cleaning
- ❑ 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 Infant Radiant Warmer into service.

- Use only the reusable nice Neötech baby temperature sensor to monitor the patient's baby temperature. Use of other manufacturer's sensors may affect the accuracy of Infant Radiant Warmer operation and the electrical safety of the patient.
- Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.
- Switch off the equipment and disconnect the Power cord from the mains before take in to cleaning
- Don't pour the water for cleaning, it may enter into the electronics circuits it cause short circuit and get shock.
- Disconnect power to the Infant Radiant Warmer and allow the heat rod to cool before cleaning to avoid the possibility of a burn.

- Don't keep the metal surface in wet condition it may cause corrosion and damage the part
- Use the cleaning solution sparingly on a cloth when cleaning the Infant Radiant Warmer. Do not saturate the unit - excessive solution causes damage to internal components.
- **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

The service period for this equipment is six years.

4.1.1 Disassembly of Mattress, X-ray tray for cleaning

Follow the reverse process of Installation for cleaning:

- Side panels (refer 2.7)
- Mattress (refer 2.8)
- X-Ray (refer 2.12)

4.1.2 Cleaning and disinfection of Infant Radiant Warmer

During cleaning the Infant Radiant Warmer, the processing shall comply with EN ISO 17664:2017 for reusable of the device:

1. Clean the equipment with damped cloth using soap (e.g. liquid dish soap) and clean water.
2. Rinse the equipment completely with water damped cloth.

3. Disinfect the equipment by using 2% Glutaraldehyde to inactivate any remaining pathogens.

❑ When the equipment is not in use, all approachable external surfaces should be cleaned daily with an antiseptic solution like **2% glutaraldehyde**. Every seventh day, after shifting the baby to another cot, the equipment should be cleaned thoroughly, first by mild detergent solution and then by antiseptic solution for **3 minutes**. All detachable assemblies, are to be treated similarly

4. Rinse with damped cloth using sterile or clean water (i.e. water boiled for 5 minutes and cooled). Sterile water is preferred for rinsing off residual liquid chemical disinfectant from Infant Radiant Warmer that has been chemically disinfected for reuse, because tap or distilled water may harbour microorganisms. However, when rinsing with sterile water is not feasible, instead, rinse with tap water or filtered water (i.e. water passed through a 0.2 µ filter).

5. Dry Infant Radiant Warmer using dry towel or cloth.

- Use of cleaning/disinfecting solutions containing chemicals that are not listed above (i.e. alcohol, acetone, etc.), or chemicals in greater concentrations than those listed above, may damage the patient sensor or other material being cleaned.

- Do not autoclave or gas sterilize the mattress.

4.1.3 Cleaning and disinfection of Temperature Sensor

The cleaning methods listed below and do not affect the integrity or performance of the sensor. It is the user's responsibility to qualify any deviations from these procedures, both for disinfecting efficacy and physical effect on the probe.

Physically clean the skin temperature sensor with soft cloth, removing all visible contaminants by wiping using water general cleaning.

1. When the equipment is not in use, temperature sensor cable surfaces should be cleaned daily with an antiseptic solution like 2% glutaraldehyde and left for 3 minutes.

2. Then rinse the temperature sensor by wiping using water damped cloth

3. Dry temperature sensor using dry towel or cloth

- Do not autoclave or gas sterilize the baby temperature sensor.

- Do not immerse the sensor in liquid cleaner. Avoid placing excessive strain on the sensor lead. Always remove the sensor by grasping the plug at the panel. Do not pull on the sensor lead. These precautions will help avoid damage to the sensor.

- After every treatment, detach the temperature sensor and clean thoroughly on the cable surface, first by light detergent solution and then by antiseptic solution for 3 minutes.

- 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.

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

- Do not apply cleaning solutions to the sensor connector.

4.1.4 Cleaning and Disinfection of Mattress, X-ray tray, Bed frame, Pillar, Heater box, Side panels, Mayo tray, IV rod

1. Physically clean the components/parts with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. Rinse the components/parts with water damped cloth.
3. Disinfect the components/parts by using 2% Glutaraldehyde to inactivate any remaining pathogens and leave it for 3 minutes.
4. Then rinse the components/parts by wiping using water damped cloth
5. Dry components/parts using dry towel or cloth

4.2 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.

4.3 Life time of IR Heater

The life time of the IR heater can be considered as minimum three years, after which it should be replaced.

Section 5: Specifications

Mains Voltage	~230V/50Hz
Maximum Rated Power	700 VA
Circuit Breaker	10A
Micro controller-based control system	Self-test function performed at power up and continuous during normal operation
Modes	Baby (Servo Skin), Servo Air*, Safe, Manual, Prewarm, HIE
Baby Set Temperature Range	32 – 38°C in increment of 0.1°C
Air* Set Temperature Range	20 – 38°C in increment of 0.1°C
Manual Timer alert	15 minutes
Audio paused Time	15 minutes
Heater Output	0% to 100%, increment 5%
Skin Temperature Sensor	Thermistor based, Interchangeable with Accuracy ± 0.2°C
Air* Temperature Sensor	Thermistor based, Interchangeable with Accuracy ± 0.2°C
Temperature Sensor Accuracy	±0.2°C @ 30°C to 40°C (Calibration not required)
Sensor Interchangeability	Accuracy ± 0.2°C
Heater	Quartz heating element 600 W
Observation Lamp	1 W LED x 6 Dual LED lamp with variable intensity facility
Heater Module Rotation	±90° to the side to facilitate X-ray procedures.
Bed Head Up / Down Facility	±15° Trendelenburg and Reverse Trendelenburg.
Safety Features	Safety Cut Offs & Comprehensive Indications If Temperature > 39°C in any mode, i-sense technology, Check-sensor alert
APGAR Timer	1 – 59 minutes (count up/count down)
Audio & Visual Indication	
Baby temperature High	If baby skin temperature is > 1°C from set temp.
Baby temperature Low	If baby skin temperature is < 1°C from set temp.
Air* Temperature High	If baby skin temperature is > 1°C from set temp.
Air* Temperature Low	If baby skin temperature is < 3°C from set temp.
Sensor Fail	If skin temperature sensor or air* temperature sensor is removed or damaged.
System Fail	When the skin/ air temperature goes beyond 45°C, system fail alarm is triggered.
Over Temperature	If skin/air* temperature is > 39°C in any mode
Heater Fail	If the heater is disconnected or fails
Power Fail	If the power supply is disconnected or fails

Display	
Temperature unit	Centigrade
Baby temperature Display	10 .1– 50.1°C
Air* Temperature Display	10 .1– 50.1°C
Resolution	0.1°C
Calibration	Not required
Castors	4” castors – 4 Nos. (2 with brake, 2 without brake)
IV Pole	maximum load: 1.5 Kgs
Mayo tray	maximum load 3 Kg
Cabinet	Maximum load 3 Kgs
Algorithm of the Alarm	
High Priority	Pulse Frequency – 294.2 Hz, More than 4 Harmonics, 10 Pulse burst, Pulse spacing: 102.5ms, 101ms, 367.8ms, 100.4ms, 512.1ms, 102.5ms, 98.7ms, 368.2ms, 98.8ms Repeat time: 0.25s, Visual - Red
Medium Priority	Pulse Frequency – 742.9 Hz, More than 4 Harmonics, 3 Pulse burst, Pulse spacing: 225.6ms, 231.1ms Repeat time: 7.5s, Visual - Amber
Sound Pressure Level	High Priority Alarm - 69 dB, Medium Priority Alarm – 67 dB
Factory Default Settings	
Mode of Operation	Baby Control (Servo Skin) Mode
Baby Control Temperature	36.5ºC
Heater Percentage in Manual Mode	30%
Air* Control Temperature	34.0ºC
Apgar Time	20 Minutes Count-up
Observation lamp intensity with ON time	50% - 30 minutes
Manual mode timer	15 minutes
Alarm Silence time	15 minutes

MDD Product Classification	**Class IIb**

IEC 60601-1 Specifications	
Type of Protection against electric shock	Class I
Degree of Protection against electric shock	Type BF (Baby Temperature (T1) Sensor, Type B (Mattress)
Mode of Operation	Continuous
Protection against hazardous of explosion	Not protected
Protection against increase of liquid	Not protected
Quality Test Approval	
Quality	ISO 13485:2016

Electrical Safety	IEC 60601-1
Product Safety	IEC 60601-2-21, ISO 10993
EMC Safety	IEC 60601-1-2
Alarm	IEC 60601-1-8
Graphical Symbol	ISO 7010
Environmental Specifications	
Operating Temperature	15°C to 35 °C
Operating Relative Humidity	15 – 90% RH, non-condensing
Storage temperature	-10°C to 60 °C
Storage Relative Humidity	50% - 90% RH, non-condensing
Altitude	Sea level to 1.9 miles (3 kms)
Atmospheric Pressure Range	50 – 106 Kpa
Pollution degree	2

Optional features	Battery backup for display, Oxygen delivery

Dimensions and weight	
Dimensions	185 cm (H) x 100 cm (L) x 75 cm (W)
Mattress	77.5 cm (L) x 52.5 cm (W) x 5 cm (H)
Weight	52 kgs
Power Cord	
Technical Specifications	
Plug	3 Pin, 16A/250VAC/50 Hz
Type of Cable	3 x 1.5 mm^2 /1100VAC
Length of cable	3 m
Max. Rated Current	16A

Air* - Optional mode

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 sensor & 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 Neötech/authorized Neötech dealer.
10. Warranty is not applicable if the warranty card is not filled and sent back to Neötech.
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 send the same

From _____
_____
_____

To:
The Service In-charge
nice Neötech Medical Systems Pvt. Ltd.
No.85, Krishna Industrial Estate,
Vanagaram, Mettukuppam,
Chennai-600095. Tamil Nadu, INDIA.
Ph: 91-44-24762594, 24764608
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

Sl. No	Problem	Cause	Remedy
1	Power failure LED is ON with audio indication	Power failure	Check the unit is plugged in to main supply
			Check the mains are switched ON.
			Otherwise contact nice Neötech
2	System failure LED is ON with audio indication	System failure	Contact nice Neötech.

7.2 System Fault Infant Radiant Warmer

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 if the circuit breaker in the rear side of pillar is tripped
		Otherwise, contact nice Neötech
2	No heater output	Check internal wiring between control module to heater module
		Set temperature may be less than actual temperature
		Check heater connection
		Otherwise contact nice Neötech
3	Machine working, but observation lamp & heater output not working	Check internal wiring between control module to heater module
		Check if the circuit breaker in the rear side of pillar is tripped
		Replace observation lamp
		Replace IR heater
4	Machine not give the audio indication	Check the temperature it may be near to the set temperature
		Check audio paused is ON.
		Otherwise contact nice Neötech
5	Baby temperature display shows “S-O” or “S-S” with continuous audio indication (S-O: Sensor Open) (S-S: Sensor short)	Check if skin temperature sensor is disconnected from the machine or short.
		If skin temperature sensor is defective, replace new sensor
		Otherwise contact nice Neötech
6	Air* temperature display shows “S-O” or “S-S” with continuous audio indication (S-O: Sensor Open) (S-S: Sensor short)	Check if air* temperature sensor is disconnected from the machine or short.
		If air* temperature sensor is defective, replace new sensor
		Otherwise contact nice Neötech
7	Display shows H - F (H-F: Heater Failure)	Check heater connection
		Otherwise contact nice Neötech

8	Over temperature indication (i.e. Temp. > 39 ° C)	Check environment temperature above 39° C
9	Continuous baby temperature high indication	Check patient temperature is 1°C above set temperature
		Check environment temperature is 1°C above set temperature
		Otherwise contact nice Neötech
10	Continuous baby temperature low indication	Check patient temperature is 1°C below set temperature
		Sensor may be wet.
		Otherwise contact nice Neötech
11	Continuous air* temperature high indication	Check environment temperature is 1°C above set temperature
		Otherwise contact nice Neötech
12	Continuous air* temperature low indication	Check environment temperature is 1°C below set temperature
		Sensor may be wet.
		Otherwise contact nice Neötech
13	Temperature over mattress does not rise	Check low ambient temperature it should be approximately (22-30°C)
		Check draft around air conditioning outlet
		Check percentage heater output is set at low in manual mode
		Low supply voltage
14	Temperature over mattress rises excessively	Check direct sun light, heating device or other heat source
		Percentage heater output is set at high in manual mode
15	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	Sensor thermal sensitive portion attached improperly
		Check thermal sensitive portion of sensor covered improperly
17	Baby temperature not correlating with display temperature	Check sensitive portion of the sensor is fixed with baby skin properly.
		Check sensor is fixed to the lower abdomen of baby
18	Heater output is off after some time in manual mode	Check manual timer time is 15 minutes.
		Check the heater output is off after set time
		If heater output is off before set time contact nice Neötech
19	In baby mode, baby getting over heat but machine gives low temperature indication	Check the sensor is intact with lower abdomen of baby
		Check the sensor is removed and keep away
		Check the set temperature is high
		Check the set heater output is high (manual mode)

20	Heater ON during HIE mode	Check if HIE mode indicator is lit, switch OFF the device if it is lit
		Contact nice Neötech, if heater is still ON during HIE mode

*Air – Optional mode

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 Neötech's original parts for maintenance.

- Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.
- Don't misalign the EMI Shielding and the beads it may cause the EMI interference to the equipment

- **Observation Lamps**: To be replaced if defective by trained service personnel.
- **IR Heater**: To be replaced if defective by trained service personnel.
- **Side Panels**: To be visually inspected every day for proper fixation, breakage or loosening.
- **Temperature measuring system**: Measuring system should be checked by trained service personnel with calibrated test sensor every year.

Note: No need of calibration if a new temperature sensor 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.

7.4 Disposing of the Unit

- At the end of its service life dispose of the equipment in accordance with national waste disposal regulations or ask a suitable disposal contractor to dispose of the unit. The local environmental agency can supply further details.

Section 8: Spare Parts List

Sl. no	Part No	Part Name	Qty	Unit
1	20-05-145	PCB Control assembly	1	No.
2	20-05-131	Speaker assembly	1	No.
3	20-05-132	Infant radiant warmer Transformer assembly	1	No.
4	20-05-160	Air* Probe assembly nice 5000	1	No.
5	99-00-183	Mayo Tray	1	No.
6	20-05-146	Single Cabin storage compartment assembly	1	No.
7	99-00-704	Access Panel Assembly FR/RR	2	No.
8	99-00-705	Access Panel Assembly LH/RH	2	No.
9	20-05-239	Skin Probe Assembly	1	No.
10	87-00-139	Mattress	1	No.
11	91-00-241	Circuit breaker 10 A	2	No.
12	91-00-172	DPST switch non illumination	1	No.
13	91-00-034	Lamp IR Heater 600W	1	No.
14	91-00-073	Thermostat, 90 Dec NC	1	No.
15	91-00-051	Battery 9 V, unchargeable	1	No.
16	93-00-028	Castor 3 inch thread type with brake	2	No.
17	93-00-029	Castor 3 inch thread type without brake	2	No.
18	98-00-009	Silicon Bush IR Lamp	2	No.

*Air – Optional mode

Section 9: Manufacturer's EMC Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The Infant Radiant Warmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant Radiant Warmer should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Class A	The Infant Radiant Warmer 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	

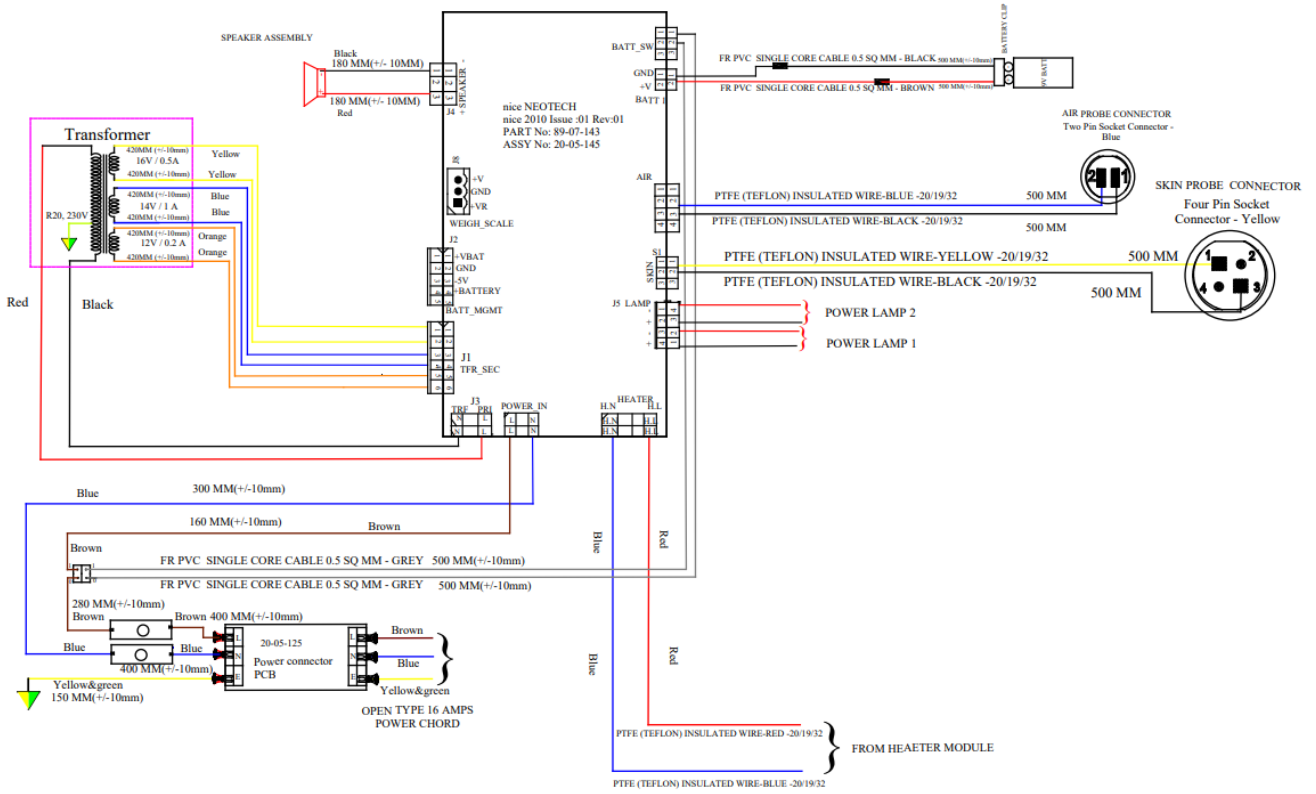
Guidance and manufacturer's declaration – electromagnetic immunity			
The Infant Radiant Warmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant Radiant Warmer should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 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	0% of dips for 0.5 & 1.0 cycle	Criteria A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Infant Radiant Warmer requires continued operation during power mains interruptions, it is recommended that the Infant Radiant Warmer be powered from an uninterruptible power supply or a battery.
	70 % dips for 25 cycles 0% short interruption for 250 cycles	Criteria A	
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 Infant Radiant Warmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant Radiant Warmer 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 bandsa 10 Vrms 150 kHz to 80 MHz in ISM bandsa	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.			

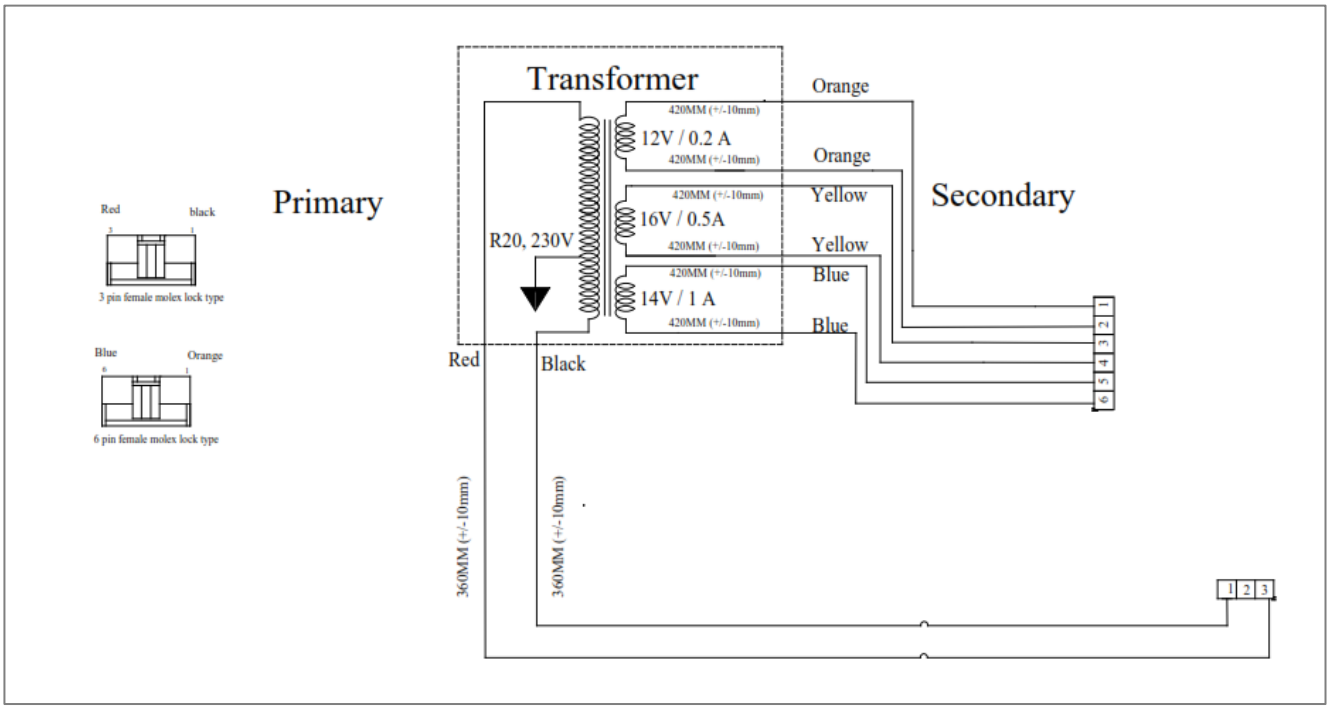
Acceptance criteria

Performance criteria	Description
A	Normal performance within limits specified by nice Neötech
B	Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention
C	Temporary loss of function or degradation of performance, the correction of which requires operator intervention
D	Loss of function or degradation, which is not recoverable, owing damage to hardware or software, or loss of data

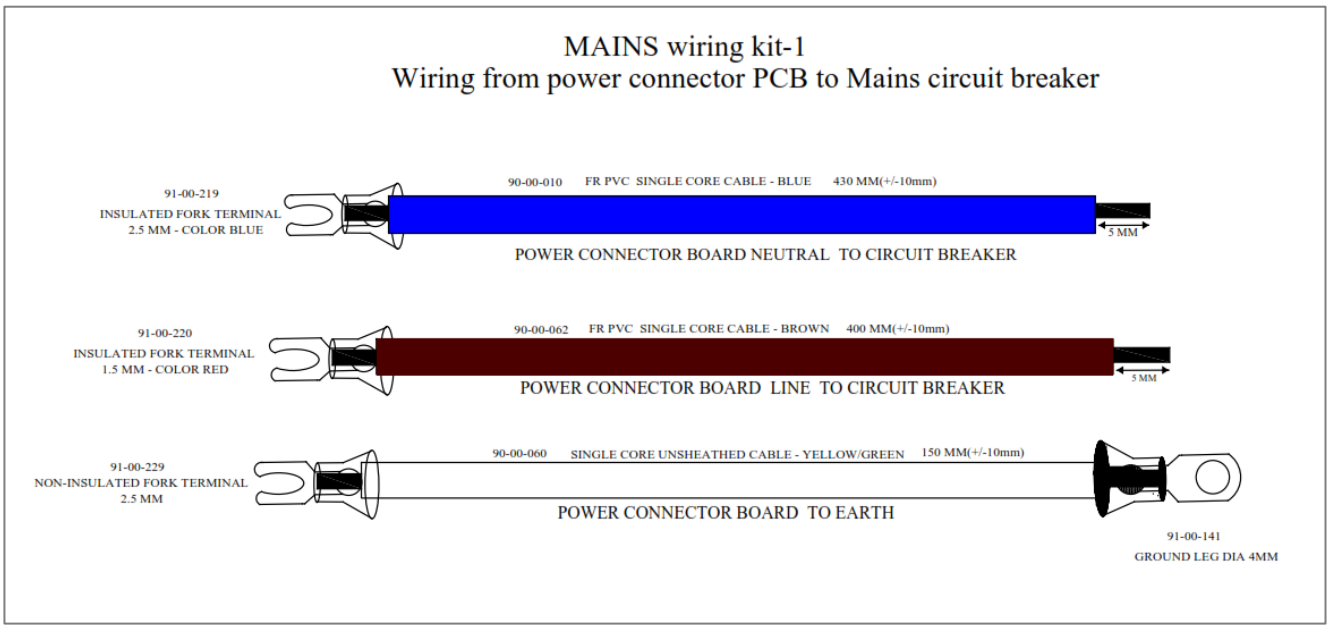
Section 10: Wiring Drawing



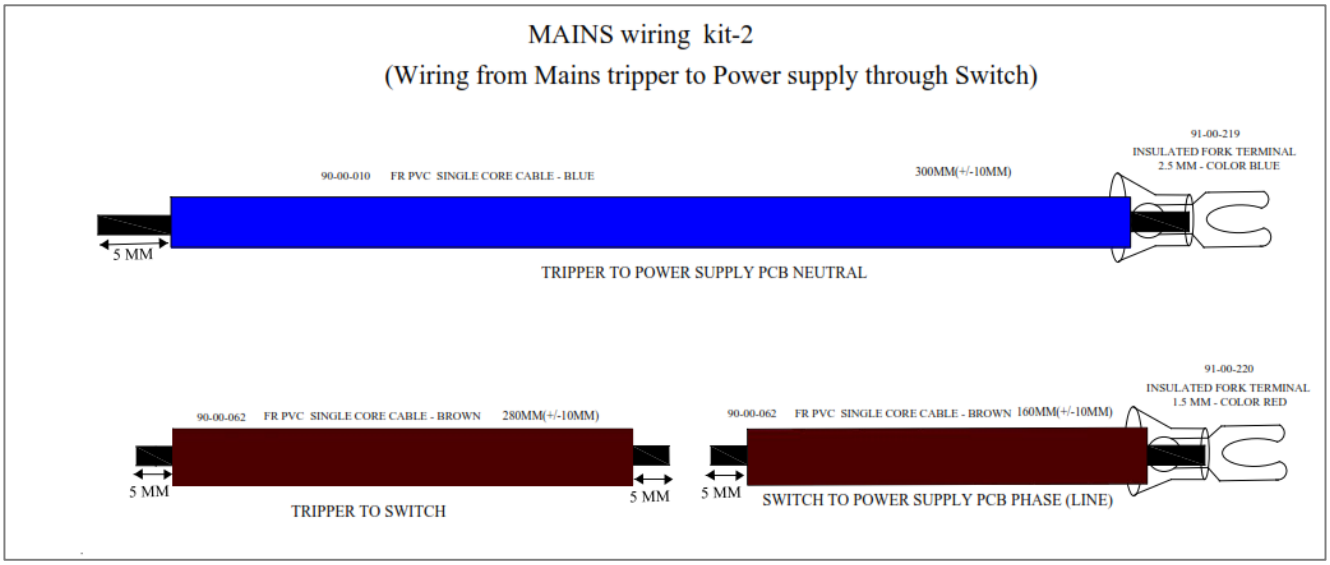
Pillar assembly



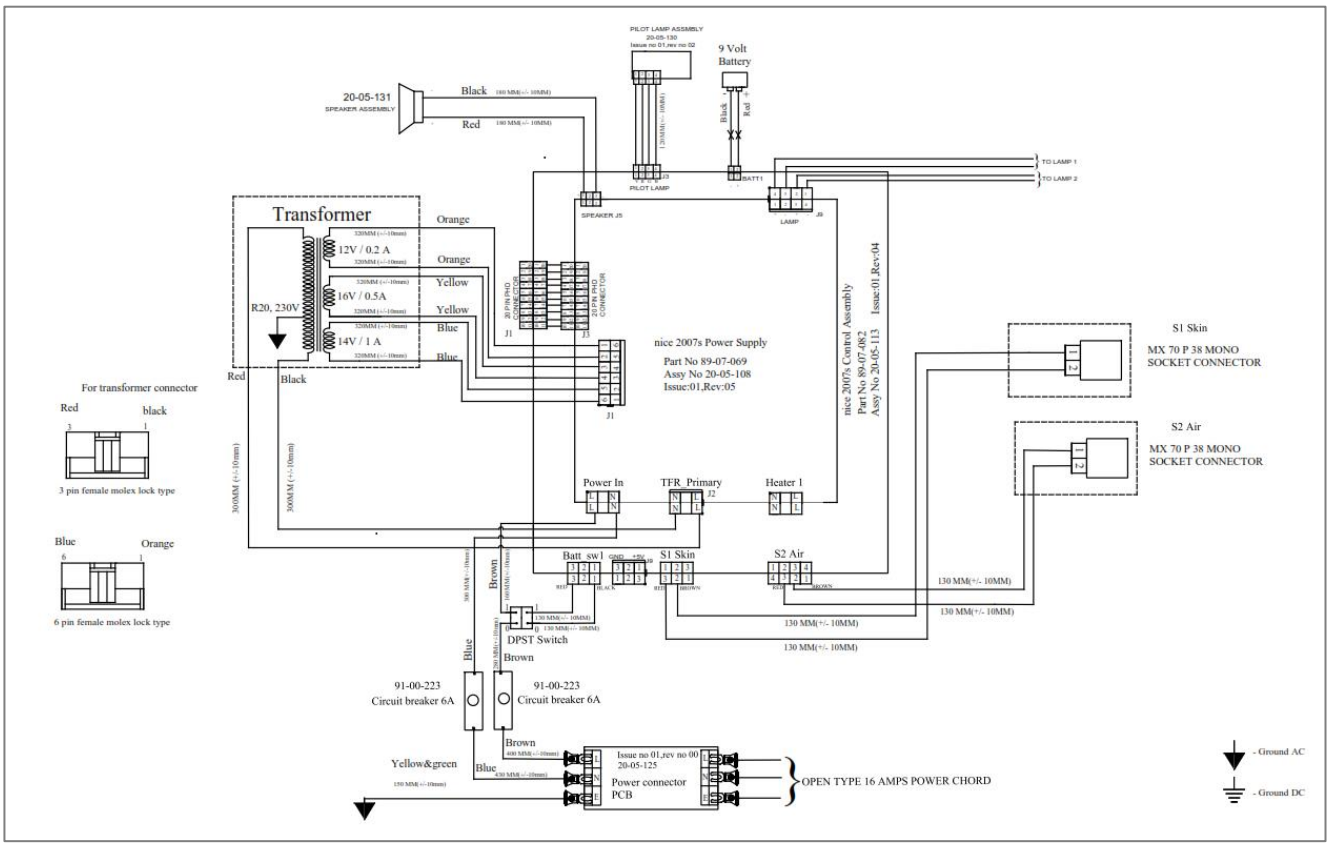
Transformer assembly



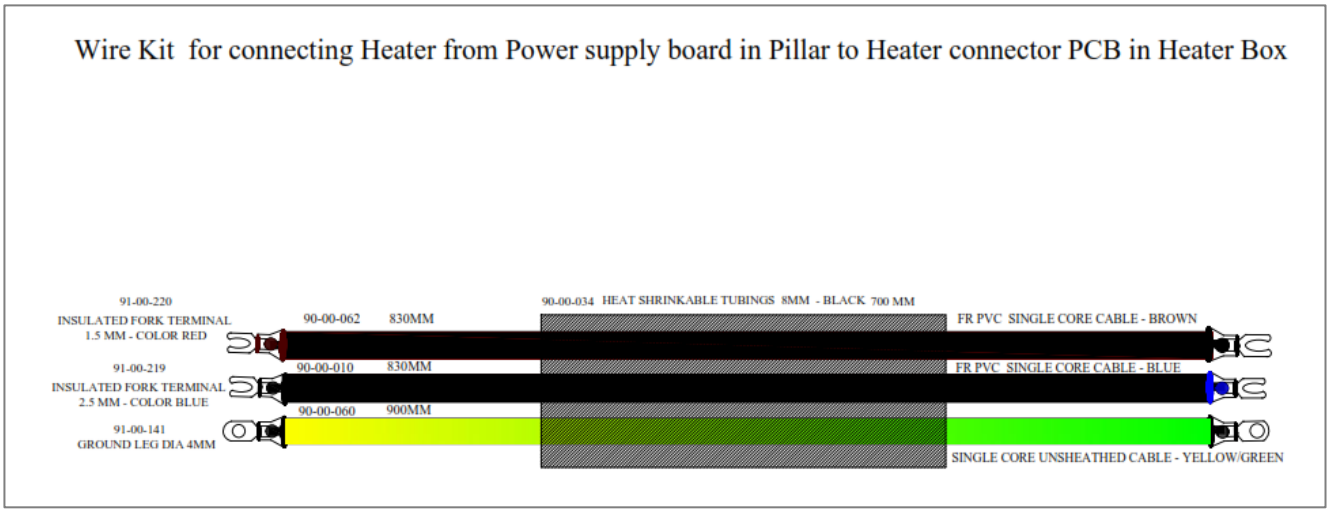
Mains wiring kit-1



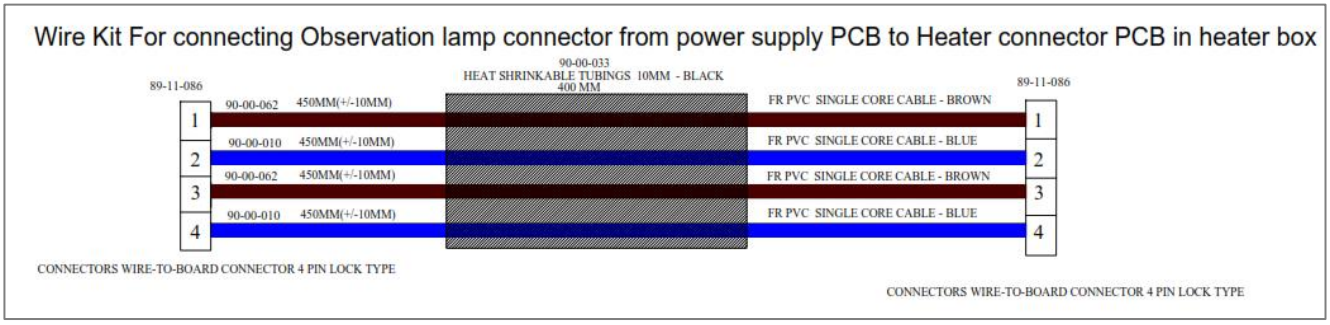
Mains wiring kit-2



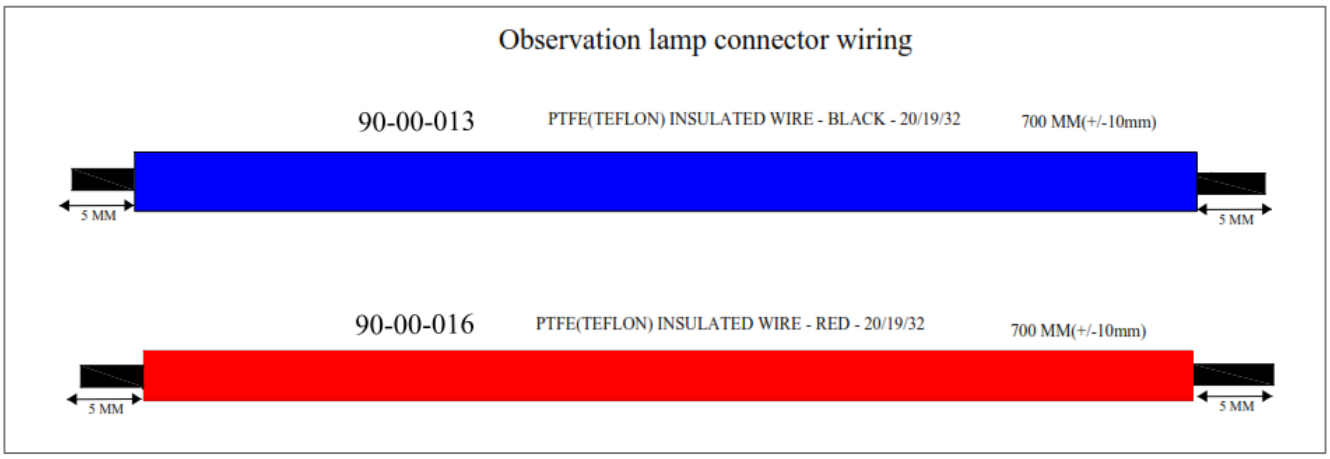
Heater box module assembly



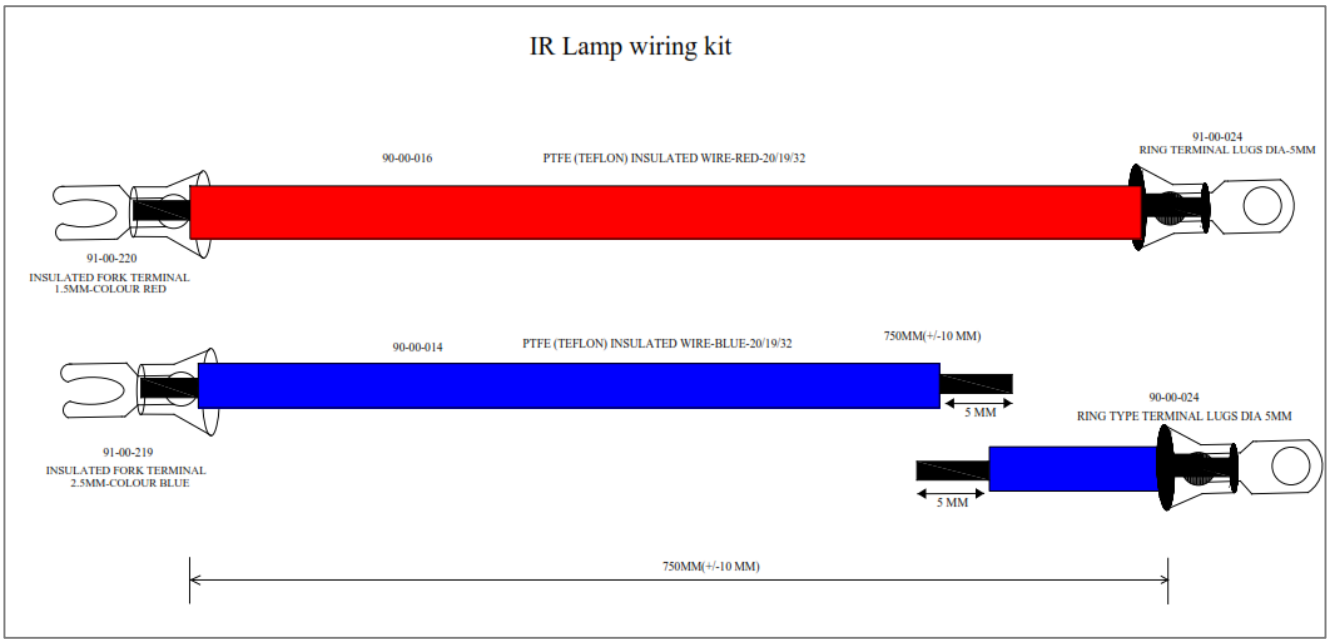
Heater box to pillar wiring kit



Heater Module Wire Kit assembly-1



Heater Module Wire kit assembly-2



Heater Module Wire kit assembly-3

Section 11: For Complaints/Adverse Events/Comments/Feedback

			Date:		
Hospital Name & Address:					
Contact Person & Contact No. & Email:					
Department:	NICU / PICU / OT / Casualty / Others _____				
Equipment name:			Model no.:		
UDI / Serial No.:		Date of purchase:		Date of Installation:	
Pick one:	☐Complaints ☐ Adverse Events ☐Comments ☐Feedback				

In case of adverse events, fill the below details:

Incident happened to: (Patient / User)	
Details of incident happened person: (Name/Age/type of incident)	
Severity of the event (Minor injury / Major injury / Death)	
Brief description of the event	

For comments:

For Complaints:

For Feedbacks:

Kindly fill the above and send the same

From:

_____

_____

_____

To:
The Marketing In-charge
nice Neotech Medical Systems Pvt. Ltd.
No, 85-86, Krishna Industrial Estate,
Vanagaram, Mettukuppam,
Chennai-600095. Tamil Nadu,
INDIA.
Ph: 91-44-24762594, 24764608
Email: marketing@niceneotech.com
Toll Free No. 1800-425-2594 (India only)

NOTE: In case of serious/adverse events, report the incident to nice Neotech, European Authorized Representative and the competent authority of the Member State by filling and sending the below form as letter post or email.

Service Contact
nice Neötech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Vanagaram, 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