

Infant Radiant Warmer

**nice 2010 BC,
2010, 2007 S,
User manual**

This user 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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nice 2010 BC



nice 2010



nice 2007 S

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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 probe are biocompatible, complies with ISO 10993-1, ISO 10993-5, ISO 10993-10 requirements.

Model Descriptions

All models of the nice Neötech Infant Radiant Warmer provide 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 2010 BC is an Infant Radiant Warmer having integral bed and Cabinet – TFT model.
- The model nice 2010 is an Infant Radiant Warmer - standalone model.
- The model nice 2007 S is a Servo control Infant Radiant Warmer having integral bed 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



Warning

- 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 the Infant Radiant Warmer power cord and allow the unit to cool before replacing the observation lights.
- In a dust free area, keep hands clean and then install the equipment.
- **Do Not Lift the Infant:** Always keep the infant in the bed of the warmer. Lifting the infant toward the heater head can expose them to excessive heat, leading to severe burns.
- Bed-to-heater spacing which differs from the specified 80-85 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 "pre-use check instructions" 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, you 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.
- In the air* mode, you can set the required environmental temperature; indirectly maintain the baby skin temperature automatically as required when the baby's skin is very delicate to fix the Temperature Probe.
- In the baby mode , the infant warmer automatically adjusts heater output to maintain the desired skin 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 probe lead as far away as possible from electrosurgical cables.
- Do not allow excess electrical cables to be laid on the bed platform. Use of electrosurgical units or other instruments which radiate electrical fields can cause indirect heating, by several tenths of a degree of the skin temperature probe due to absorbed electrical energy.
- When using these devices near the 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 of nice Neotech temperature probes and cables only. Use of accessories such as temperature probes and cables other than those specified or provided by the nice Neotech of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The skin temperature probe should be located on the patient's skin in an area which is directly in the path of the radiant heat. It should not be attached to an area which is shielded from the radiant heat or between the patient and the mattress. Large temperature gradients and very long servo response times will result from improper probe placement.
- Rectal temperatures must never be used to servo control a patient's temperature.
- Intimate contact between the skin temperature probe tip and the patient's skin must be maintained for accurate skin temperature measurement. Under heating or overheating may result from poor contact between the skin temperature probe and the patient. Verify that the skin temperature probe is securely attached to the patient at least once every half an hour.
- In the baby mode, verify that the patient temperature probe is securely attached to the patient at least once every half an hour. A dislodged probe may not trigger an indication. If the probe 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 (retinopathy or prematurity). 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.)
- Infant Radiant Warmer should not be used near active high-frequency equipment, MRI machines, high-frequency ventilators, defibrillators or strong RF sources such as mobile phones and wireless communication systems. Exposure to high electromagnetic disturbances may cause inaccurate monitoring, unexpected device behavior, or malfunction. Proper shielding and there must be a separation distance of at least 1.0m (3.3 ft) between this device and wireless communication device/ systems.
- Infant Radiant Warmer should not be used adjacent to or stacked with other equipment, as this may lead to improper operation. If such use is unavoidable, both the Infant Radiant Warmer and the other equipment must be carefully monitored to ensure they are functioning correctly. Failure to do so may result in device malfunction, inaccurate performance, or potential safety risks.
- Infant Radiant Warmer is a Class A equipment (CISPR 11, Group 1 Classification) make it suitable for use in hospitals. Use in a residential environment may cause radio-frequency interference, as CISPR 11 Class B is normally required for such settings. To prevent potential disruptions to communication services, users should take mitigation measures, such as relocating or re-orienting the equipment if interference occurs.
- 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)

- Do not use if any parts appear damaged or if there is any reason to believe that it is not functioning properly. Contact nice Neötech Medical Technical Service or your authorized service provider. This light may cause radio interference, in which case adequate measures may be required to prevent interference.
- **Skin temperature:** The use of baby-controlled mode of the radiant warmer is recommended. In addition, use of reflective foils may cause hazardous body temperatures. Monitor the infant's temperature per your hospital policy during phototherapy to avoid fluctuations in body temperature.

Section B: Cautions



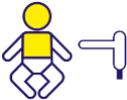
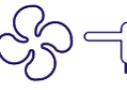
- Isolation from the supply mains is Detachable Power cord provided.
- Keep the patient in the effective area, monitor periodically on failing which patient falling off from the effective area.
- Do not use the equipment on the uneven surfaces.
- Use cleaning solution sparingly on a cloth when cleaning 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 probe. Do not immerse the probe in liquid cleaner. Avoid placing excessive strain on the probe lead. Always remove the probe by grasping the plug at the panel. Do not pull on the probe lead. These precautions will help avoid damage to the probe.
- 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 39deg, 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 90deg.
- 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 has non-detachable power cord used.
- If the transport position of the infant radiant warmer is more than 10°, over balance may occur.
- 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
Monitor Tray	:	maximum load 3 kg (per tray)
X-ray Tray	:	maximum load: 1.5 kg.
Mattress	:	maximum load: 10 kg.
Infusion pump pole	:	maximum load: 3 kg.
Storage Cabinet	:	maximum load 3 kg (per cabin)
- **Other equipment:** Do not attach other equipment to the Neötech heater module or place anything on top of the heater module. The pedestal stand and heater module are not designed to support additional equipment.
- Keep the patient in the effective area monitor periodically failing which patient falling off from the effective area.
- Do not leave the patient unattended when the side panels are lowered. Periodically monitor the side panels are properly locked.
- If the equipment is dropped or damaged or fails to operate correctly take it out of service for examination by a qualified Service Engineer to ensure safety an operational integrity.
- Keep the equipment clean and dry. Do not allow liquid to penetrate the case or operation and safety could be impaired.

- To prevent a possible explosion hazard do not use the equipment in the presence of flammable anesthetic gases.
- Servicing should be performed only by qualified technical personnel.
- Isolation from the Supply mains is separable Plug provided.
- For shipping and storage place the removed P.C. board in an antistatic protective bag, equipment damage could occur.
- Do not use silicone-based lubricants. Equipment damage could occur.
- When removing the equipment from the cartons, take care not to scratch or otherwise damage unprotected surfaces.
- **Electrical Shock Hazard:** Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

Section C: Symbols & Labels

nice 2010 BC, nice 2010, nice 2007S

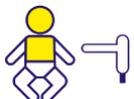
Mark	Description
	Caution
	Caution, ignition (Indicates possible ignition under certain condition)
	Caution, electric shock
	Warning
	Warning - Hot Surface area – Protective grill
	Timed Acknowledged key
	Power failure
	Skin temperature sensor
	Peripheral/Auxiliary* temperature sensor
	Air* temperature 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

nice 2010, nice 2007S

Mark	Description
	Baby temperature
	Set Temperature
	Air* Temperature
	Heater output
	Timed Acknowledged Key
	Increase
	Decrease
	Power failure
	Mode selection
	Baby mode
	Safe mode
	Air* mode
	Manual mode
	Prewarm mode

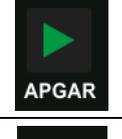
	HIE mode
	APGAR Timer
	Lock
	Observation lamp
	ECO function
	Celsius / Fahrenheit conversion key
	Skin temperature sensor
	Air* temperature sensor

*Air – Optional mode

*Peripheral temperature – Optional feature

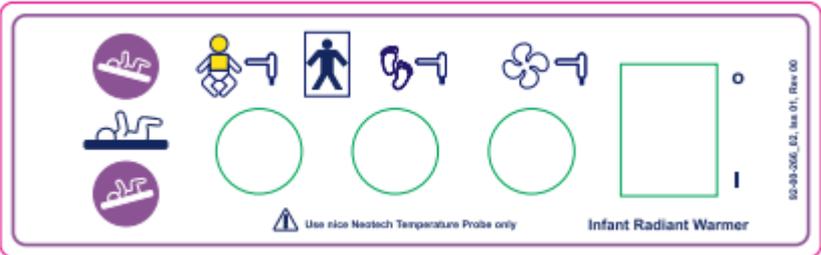
nice 2010 BC

Mark	Indication
	Skin temperature
	Set temperature
	Auxiliary temperature
	Air temperature
	Baby Mode

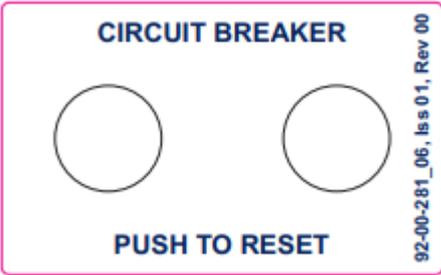
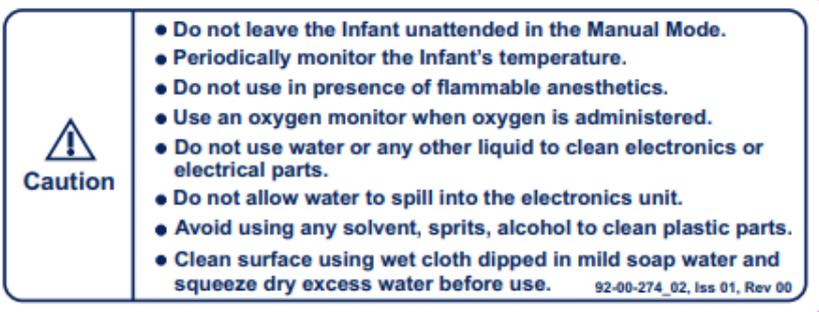
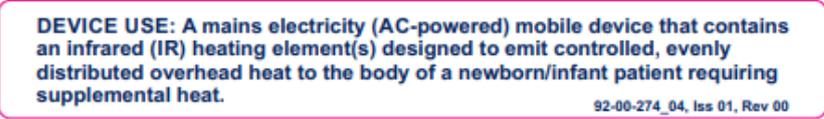
 Safe Mode	Safe mode
 Manual Mode	Manual mode
 Prewarm Mode	Prewarm mode
 HIE	HIE
 Eco	Eco
 %	Heater power output
 APGAR	APGAR timer start
 APGAR	APGAR timer stop
 Timer	Timer
 Weight	Weighing scale display
 Lamp 75%	Observation Lamp
 Lock	Lock
 Unlock	Unlock
 Settings	Settings
 +	Increase key

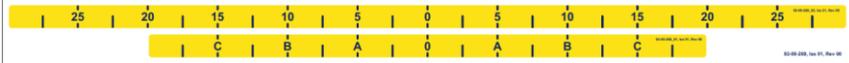
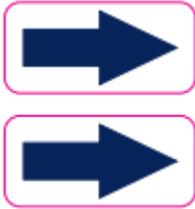
	Decrease key
	Calendar
	Back
	Home/ Exit
	Defaults
	OK
	Cancel
	Save
	Screen timer
	Bed tilting up/down
	Main switch

Labels

S. N o	Label	Part Number	Label Description
1.		92-00-266_01	nice 2010 BC- front panel label
2.		92-00-266_02	nice 2010 BC – Sensor connectors

<p>3.</p>		<p>92-00-265</p>	<p>nice 2007S, 2010 Front panel label</p>
<p>4.</p>		<p>92-00-248_02</p>	<p>Sensor connectors</p>

5.	 <p>nice Neotech Medical Systems Pvt. Ltd. No. 44-45, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600095, INDIA. www.niceneotech.com, info@niceneotech.com. Tel: +91-44-24762594, EU SRN: IN-MF-000010243 M.L - MFG/MD/2023/000906</p> <p>MD Device Generic Name Infant Warmer</p> <p>REF <input type="text"/> Power <input type="text"/></p> <p>V <input type="text"/> Voltage <input type="text"/></p> <p>SN <input type="text"/> Equipment Weight <input type="text"/> with Accessories: <input type="text"/></p> <p>Dimensions: <input type="text"/></p> <p>Corporate Office: nice Neotech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600095, INDIA.</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">92-00-274_03, Iss 01, Rev 00</p>	92-00-274_03	nice 2007S,2010 , 2010 BC - Marking plate
6.	 <p>CIRCUIT BREAKER</p> <p>PUSH TO RESET</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">92-00-281_06, Iss 01, Rev 00</p>	92-00-281_06	nice 2007 S, 2010, 2010 BC – circuit breaker
7.	 <p>Caution</p> <ul style="list-style-type: none"> ● Do not leave the Infant unattended in the Manual Mode. ● Periodically monitor the Infant's temperature. ● Do not use in presence of flammable anesthetics. ● Use an oxygen monitor when oxygen is administered. ● Do not use water or any other liquid to clean electronics or electrical parts. ● Do not allow water to spill into the electronics unit. ● Avoid using any solvent, sprits, alcohol to clean plastic parts. ● Clean surface using wet cloth dipped in mild soap water and squeeze dry excess water before use. <p style="text-align: right;">92-00-274_02, Iss 01, Rev 00</p>	92-00-274_02	caution label
8.	 <p>Neotech®</p>	92-00-272	Neotech logo - Heater module
9.	 <p>DEVICE USE: A mains electricity (AC-powered) mobile device that contains an infrared (IR) heating element(s) designed to emit controlled, evenly distributed overhead heat to the body of a newborn/infant patient requiring supplemental heat.</p> <p style="text-align: right;">92-00-274_04, Iss 01, Rev 00</p>	92-00-274_04	nice 2007S, 2010, 2010 BC - Device use

<p>10.</p>	 <p>Ph.: +91-44-24762594, www.niceneotech.com</p> <p>92-00-240, Iss 01, Rev 01</p>	<p>92-00-240</p>	<p>Skin temperature sensor tag</p>
<p>11.</p>	 <p>92-00-269</p>	<p>92-00-269</p>	<p>2010 BC, 2007S-Side panel label</p>
<p>12.</p>	 <p>92-00-274_07, Iss 01, Rev 00</p>	<p>92-00-274_07</p>	<p>nice 2007S-Power IN</p>
<p>13.</p>	 <p>92-00-274_08, Iss 01, Rev 00</p>	<p>92-00-274_08</p>	<p>nice 2007 S, 2010, 2010 BC - EC Rep</p>
<p>14.</p>		<p>92-00-274</p>	<p>nice 2010 Arrow mark label</p>
<p>15.</p>	 <p>(01) 0 8908003 98925 9 (21) IRW230600368</p>	<p>--</p>	<p>UDI label</p>
<p>16.</p>		<p>92-00-239</p>	<p>nice 2007 S, 2010, 2010 BC -Safety sign, do not step on surface</p>

17.		92-00-239	Safety sign, Do not lean on warmer
18.		92-00-239	Safety sign, Hot surface
19.	  <p>REF 87-00-126/87-00-139/87-00-008/87-00-009 - Mattress</p> <p>Caution Before using the mattress clean with cloth damped with soft soap water. Cover the mattress with cloth before placing the baby. Don't Clean the mattress with hard brush. it may damage. Mattress are only cleaned with soft cloth and packed in the process, not sterilized or disinfected.</p> <p>Warning Do not immerse the mattress in any kind of liquid. This will cause damage to the mattress and will void the warranty.</p> <p>Ph.: +91-44-24762594, www.niceneotech.com</p> <p style="writing-mode: vertical-rl; transform: rotate(180deg);">92-00-239_01, Iss 01, Rev 02</p>	92-00-239_01	nice 2007 S, 2010 BC -Mattress
20.		92-00-239	nice 2007S, 2010, 2010 BC -Max weight 3 kg in mayo tray and cabinet
21.		92-00-239	nice 2007 S, 2010, 2010 BC- Max weight 1.5 kg in IV pole
22.	 <p>TOLL FREE 92-00-098 Rev 00 1800-425-2594 (INDIA only) Email: service@niceneotech.com</p>	92-00-098	Label-Toll free

<p>23.</p>	<p>nice Neotech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai-600095, India. Tel: +91-44-24762594, Web: www.niceneotech.com</p> <p>Product Name Skin Temperature Probe</p> <p>Generic Name Accessory of "Infant Radiant Warmer or Incubator or Transport Incubator"</p> <p>Device use Intended to measure the baby's skin temperature and provide feedback to the control unit of Infant Radiant Warmer or Incubator or Transport Incubator.</p> <p>Mfg. Lic. No. MFG/MD/2023/000906 *Sold only as a part of device "Infant Radiant Warmer or Incubator or Transport Incubator"</p>	<p>REF 50-05-239</p> <p>LOT XXXXXXXXX</p> <p>XXXXXX</p> <p>Dimension in cm XX(L) x XX(W) x XX(H)</p> <p>Weight in kg XX kg</p> <p>No. of units inside XX nos.</p> <p>CE 1434 EC REP Amstermed B.V. Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl; info@amstermed.nl +31 23 565 6337 SRN: NL-AR-000001971</p>	<p>--</p>	<p>Packing label -Skin Probe</p>
<p>24.</p>	<p>nice Neotech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai-600095, India. Tel: +91-44-24762594, Web: www.niceneotech.com</p> <p>Product Name Auxiliary Skin Temperature Probe</p> <p>Generic Name Accessory of "Infant Radiant Warmer or Incubator or Transport Incubator"</p> <p>Device use Intended to measure the baby's peripheral skin temperature and provide feedback to the control unit of Infant Radiant Warmer or Incubator or Transport Incubator.</p> <p>Mfg. Lic. No. MFG/MD/2023/000906 *Sold only as a part of device "Infant Radiant Warmer or Incubator or Transport Incubator"</p>	<p>REF 50-05-241</p> <p>LOT XXXXXXXXX</p> <p>XXXXXX XXXXXX</p> <p>Dimension in cm XX(L) x XX(W) x XX(H)</p> <p>Weight in kg XX kg</p> <p>No. of units inside XX nos.</p> <p>CE 1434 EC REP Amstermed B.V. Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl; info@amstermed.nl +31 23 565 6337 SRN: NL-AR-000001971</p>	<p>--</p>	<p>Packing label - Auxiliary Skin Temperatur e Probe</p>
<p>25.</p>	<p>nice Neotech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai-600095, India. Tel: +91-44-24762594, Web: www.niceneotech.com</p> <p>Product Name Mattress</p> <p>Generic Name Accessory of "Infant Radiant Warmer or Incubator or Transport Incubator"</p> <p>Device use Intended to provide cushion to the Baby placed on the bed platform.</p> <p>Mfg. Lic. No. MFG/MD/2023/000906 *Sold only as a part of device "Infant Radiant Warmer or Incubator or Transport Incubator"</p>	<p>REF 87-00-xxx</p> <p>LOT XXXXXXXXX</p> <p>XXXXXX</p> <p>Dimension in cm XX(L) x XX(W) x XX(H)</p> <p>Weight in kg XX kg</p> <p>No. of units inside XX nos.</p> <p>CE 1434 EC REP Amstermed B.V. Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl; info@amstermed.nl +31 23 565 6337 SRN: NL-AR-000001971</p>	<p>--</p>	<p>Packing label - Mattress</p>
<p>26.</p>	<p>nice Neotech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600 095, Tamil Nadu, India. TEL - +91-44-24762594/24764608 www.niceneotech.com, info@niceneotech.com SRN: IN-MF-000010243</p> <p>Manufactured at: Site 2: No. 44-45, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600 095, Tamil Nadu, India.</p> <p>Product Name: Infant Radiant Warmer Generic Name: Infant warmer Brand Name: Conair Model: Final Assembly Serial no: (01) 0 6968003 98907 5 Dimensions in cm: 125(L) x 103(W) x 185(H) Weight in kg: 119 kg No. of units inside: 01 nos. MRP: Rs. XX,000/-</p> <p>HANDLE WITH CARE LIFE SAVING MEDICAL EQUIPMENT</p> <p>CE 1434 EC REP Amstermed B.V. Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl; info@amstermed.nl +31 23 565 6337 SRN: NL-AR-000001971</p>		<p>--</p>	<p>Packaging, transport and storage Instruction</p>

Section 1: Description

1.1 Intended Use

Infant Radiant warmer for warming pre-mature babies, neonates and infant with a body weight of up to 8 kg to maintain the body temperature at the desired level.

1.2 Medical Indication/Conditions

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

1.3 Contraindication

- Infant Radiant Warmer is contradicted 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 with a body weight up to 8 kg.

1.6 Device Intended User

Neonatologist and Healthcare Professionals.

1.7 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 skin 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 tray to achieve uniformity. The skin temperature of the baby can be monitored by a temperature sensor attached to the skin. The variation in the skin temperature can be seen on the display panel which continuously shows the skin 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 skin temperature. The skin temperature is set at 36.5 degree Celsius). 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.

1.8 Product Description

1.8.1 Mechanical Layout

nice 2007S:

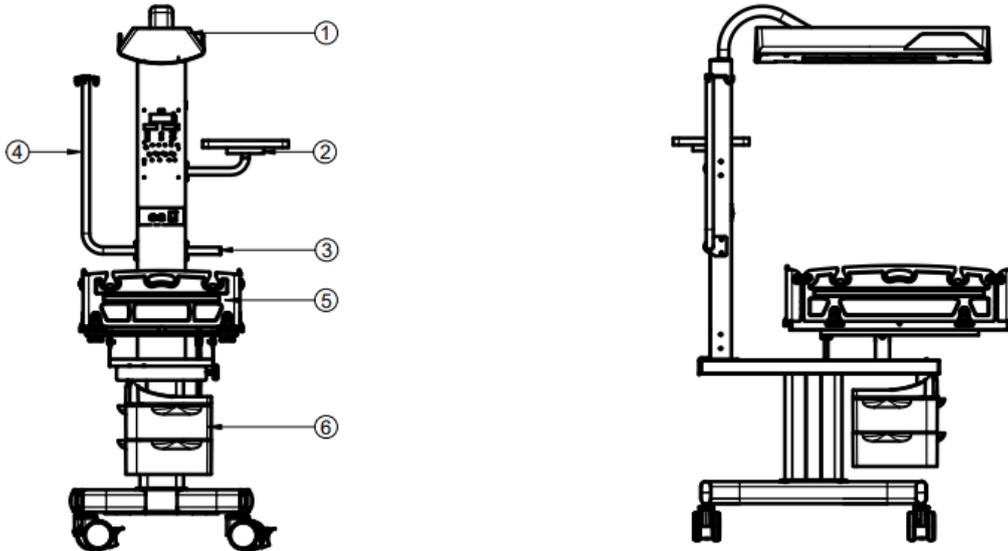


Figure 1

S. No	Material Description
1	IV Pole
2	Heater Module Assembly
3	Mayo Tray
4	Bed Assembly
5	Single Cabin Assembly

nice 2010:

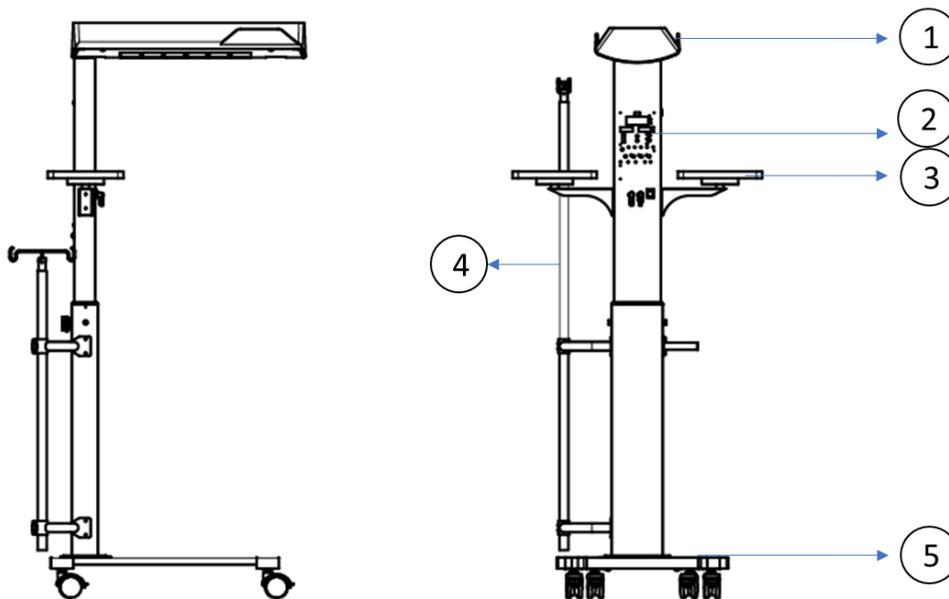


Figure 2

S. No	Material Description
1	Heater Module Assembly
2	Control unit
3	Mayo Tray
4	IV Pole
5	Base Assembly

nice 2010 BC:

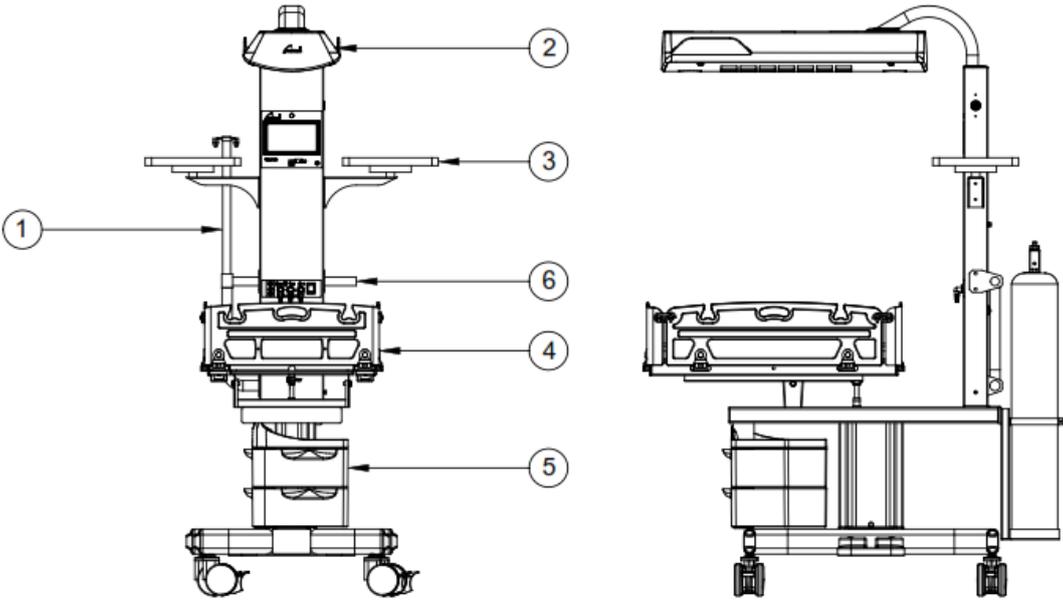


Figure 3

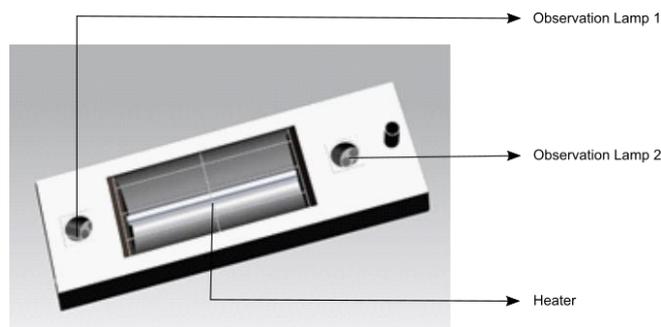
S. No	Material Description
1	IV Pole
2	Heater Module Assembly
3	Mayo Tray
4	Bed Assembly nice 2010 BC
5	Single Cabin Assembly
6	Pillar handle

All models of Infant Radiant Warmers provide a controlled source of radiant heat for infants. The control system uses a microprocessor and provides modes i.e. baby, safe, air*, manual, prewarm, 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.

1.8.2 Support Structure

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

1.8.3 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 80-85 cm will result in incorrect operation and may affect the patient's condition.

The heater assembly consists of a radiant heater, parabolic reflector and an 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 observation light provides intense light for 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.

1.8.4 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, safe mode, air* mode, manual 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.

i-sense technology:

When the skin temperature probe is detached from the baby's skin, the device can automatically sense the temperature reduction and minimizes 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).

Safe mode:

In safe mode of operation, the heater output power 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.

Air mode (optional mode):

Air mode is a servo-controlled operation which automatically controls the radiant heater based on the set required temperature and actual ambient temperature. The air control temperature is adjusted by pressing the increase and decrease in control panel. The control temperature can be adjusted from 20 to 38°C in nice 2010, nice 2007S and 23 to 39°C in nice 2010 BC. In the air mode, the temperature sensed by the air temperature probe is used by the control system to modulate the radiant heat and maintain the Environment temperature at the selected control temperature.

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 reduce to 30% to avoid the risk of over-heating. If heater output is lesser than or equal to 45%, the heater output remains the same.

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.

1.8.5 Bed Platform

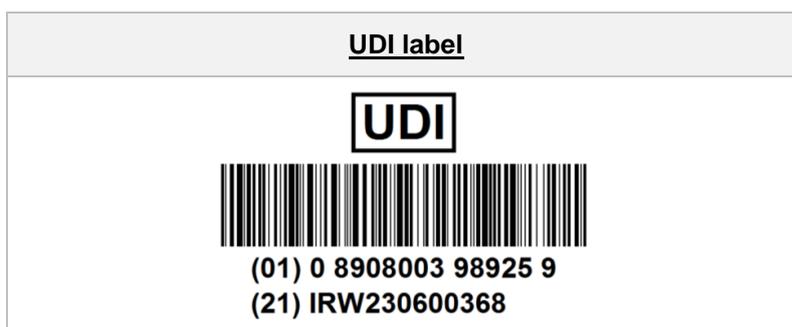
Infant Radiant Warmer with bed includes a mattress and transparent side panels. The side panels fold down for easy access to the patient and can be removed for cleaning. The X-ray cassette tray (located beneath the bed) pulls out for insertion of X-ray cassettes and allows X-rays to be taken without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

1.9 UDI Carrier

The UDI identifies Infant Transport Incubator with Accessories throughout distribution and product life. The UDI appears on the Infant Transport Incubator with Accessories label and it contains two parts i.e., device identifier (DI) and production identifier (PI). The UDI is established as per the requirements Chapter III and Annex VI of Regulations (EU) 2017/745.

Device Variant	Device Identifier (DI)	Production Identifier (PI)
nice 3000	08908003989136	ITIYYMMXXXXX (3 digit Product code + YY + MM + 5 digit serial number)



Section 2: Installation

2.1 nice 2010 BC

2.1.1 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.



Warning

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

2.1.2 Installation of base



Picture 1



Picture 2

Picture 1 & 2: Lift the base assembly from the package box, handle it with gentle care to avoid any potential damage to the base. Note that the wheels with brakes should be recognized as the front side of the warmer. This step serves as a crucial reference point during the installation process.



Picture 3

- Position the Fixed pillar on top of the base assembly. Then, align the corresponding holes in the Fixed pillar and the base assembly. Insert the provided 12X25 button head Bolts through the holes, using the Allen key size 8mm, tighten the bolt firmly.



- Ensuring its alignment corresponds to the orientation of the base wheel brakes, which are designated as the front side. Ensure Fixed pillar is securely attached in the exact position as shown in the image.

Picture 4

2.1.3 Installation of Pillar Mounting Frame



Picture 5



Picture 6

Picture 5 & 6: After fixing the fixed pillar, mount the frame plate onto fixed pillar, aligning it with the corresponding holes on the fixed pillar, then insert the 21 x 25 button head bolts and use 8mm Allen key to firmly tighten the bolts. Ensuring a secure and stable connection between the plate and the fixed pillar. Orientation specified in the images to ensure the accurate alignment of the plate with respect to the fixed pillar and brake wheel.

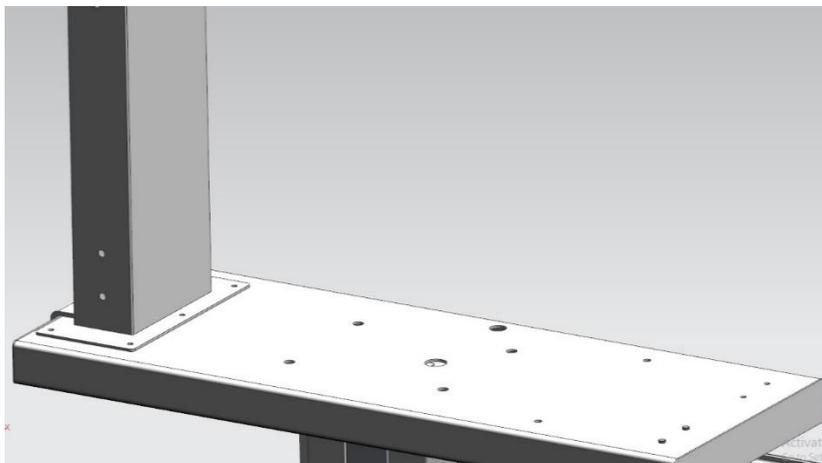
2.1.4 Installation of Equipment

2.1.4.1 Installation of Pillar



Picture 7

- Remove the pillar from its packaging box, then, position the nice 2010 BC pillar assembly onto the frame plate, ensuring that it aligns perfectly with the corresponding holes on the plate. Ensure to fix it the correct position. Insert the provided 8 x 25 button head bolts into the holes of the pillar. Use 5mm Allen key to firmly tighten the bolts.



Picture 8

Picture 8: After fixing the pillar, ensure it is securely and properly fixed. Verify that all bolts are tightened firmly. As the image shows, fix the pillar in the correct holes.

2.1.4.2 Installation of Heater module



Picture 9

- Before positioning the heater onto the top of the pillar, follow this specific step. Identify the Heater box spacer component on the pillar, there will be a clearly flat surface/ facet plane in it. Orient the circular Heater box spacer in such a way that its flat facet plane is facing toward the back side, as indicated in the provided image.
- Note: Adjust flat mark on Heater box spacer (black plastic) as displayed in the image.



Picture 10

- Remove the 8 x 10 bolt from the heater assembly. This step ensures that there are no obstructions, when inserting the heater into the pillar. Once the bolt has been removed, carefully insert the heater assembly into the pillar.



Picture 11



Picture 12

Picture 11 & 12: Handle the heater assembly carefully. Attach it to the top of the pillar while considering the flat surface (facet plane) on the Heater box spacer of the pillar. Guide the wires inside the hole within the pillar. Ensure that the heater is placed accurately and securely in alignment with the pillar assembly.



Picture 2

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



Picture 6

- Perform the Observational lamp wiring connection as per the wiring diagram. (OBS L1, OBS L2 mentioned in the PCB)



Picture 7

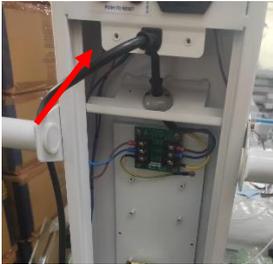
- Perform the heater wiring connection as per the wiring diagram. (HEATER mentioned in the PCB)



Picture 8

- The top back cover is closed using the given screws.

2.1.4.3 Installation of Power cord from the Pillar Assembly

	<ul style="list-style-type: none">➤ Remove the bottom back cover.
<p>Picture 9</p>	
	<ul style="list-style-type: none">➤ Before fixing the power cord in the socket, fix the power cord grip to be connected with pillar assembly.
<p>Picture 10</p>	
	<ul style="list-style-type: none">➤ Perform the pillar wiring connection as per the wiring diagram. (ACTUATOR mentioned in the PCB)
<p>Picture 11</p>	
	<ul style="list-style-type: none">➤ Close the bottom back cover with 4 x 8 PNPLWH.
<p>Picture 12</p>	

2.1.4.4 Installation of Bed Assembly

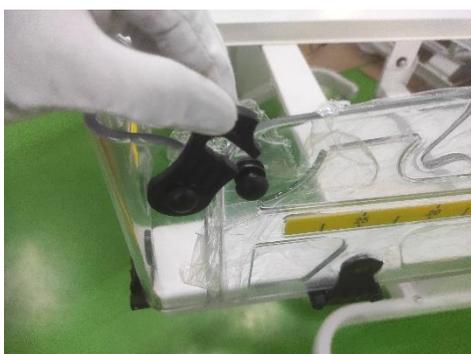
	<ul style="list-style-type: none">➤ Fix the tilting box clamp with 6x35mm allen bolt and 6 mm washer on the bed platform.
<p>Picture 13</p>	
	<ul style="list-style-type: none">➤ After locking the bed over the actuator motor, fix the front end of the bed frame with the tilting rod with special bolts on either side along with 8 mm lock nut.
<p>Picture 14</p>	
	<ul style="list-style-type: none">➤ Mount the bed frame with actuator motor using 4x12 CSK screw.
<p>Picture 15</p>	

2.1.4.5 Installation of Side Panels



Picture 32

- To install the side panels, first, position them alongside the bed frame. Begin by removing the hinge lock nut from the hinge. Next, carefully place the side panels onto the hinge mechanism. Insert the lock nut into the hinge and gently tighten it using an 8mm Allen key.



Picture 33

- The same action is repeated to fix the rest of the side panels. 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.



Picture 34

- Panel on the long side, ensure that the yellow strip line marking points outwards. Ensure the panel are correctly placed in the correct position as shown in the image.



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.

2.1.4.6 Installation of Mattress



Picture 18

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

2.1.4.7 Installation of IV Pole



Picture 19

- Fix the IV holder in the pillar assembly using 5mm Allen key.



Picture 20

- Fix the IV holder in the pillar assembly using 5mm Allen key.



Picture 21

- Fix the Pillar handle in the Pillar assembly by using the 5mm Allen Key like shown in the picture.

2.1.4.8 Installation of Mayo tray



Picture 22

- The Mayo tray is fixed with the pillar on left side using 6x15 Allen bolt for placing monitors, small articles and parts.



Picture 23

- Another 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 on both sides.

2.1.4.9 Installation of X-ray Cassette tray



Picture 24

- 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.

2.1.5 Mechanical Pre-use check instructions



Warning

- 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.

2.1.5.1 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.

2.1.5.2 Heater Assembly Rotation



- ❖ The heater box can be rotated $\pm 90^\circ$ on both sides and check for smooth movement of heater box.

Picture 25

2.1.5.3 Mechanical Checks

I. Side Panels



Picture 26

- ❖ 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.



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

2.1.5.4 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
- Skin temperature sensor
- Auxiliary 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.



- 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.

2.1.6 Control Unit Pre-use check instructions



- 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.

2.1.6.1 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.

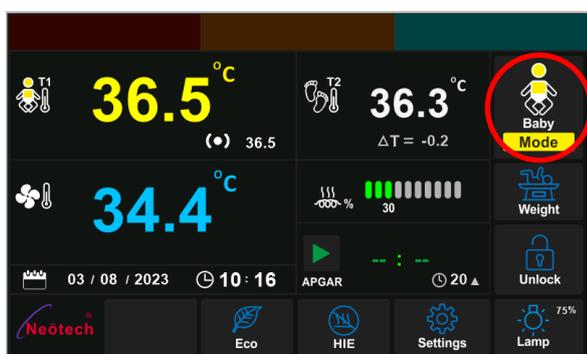
Switch ON the unit and verify the following on the Control Panel:

- ❖ Check that the control panel switches ON with Neotech logo displayed on the screen.
- ❖ Check that the system initializes on self-check mode, verify pink light on the Visual alarm indicator in the pillar assembly.

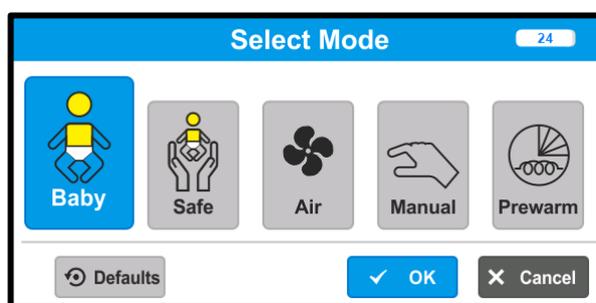
Note: During this self-check functions time, if the controller detects a failure, the Indication stays on and service is required.

- ❖ Check that infant radiant warmer modes can be selected and changed.
(Refer to Section 3.5 for full information on operation)

Select MODE option in the control panel (red circled)



Select the desired mode and then press OK



- ❖ Check that all the modes can be selected and the selected mode is displayed in the control panel.
- ❖ Select the Baby mode and unplug the skin temperature sensor to check that the Baby sensor fail indication lights up with both audio & visual indication.
- ❖ Press the Timed Acknowledged key to check that the audio indications are paused for 15 minutes time duration.
- ❖ Press the lamp icon on the control panel and check that two observation lamps lit up.
- ❖ Select the APGAR timer and select the desired time and check that the timer is displayed on the control panel.

2.1.6.2 Power Fail, Memory Back up

- **Power Fail:**
 - When the main power supply is cut off while the equipment is in ON condition.
 - 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°C.
 - Switch Off the equipment. Switch On the equipment again.

- The mode and the set value remain the same.

2.2 nice 2010

2.2.1 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.



Warning

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

2.2.2 Installation of Equipment

2.2.2.1 Installation of Pillar



Picture 27



Picture 28



Picture 29



Picture 30

Picture 27: The first step is to fix the fixed pillar to the base assembly, place the pillar on the base

Picture 28: Fix the fixed pillar with 6x15 bolts. 6 bolts are to be fixed to hold the pillar firmly.

Picture 29: The next step is to place the movable pillar on the fixed pillar.

Picture 30: A knob is given on the back side of the pillar to hold the moveable pillar firmly.

2.2.2.2 Installation of Heater module



Picture 31

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



Picture 32

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



Picture 33

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



Picture 34

- Place the plastic washer (spacer) on top of the pillar.
- Now hold the knob down to fix the heater box firmly.



Picture 35

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



Picture 36

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



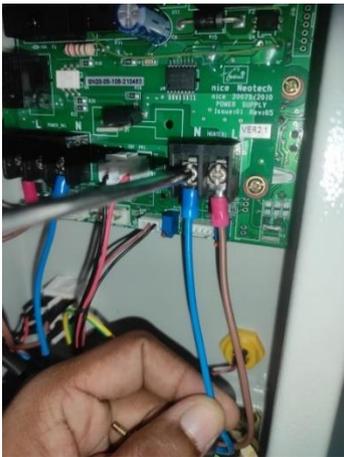
Picture 37

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



Picture 38

- Lock type 4 pin Molex female connector is connected with 4 pin male connector.



Picture 39

- Connect fork terminal with PCB BARRIER TERMINAL BLOCK CONNECTOR (Heater) in the power supply PCB (blue fork terminal with neutral (N) side of the barrier connector and Red fork terminal with line (L) side of the barrier connector)



Picture 40

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



Picture 41

- Fix the back cover to the pillar assembly.

2.2.2.3 Installation of Fixed Monitor Tray



Picture 42

- The fixed monitor tray is fixed with the Pillar on right side using 6x8 hex bolt and 6mm washer for placing small articles and parts.
- The same action is repeated to fix another monitor tray on the other side.
- The maximum load applicable is 3 Kg.

2.2.2.4 Installation of IV Stand



Picture 43



Picture 44



Picture 45

Picture 43: Place the Column IV pole (fixed) on the Clamp Base IV Pole which is a part of the Base assembly like shown in the picture.

Picture 44: The movable IV pole is inserted in the Column IV pole (fixed) through the handle bush and it is attached to the pillar and tightened using the knob.

Picture 45: The IV pole is fixed to the pillar using Allen key. After fixing all the above mentioned parts the IV hook is fixed on the top side of the movable column IV pole.

2.2.3 Mechanical Pre-use check instructions



Warning

- 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.

2.2.3.1 Overall Appearance

- Disconnect the power cord from the AC power source for the mechanical checks portion of this procedure.
- Check the overall appearance of the 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

- 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 pose a fire hazard.

2.2.3.2 Heater Assembly Rotation



Picture 46

- ❖ 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.

2.2.3.3 Accessory Checks

List of Items supplied with the Product

- IV pole

List of Items used with Product to perform its intended use

- Skin Probe
- 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 to 5 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 5 Kgs.

2.2.4 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.

2.2.4.1 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)
- ❖ 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 heat 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 probe to the Infant Radiant Warmer.

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

- The baby mode indicator is lit.
- The Temperature Low Indication will sound if Set Temperature > Actual Temperature by 1°C. Warm the probe with your fingers or silence the indication. The Temperature High Indication will sound if the Set Temperature < Actual Temperature by 1°C.
- Press the increase ▲ touch switch and verify that the maximum skin control temperature attainable is 38.0°C.

Note: A patient temperature high indication occurs if the difference between the patient temperature and the control temperature is greater than 1°C.

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

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

- The probe failure indicator light is lit (SO).

Note: A patient temperature indication occurs if the difference between the patient temperature and the control temperature is greater than 1°C.

- Press the decrease touch switch and verify that the minimum air control temperature attainable is 20.0°C.

c. Press the mode touch switch to place the Infant Radiant Warmer in the air* mode and verify the following:

- The air mode indicator is lit.
- The Temperature Low Indication will sound if Set Temperature > Actual Temperature by 1°C. Warm the probe with your fingers or silence the indication. The Temperature High Indication will sound if the Set Temperature < Actual Temperature by 1°C.
- Press the increase ▲ touch switch and verify that the maximum skin control temperature attainable is 38.0°C.

Note: A patient temperature indication occurs if the difference between the patient temperature and the control temperature is greater than 1°C.

- Press the decrease touch switch and verify that the minimum air control temperature attainable is 20.0°C.

d. Disconnect the air* temperature probe. Verify the following:

- The air probe failure indicator light is lit (SO).

e. Press the Mute switch and verify the following:

- Audible indications are silenced for Low temperature.
- Mute function is enabled and the Mute indicator light is lit.
- The Mute function is disabled automatically after 10 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 Mute for low temperature and when the second audio indication is triggered, the Mute function is disabled and the audio indication is activated.

*Air mode - Optional

2.2.4.2 Manual Mode Timer

- Switch to the manual mode.
- The manual mode indicator is lit.
- The manual timer indicator is lit.
- Adjust the heat output with the increase ▲ and decrease ▼ touch switches to attain the high and low limits as indicated by the % power display.

2.2.4.3 APGAR Timer

- Switch to the APGAR mode.
- The APGAR mode 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

2.2.4.4 Observation Light Check

- Press the Light On/Off touch switch. Verify that the observation light functions.

2.2.4.5 Power Fail, Memory Back up

- **Power Fail:**

- Remove the power cord and then switch on the equipment.
- Power Fail LED is lit (9v non rechargeable battery is provided).

- **Memory Back up:**

- Switch to the Baby mode.
- Set the skin set temperature at 36.5°C.
- Switch Off the equipment. Switch On the equipment again.
- The mode and the set value remains the same.

- **Mute Time**

- Press the Audio pause Key and switch ON the equipment.
- The manual timer / Apgar Display window shows the Mute time.
- Mute for 10min
- Press mode key, it comes to normal operation.

2.3 nice 2007S

2.3.1 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.

2.3.2 Installation of Equipment

2.3.2.1 Installation of base



Picture 1



Picture 2

Picture 1 & 2: Lift the base assembly from the package box, handle it with gentle care to avoid any potential damage to the base. Note that the wheels with brakes should be recognized as the front side of the warmer. This step serves as a crucial reference point during the installation process.



Picture 3

Position the Fixed pillar on top of the base assembly. Then, align the corresponding holes in the Fixed pillar and the base assembly. Insert the provided 12X25 button head Bolts through the holes, using the Allen key size 8mm, tighten the bolt firmly.



Ensuring its alignment corresponds to the orientation of the base wheel brakes, which are designated as the front side. Ensure Fixed pillar is securely attached in the exact position as shown in the image.

Picture 4

2.3.2.2 Installation of Pillar Mounting Frame



Picture 5



Picture 6

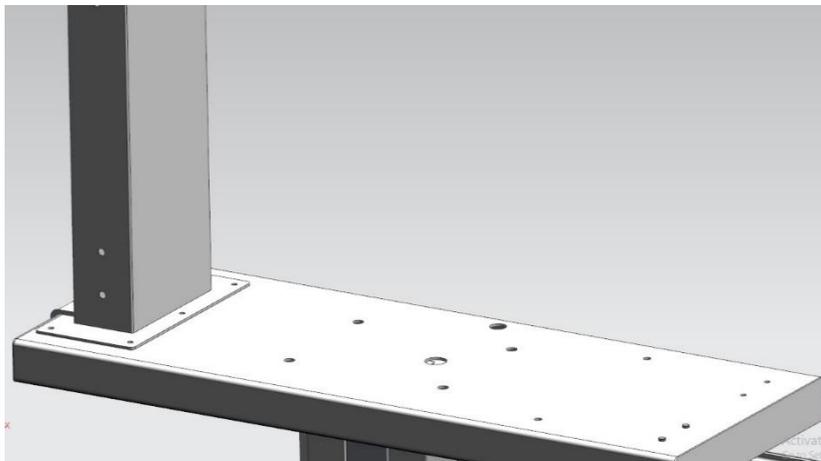
Picture 5 & 6: After fixing the fixed pillar, mount the frame plate onto fixed pillar, aligning it with the corresponding holes on the fixed pillar, then insert the 21 x 25 button head bolts and use 8mm Allen key to firmly tighten the bolts. Ensuring a secure and stable connection between the plate and the fixed pillar. Orientation specified in the images to ensure the accurate alignment of the plate with respect to the fixed pillar and brake wheel.

2.3.2.3 Installation of Pillar



Picture 7

Remove the pillar from its packaging box, Then, position the nice 2007s pillar assembly onto the frame plate, ensuring that it aligns perfectly with the corresponding holes on the plate. Ensure to fix it the correct position. Insert the provided 8 x 25 button head bolts into the holes of the pillar. Use 5mm Allen key to firmly tighten the bolts.



Picture 8

Picture 8: After fixing the pillar, ensure it is securely and properly fixed. Verify that all bolts are tightened firmly. As the image shows, fix the pillar in the correct holes.

2.3.2.4 Installation of Heater Box



Picture 9

Before positioning the heater onto the top of the pillar, follow this specific step. Identify the Heater box spacer component on the pillar, there will be a clearly flat surface/ facet plane in it. Orient the circular Heater box spacer in such a way that its flat facet plane is facing toward the back side, as indicated in the provided image.

Note: Adjust flat mark on Heater box spacer (black plastic) as displayed in the image.



Picture 10

Remove the 8 x 10 bolt from the heater assembly. This step ensures that there are no obstructions, when inserting the heater into the pillar. Once the bolt has been removed, carefully insert the heater assembly into the pillar.



Picture 11



Picture 12

Picture 11 & 12: Handle the heater assembly carefully. Attach it to the top of the pillar while considering the flat surface (facet plane) on the Heater box spacer of the pillar. Guide the wires inside the hole within the pillar. Ensure that the heater is placed accurately and securely in alignment with the pillar assembly.



Picture 12

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



Picture 13

Fix the ring type ground leg from the heater module mounting with pillar using 3X8 PNPL screw.

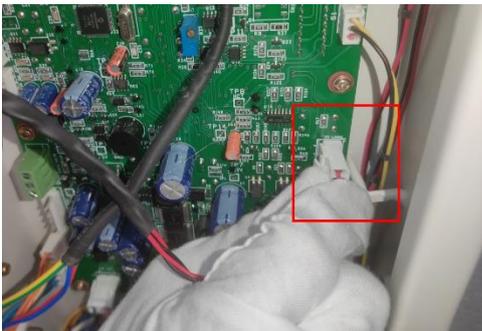


Picture 14



Picture 15

Picture 14 & 15: Perform heater wiring connection, connect the wire from heater to the BPT connector, as per the wiring diagram. (HEATER mentioned in the PCB). As two set of wire will be out from the heater module as one set of wire for IR Heater and another one for observation lamp (4 pin Molex female connector).



Picture 16

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) as J5.



Picture 17

Tighten the 6 x 10 Allen bolt heater module using 5mm Allen key.



Picture 18



Picture 19

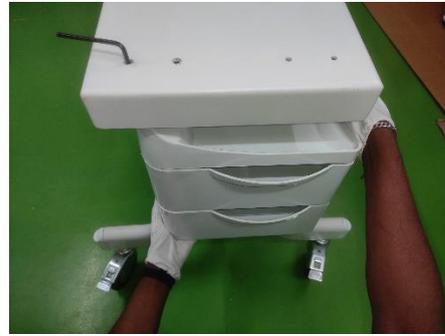
Picture 18: Fix the back cover to the pillar assembly using 4 x 8 PNPL screw.

Picture 19: Fix Locate the knob and the designated area on the pillar assembly as shown in the image.

2.3.2.5 Installation of Storage Compartment



Picture 20



Picture 21

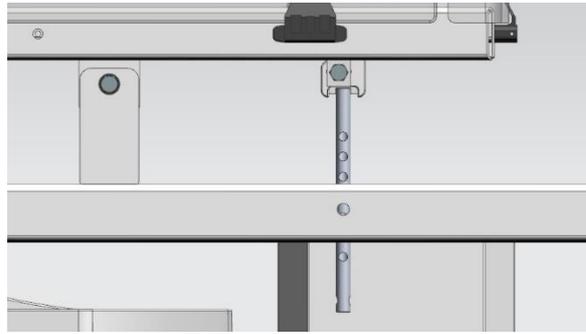
Picture 20 & 21: Place the Cabinet below the frame plate, and attach the storage Cabinet to the frame plate as displayed in image. Insert the bolts in the slots, then Secure the connection by tightening it using a 4mm Allen key.

2.3.2.6 Installation of Bed Frame.



Picture 22

To assemble the bed, Take the bedframe mounting clamp and attach it to frame plate securely onto it. Align the clamp properly and insert the bolts into the designated slots on the clamp. Use a 4mm Allen key to firmly tighten the bolts.



Picture 23

Picture 23: Before securing the bed frame onto the clamp, the tilting rod that is attached to the bed frame. Identify the designated holes in the mount plate, as illustrated in the image provided above. Carefully insert Tilting rod into the specified holes in the mount plate.



Picture 24



Picture 25

Picture 24 & 25: Position the bed frame onto the clamp plate. Securely fix the bed frame in place, making sure it aligns perfectly with the clamp plate. Insert the nut into the designated slot on the clamp plate, ensuring it aligns with the corresponding slot on the bed frame. Using a 17, 13 spanner, gently tighten the nut.



Picture 26

Ensure the bed frame firmly fixed to the clamp plate, check the orientation of the bed frame, ensuring it is correctly positioned in the intended direction as in the provided image.



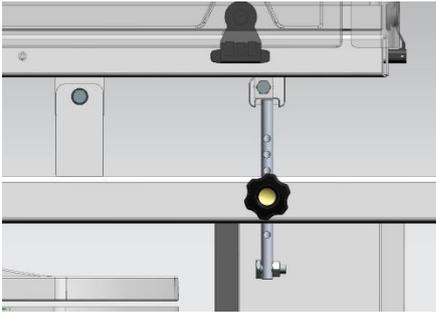
Picture 27

As tilting pole is inserted into the designated slot on the plate while fixing bed frame. Subsequently, insert the knob into the tilting pole as shown in the image.



Picture 28

After securely placing the knob in the tilting pole, proceed by fixing the screw into the pole. Utilize the spanner tool to firmly tighten the screw, ensuring it is securely fastened.



Picture 29

An illustrated image serves as a reference, displaying the knob's position and indicating. It specifically outlines the bedframe and tilting pole positions concerning the mount frame plate.



Picture 30

Ensure the bed frame is properly placed as shown in the image.

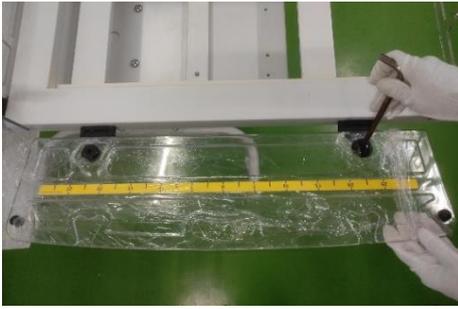
2.3.2.7 Installation of X-ray Cassette tray



Picture 31

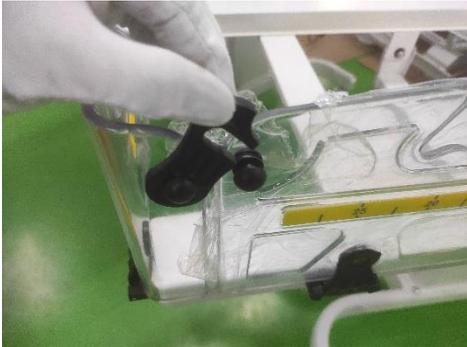
The X-Ray tray can be placed in the bed frame, Position it beneath the bed frame following the picture. Carefully slide the tray completely inside the bed frame.

2.3.2.8 Installation of Side Panels



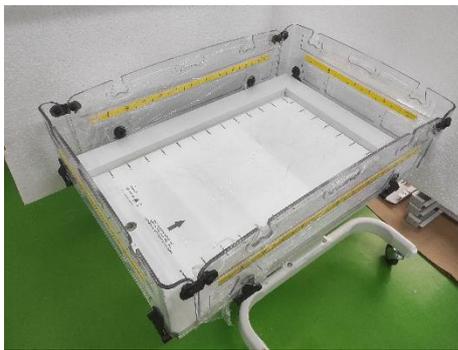
Picture 32

To install the side panels, first, position them alongside the bed frame. Begin by removing the hinge lock nut from the hinge. Next, carefully place the side panels onto the hinge mechanism. Insert the lock nut into the hinge and gently tighten it using an 8mm Allen key.



Picture 33

The same action is repeated to fix the rest of the side panels. 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.



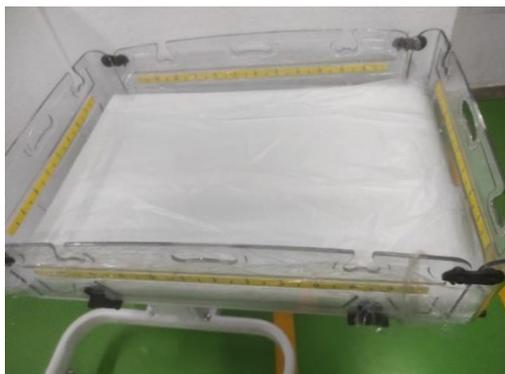
Picture 34

Panel on the long side, ensure that the yellow strip line marking points outwards. Ensure the panels are correctly placed in the correct position as shown in the image.



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.

2.3.2.9 Installation of Mattress



Picture 35

Lay the mattress flat in the bed frame as shown in the image.

2.3.2.10 Installation of Mayo tray



Picture 36

To attach the mayo tray to the right side of the pillar, position the tray in the correct orientation for placing monitors, small articles, and parts. Insert the bolts into the designated holes, then use a 5mm Allen key to firmly tighten it.

The maximum load applicable is 3 Kg.

2.3.2.11 Installation of IV Stand



Picture 37



Picture 38

Picture 37: Fix the IV pole in the pillar assembly using 5mm Allen key.

Picture 38: Fix the Holder in the pillar assembly using 5mm Allen key, ensure to fix in the intended position as shown in the image.

2.3.2.12 Installation of Power cord from the Pillar Assembly



Picture 39



Picture 40

Picture 39 & 40: Remove the bottom back cover, Take the power cord out of the pillar assembly.



Picture 41



Picture 42

Picture 41: Before connecting the power cord to the socket, first, insert the power cord grip into the designated slot. With a gentle push, carefully insert it into the slot, ensuring the power grip is securely fixed in place.

Picture 42: Close the bottom back cover with 4 x 8 PNPLWH screw.

2.3.3 Pre-use check instructions

2.3.3.1 Mechanical Pre-use check instructions



Warning

- 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.

2.3.3.2 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.



- 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.

2.3.3.3 Heater Assembly Rotation



Picture 43

- ❖ Loose the knob in the back side of pillar, and swing the heater box to its sides using handle in the heater module.
- ❖ The heater box can be rotated on both sides and check for smooth movement of heater box.

2.3.3.4 Mechanical Checks

III. Side Panels



Picture 44

- ❖ 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.



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

IV. Tilting Mechanism

- ❖ 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.



Picture 45



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

2.3.3.5 Accessory Checks

List of Items supplied with the Product

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

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.



- 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.

2.3.4 Control Unit Pre-use check instructions



- 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.

2.3.4.1 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.
- ❖ 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.

2.3.4.2 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

2.3.4.3 Observation Light Check

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

2.3.4.4 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°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

I. nice 2010

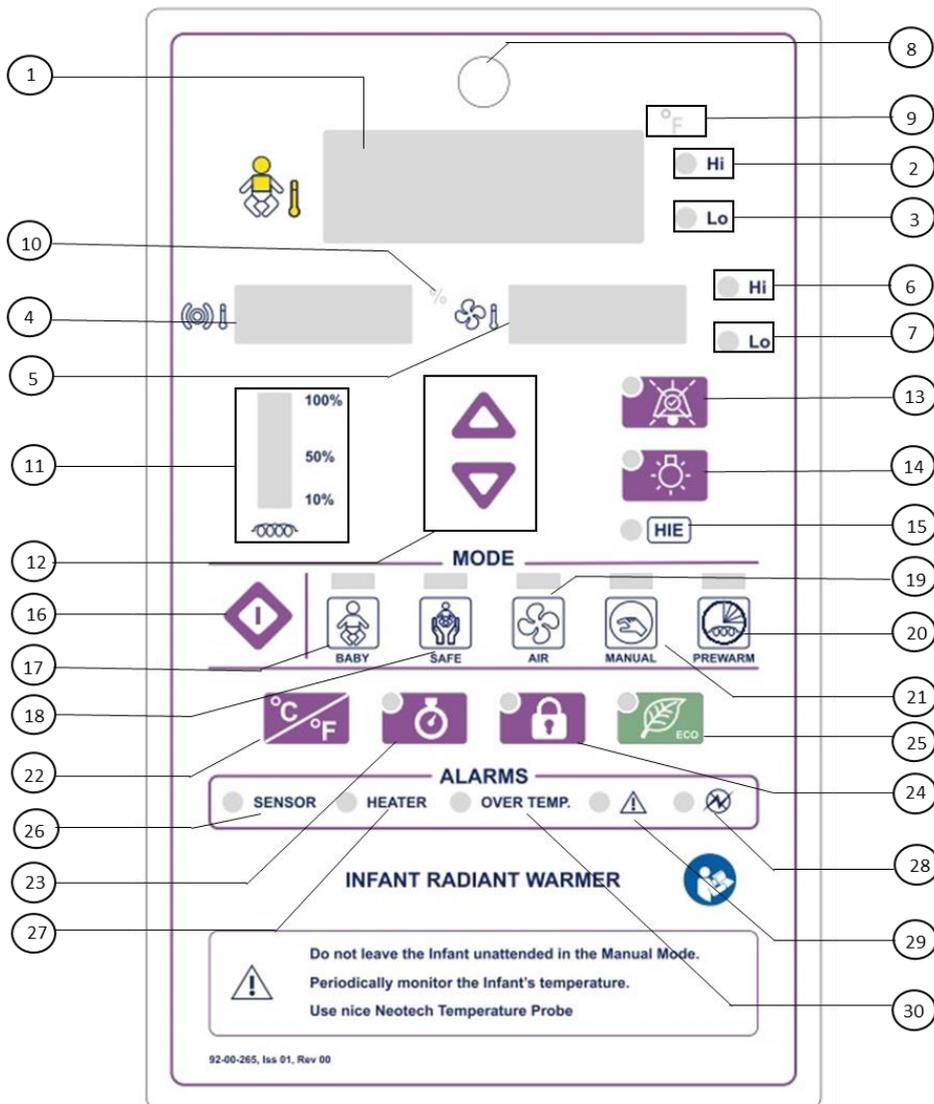
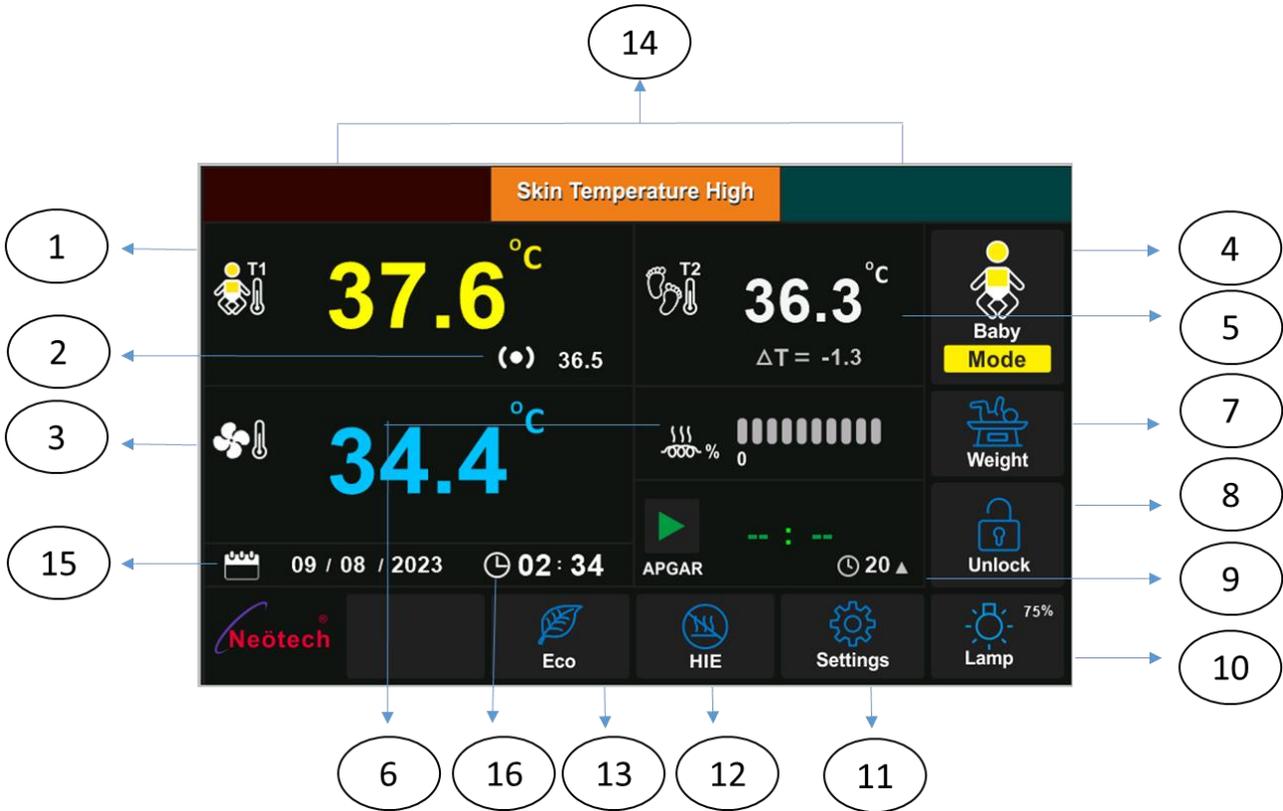


Figure 4

2010 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 Function
11	% of barcode heater output	26	Sensor failure
12	Increase and Decrease key	27	Heater failure
13	Timed Acknowledged key	28	Power failure
14	Observation lamp key	29	System failure – See manual
15	HIE Function	30	Over temperature >39°C

II. 2010 BC – TFT Touch Control Panel Display



1	Baby Temperature display	9	APGAR Timer
2	Baby Set Temperature	10	Observation Lamp
3	Air Temperature	11	Settings
4	Mode selection	12	HIE Mode
5	Auxiliary Temperature display	13	Eco Mode
6	% of Heater output power	14	Alarm Indication Panel
7	Weighing scale	15	Calendar
8	Lock/Unlock	16	Time

III. 2007 Series

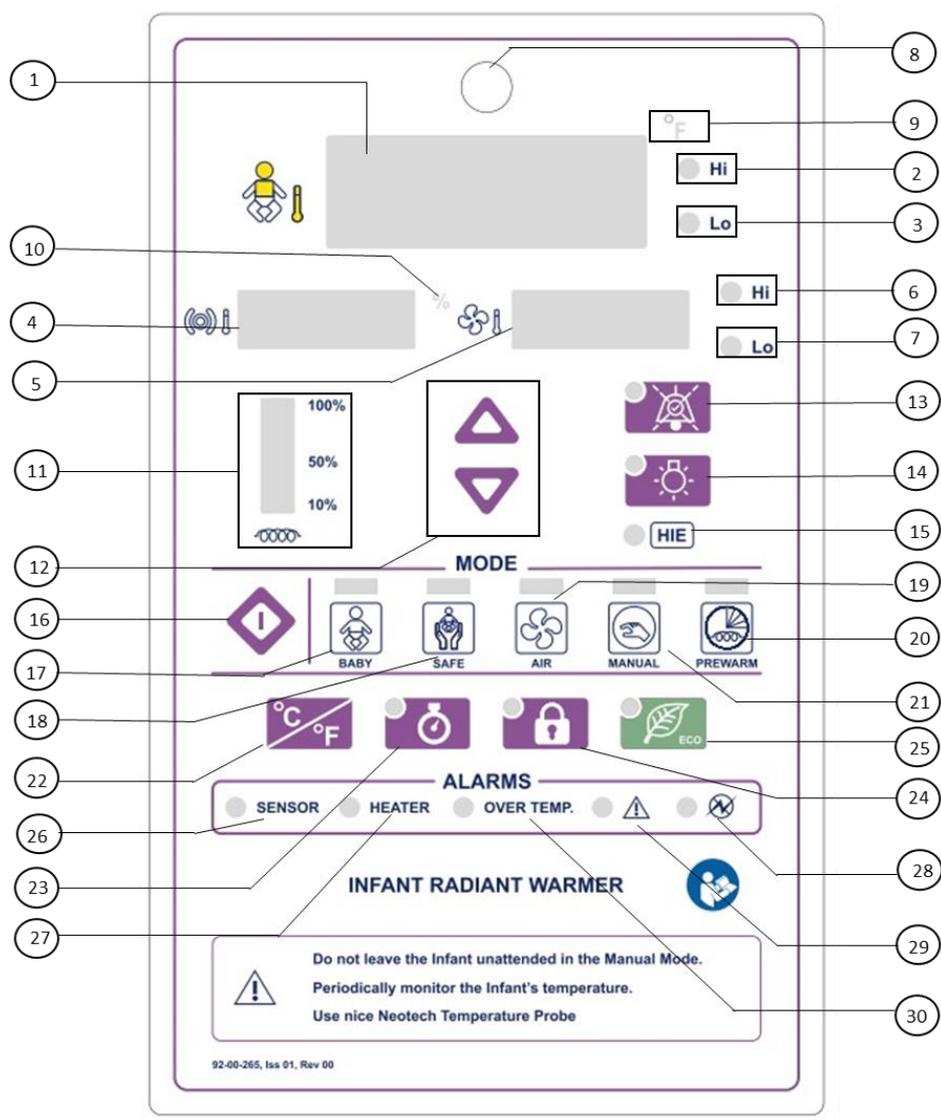


Figure 5

2007 S 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 Function
11	% of barcode heater output	26	Sensor failure
12	Increase and Decrease key	27	Heater failure
13	Timed Acknowledged key	28	Power failure
14	Observation lamp key	29	System failure – See manual
15	HIE Function	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 skin temperature sensor must be properly connected to the Infant Radiant Warmer and the infant for an accurate patient temperature measurement. The range of temperature measurement is from 32.0 to 38.0°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 air temperature sensor must be properly connected to the Infant Radiant Warmer and on the bed assembly for an accurate air temperature measurement. The range of temperature measurement is from 20.0 to 38.0°C, with a resolution of 0.1°C.

❖ **Baby Set Temperature:**

The Set temperature display indicates the control temperature selected in the baby mode. The baby control temperature range is from 32.0 to 38.0 C. The set temperature display is not active in the manual mode.

❖ **Air Set Temperature (optional):**

The Air Set temperature display indicates the control temperature select in the Air mode. The air control temperature range is from 20.0 to 38.0 C. The set temperature display is not active in the manual mode.

❖ **% of Heater Output Power:**

The % power display indicates the percentage of maximum power that is being supplied to the radiant heater in 5% increments.

❖ **APGAR Timer:**

The APGAR timer indicates the APGAR timer selected in the APGAR timer. The APGAR timer is displayed in the set temperature display.

❖ **Timed Acknowledged time:**

Timed Acknowledged time can be programmable, press the Timed Acknowledged key and switch ON the equipment the set temperature display shows the audio paused time. The default audio paused time is 15 minutes. It can be adjusted by pressing the Timed and switching ON the device which can be set between 5 minutes to 15 minutes by using increase/ decrease key. It can silence all indications except power failure indication.

3.1.2. Indicator Lights

❖ **Device status indicator:** A device status indicator is placed on the pillar, which indicates the low (for only nice 2010 BC), medium and high priority alarms. It glows in pink for self-test, green color for normal condition, blue for low priority (for only nice 2010 BC), amber for medium priority and red for high priority alarm. It is explained further in section 3.1.4.

❖ **Baby Temperature high:** The baby temperature high indicator lights when the baby set temperature is increased by 1°C.

❖ **Baby Temperature low:** The baby temperature low indicator lights when the baby set temperature is decreased by 1°C.

❖ **Air Temperature high (optional):** The air temperature high indicator lights when the air set temperature is increased by 1°C.

- ❖ **Air Temperature low (optional):** The air temperature low indicator lights when the air set temperature is decreased by 1°C.
- ❖ **Baby Mode Indicator:** The baby mode indicator lights when the Infant Radiant Warmer is in the baby mode of operation.
- ❖ **Air Mode Indicator (optional):** The air mode indicator lights when the Infant Radiant Warmer is in the air mode of operation.
- ❖ **Manual Mode Indicator:** The manual mode indicator lights when the Infant Radiant Warmer is in the manual mode of operation.
- ❖ **Prewarm Mode Indicator:** The prewarm mode indicator lights when the Infant Radiant Warmer is in the prewarm mode of operation.
- ❖ **HIE Mode Indicator:** The HIE mode indicator lights when the Infant Radiant Warmer is in the HIE mode of operation.
- ❖ **Apgar Timer Indicator:** The APGAR timer indicator lights when the APGAR timer is activated and the Apgar timer is running.
- ❖ **Lamp Indicator:** The switch lamp indicator lights up when the observation lamp is switched on.
- ❖ **Lock Indicator:** The lock indicator lights up when lock feature is enabled in the control panel.
- ❖ **ECO function Indicator:** The eco function indicator lights up when ECO function is enabled in the control panel.
- ❖ **Sensor failure Indicator:** The sensor failure indicator lights up when the skin temperature sensor falls off the baby or if the sensor is faulty. The Timed Acknowledged key disables the indicator for time duration.
- ❖ **Heater failure Indicator:** The heater failure indicator lights up when the heater is not working. The Timed Acknowledged key is used to disable the indicator.
- ❖ **Over temperature Indicator:** The over temperature indicator lights up when the temperature of the baby exceeds >39.0°C. The Timed Acknowledged key is used to disable the indicator for 15 minutes.
- ❖ **See manual Indicator:** The see manual indicator lights up when the temperature of the baby exceeds >45.0°C. The Timed Acknowledged key is used to disable the indicator for 15 minutes.
- ❖ **Timed Acknowledged Key Indicator:** The Timed Acknowledged key indicator lights up when there is an audible indication.
- ❖ **Power failure Indicator:** The power failure indicator lights up when there is a power failure.



Warning

- 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

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- ❖ **Baby Mode Switch:** This switch is used to select the baby mode (Baby mode) of operation.
- ❖ **Air Mode Switch (optional):** This switch is used to select the air mode of operation.
- ❖ **Manual Mode Switch:** This switch is used to select the manual mode of operation
- ❖ **Prewarm Mode Switch:** This switch is used to select the prewarm mode of operation.
- ❖ **HIE Mode Switch:** This switch is used to select the HIE mode of operation. Press this switch for 4 seconds to enable this mode.
- ❖ **Increase (▲) and Decrease (▼) Switches:** These switches are used to set the radiant power level (% power) in the manual mode and to set the control temperature in the skin & air mode. It is also used to set the observation lamp percentage.
- ❖ **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 key board. Further inputs are not taken. Press the Lock key again to Unlock. Other switches does not work except lamp switch and Timed Acknowledged key.
- ❖ **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.



Warning

- Prolonged exposure to the light emitted by the observation lamp in this unit may harm the unprotected eyes of the infant. For safety, cover the infant's eyes.
- ❖ **ECO function switch:** This switch is enabled for low power consumption of the equipment in any mode.

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- ❖ **Timed Acknowledged switch:** This key is used to silence the audible indication for time duration. It silences indications except the power failure indication. The Timed Acknowledged indication glows when in use.

nice 2010 BC

- ❖ **Main switch:** This switch is used to switch ON/OFF the device which is placed on the left side of the machine.
- ❖ **Bed tilting up key:** This key is used to tilt the bed up to 15° in Reverse Trendelenburg.
- ❖ **Bed tilting down key:** This key is used to tilt the bed up to 15° in Trendelenburg.

3.1.4. Audio & Visual Indication

Description

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

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Alarm Priority	Alarm indications	Alarm Description
High Priority	Skin/*Air temperature sensor failure	Activates when the temperature sensor fails electrically due to an open or short circuit, or it is disconnected from the Infant Radiant warmer. The heater deactivates and the patient temperature displays "S-O" (Sensor Open)
	Heater failure	Activates when the heater is defected or disconnected from the equipment in any mode of operation.
	Baby temperature above 39°C	The over temperature indication activates when the temperature sensed by the skin temperature sensor / air* temperature sensor exceeds 39°C in any mode. The heater deactivates and the patient temperature displays "O-t" (Over temperature).
	System failure	The system failure indication activates in any mode of operation, if any components are defect.
	Power failure	Activates when power supply to the equipment is cut-off.
Medium Priority	Baby temperature high	Activates when baby's skin temperature raises more than 1°C from the set required temperature.
	Baby temperature low	Activates when baby's skin temperature decreases less than 1°C from the set required temperature.
	*Air temperature high	Activates when air temperature raises more than 1°C from the set required temperature.
	*Air temperature low	Activates when air temperature decreases less than 3°C from the set required temperature.
	Manual timer	The manual timer indication activates in the manual mode of operation when the therapy time set has elapsed.

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Alarm Priority	Alarm message	Alarm Description
High Priority	Skin sensor over temperature	Activates when Baby's skin temperature exceeds 39°C
	Auxiliary sensor over temperature	Activates when Auxiliary's skin temperature exceeds 39°C

	*Air sensor over temperature	Activates when Air temperature exceeds 39°C in any modes of operation
	Skin temperature sensor disconnected	Activates when Primary skin temperature sensor is detached from the baby's skin
	Skin temperature sensor defect	Activates when Peripheral skin temperature sensor fails or short
	*Air temperature sensor disconnected	Activates when air temperature sensor is detached from the baby's skin
	*Air temperature sensor defect	Activates when air temperature sensor fails or short
	Power Failure	Activates when power supply to the equipment is cut-off.
Medium Priority	Skin temperature high	Activates when baby's skin temperature raises more than 1°C from the set required temperature.
	Skin temperature low	Activates when baby's skin temperature decreases less than 1°C from the set required temperature.
	*Air temperature high	Activates when air temperature raises more than 1°C from the set required temperature.
	*Air temperature low	Activates when air temperature decreases less than 3°C from the set required temperature.
Low Priority	Manual mode alert	Activates every 15 minutes once in Manual mode of operation.
	Auxiliary sensor disconnected	Activates when Auxiliary skin temperature sensor is detached from the baby's skin
	Auxiliary sensor defect	Activates when Auxiliary skin temperature sensor fails or is short.

*Air – Optional mode

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

NOTE: All the above audio alarms except for power failure cannot be paused using the Audio pause key on the pillar.

NOTE: In the event of a second indication during the Timed Acknowledged enabled state, the audible alert is automatically reactivated. The Timed Acknowledged feature, temporarily pause specific alarms, functions with preset time durations of 15 minutes.



Warning

- 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.



Warning

- 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.

3.1.4.1 Device status indicator

A device status indicator is fixed in the pillar above the control panel to produce different audio and visual indications for low, 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, blue for low priority alarms (for only nice 2010 BC), amber for medium priority alarms and red for high priority alarms. The color codes for device status indicator are explained here:

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

3.2 Operating Modes



Warning

- 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 probe lead as far away as possible from electrosurgical cables. Do not allow excess electrical cables to be laid on the bed platform. Use of electrosurgical units or other instruments which radiate electrical fields can cause indirect heating, by several tenths of a degree of the skin temperature probe due to absorbed electrical energy. When using these devices near the 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.

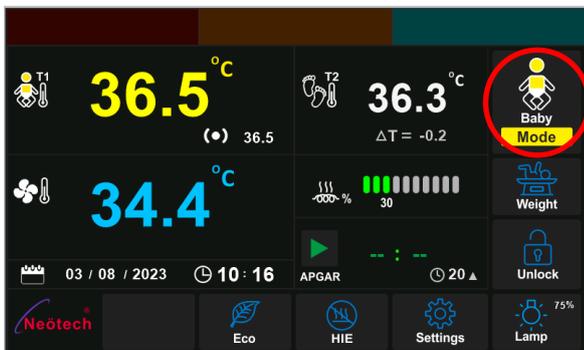
- Do not use the Infant Radiant Warmer in the presence of flammable anesthetics; a possible explosion hazard exists under these conditions.
 - Radiant energy can adversely affect blood components. When using intravenous tubing systems for delivery of blood components to patients occupying an Infant Radiant 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.

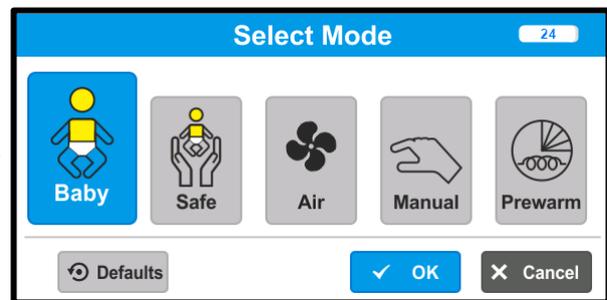
Mode selection for nice 2010 BC

Infant Radiant Warmer modes can be selected through the following process:

Select MODE option in the control panel
(red circled)



Select the desired mode and then press OK



3.2.1 Baby Mode Operation

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

nice 2010, nice 2007S

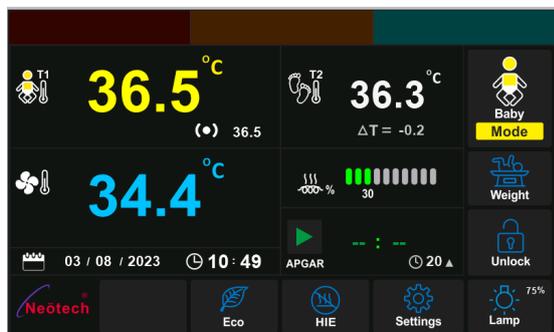
- ❖ The skin control temperature (Set required Temperature) enables the user to select the required settings when the Infant Radiant Warmer is used in the baby mode for the first time. The control panel enables the user to make this setting with an operator prompt tone and the changing of the control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

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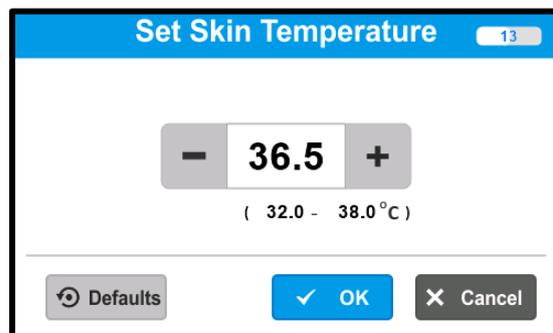
- ❖ The skin control temperature (set required temperature) enables the user to select the required settings when the Infant Radiant Warmer is used in the baby mode for the first time. The control panel enables the user to make this setting with an operator prompt tone and the changing of the control 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 patient's temperature at the selected control temperature.

To set the required temperature, follow the steps given below:

Select Skin Temperature (T1) in the control panel



Select the desired temperature by increasing or decreasing key and then press OK



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 auxiliary 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.



Warning

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

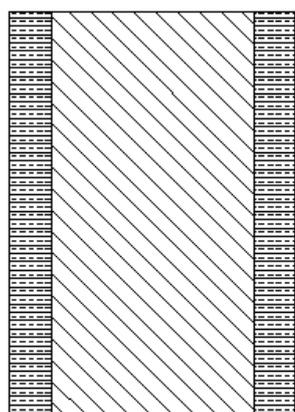
Note: If the actual temperature reaches the range within 1 degree from the Skin/ Air* set temperature, the audio and visual indication is immediately disabled. (*Air – Optional mode)

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

In the event of a second indication during the Timed Acknowledged enabled state, the audible alert is automatically reactivated. The Timed Acknowledged feature, temporarily pause specific alarms, functions with preset time durations of 15 minutes.

3.2.2.1 Radiant Energy Distribution (See Figure 2)

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



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

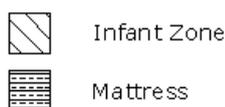


Figure 6

3.2.2.2 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.

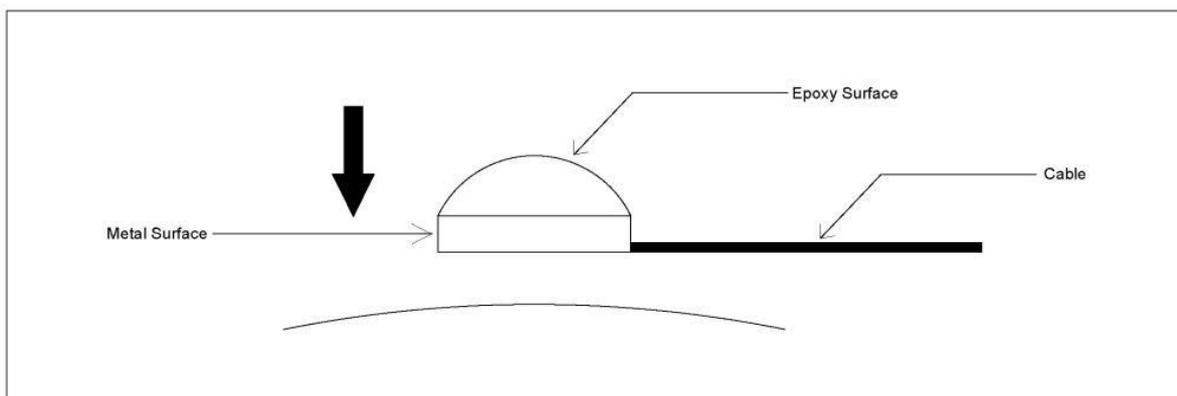


Figure 7

- ❖ 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

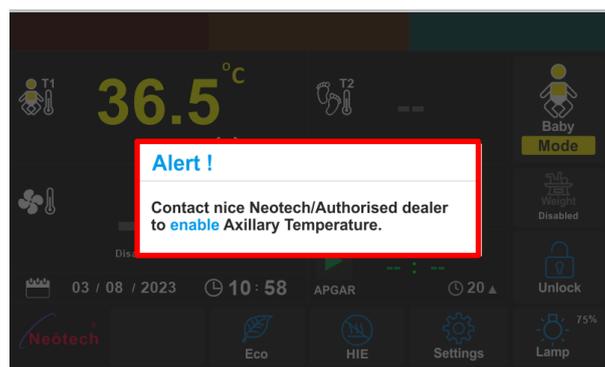
- Always remove the sensor from the patient by grasping and removing the heat reflective patch first, and then remove the sensor from the patient or the patch. Always remove the sensor from the Infant Radiant Warmer by grasping the plug at the panel. Placing excessive strain on the skin temperature sensor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

Note (for nice 2010 BC): If you try to set the Skin temperature while in a mode other than baby mode or Safe mode, the message "Change to Baby mode or Safe mode to set the Skin temperature" will appear.



Note (for nice 2010 BC): In the event that axillary temperature is disabled and you want to enable it, contact nice Neotech, an alert message will come when you try to enable it.



3.2.2 Air Mode Operation (optional)

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

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- ❖ You must select an air control temperature (Set required Temperature) setting when the Infant Radiant Warmer is used in the air mode for the first time. You are prompted to make this setting with an operator prompt tone and the changing of the control temperature display.
- ❖ The air control 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 probe is used by the control system to modulate the radiant heat and maintain the Environment temperature at the selected control temperature.

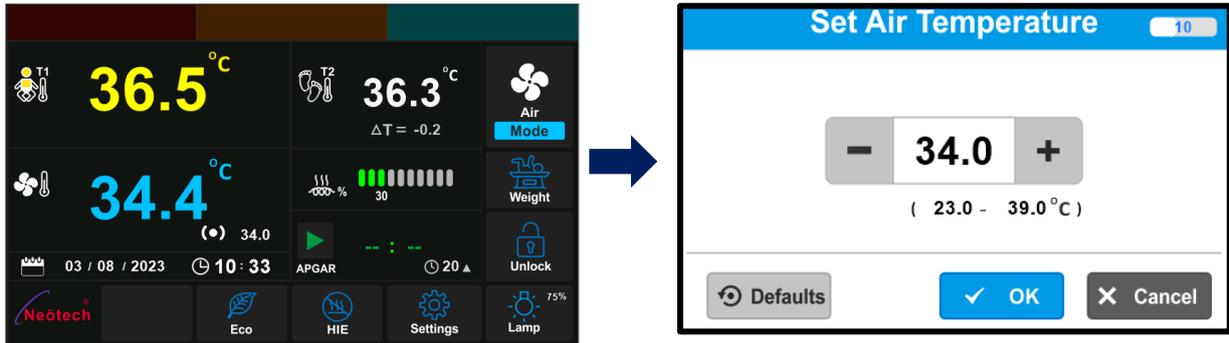
nice 2010 BC

- 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 control 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.

To set the required temperature, follow the steps given below:

Select Air Temperature in the control panel

Select the desired temperature by increasing or decreasing key and then press OK



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

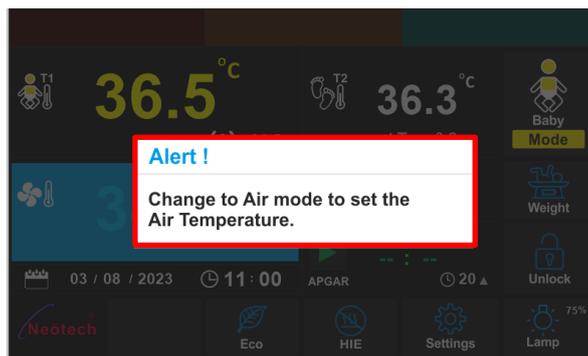


- In the air mode, verify that the air probe is securely attached to the rear panel at least every half an hour. A dislodged probe does not always trigger an indication. If the probe becomes dislodged, the Infant Radiant Warmer can over or under heat the infant.

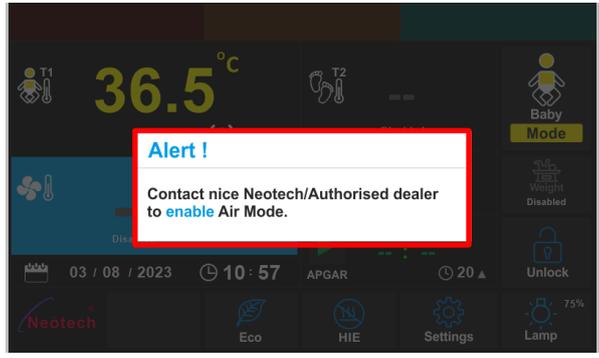
Note: A patient placed in any Infant Radiant Warmer will normally develop temperature gradients with hotter and cooler areas. This is due to radiant heat being applied above the infant, the unequal skin cooling effect from evaporative water loss, unequal heat generation within the patient, and the environmental 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 probe.

Note (for nice 2010 BC): If you try to set the Air temperature while in a mode other than air mode, the message “Change to Air mode to set the Air temperature” will appear.



Note (for nice 2010 BC): In the event that air mode is disabled and you want to enable it, contact nice Neotech, an alert message will come when you try to enable it.



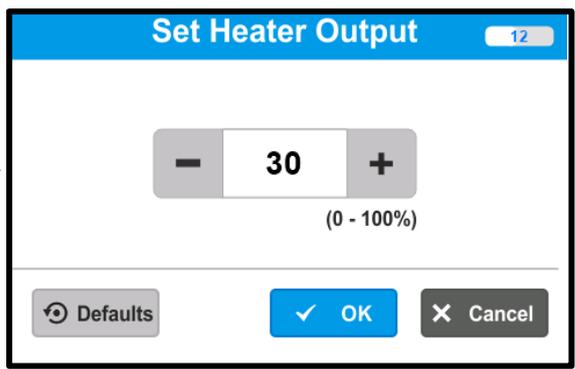
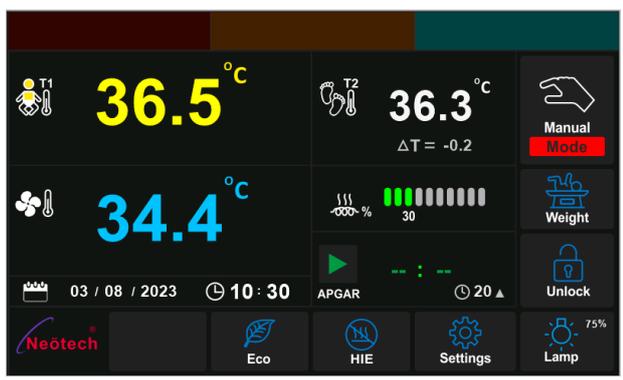
3.2.3 Manual Mode Operation

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- ❖ The environment temperature in bed platform area is manually control by varying the percentage of heater output.
- ❖ To set manual mode, follow these instructions given below:

Select the heater output power in the control panel

Select the desired heater output by increasing or decreasing key and then press OK



Heater output power bar comes in 3 colours which is shown below:

Heater Output power bar colour	Colours	Range
	Green	5 – 30%
	Amber	35 – 60%
	Red	65 – 100%

nice 2010 BC, nice 2010, nice 2007S



Warning

- In the manual mode the Skin/Air temperature will not automatically control.
- 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 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 selected more than 50%, after 15 minutes a manual mode alert activates to avoid the risk of overheating. If the heater output level selected is less than or equal to 40%, then it maintains the same temperature till the end. After checking the patient, this indication can be Audio paused for 15 minutes by pressing the Timed Acknowledged key. Continue to produce heat at the set level for duration of set time 15 min for the next cycle of operation. This indication recurs every 15 min, if the Timed Acknowledged Key is pressed, the heater is turned ON.

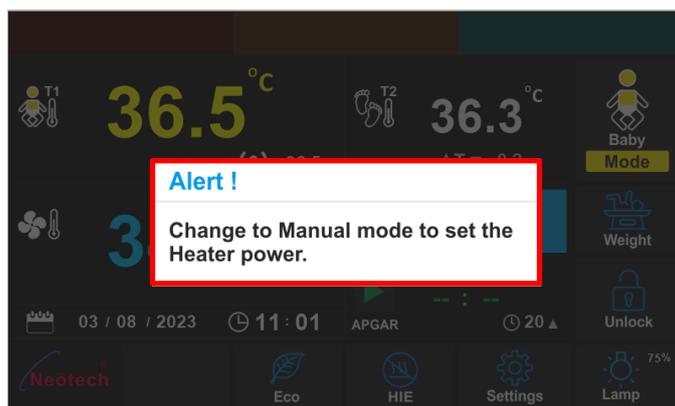
Note: The Set Manual timer and % Heater output is in the memory the values will not change unless otherwise change the settings even power goes OFF and ON again or switch of the equipment for long period

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

Note: The skin temperature probe 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.

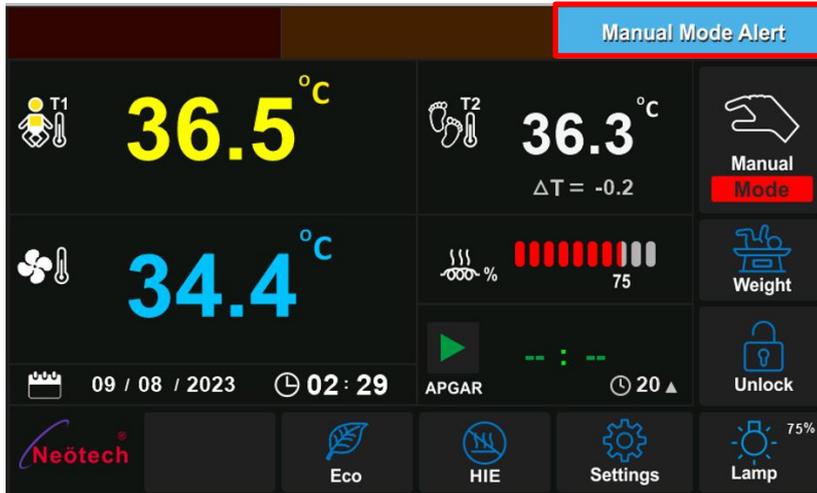
Note (for nice 2010 BC): If you try to set the heater power while in a mode other than manual mode, the message "Change to manual mode to set the heater power" will appear.



Manual mode alert (for nice 2010 BC)

In manual mode, when the heater output is set above or equal to 50%, a manual mode alert is triggered every 15 minutes.

- The following indications appear once the warmer has a heater output equal to or above 50%:
 - In the alarm indication panel, indicates the message “manual mode alert”.



- A low priority alarm is activated along with the visual alarm indication.

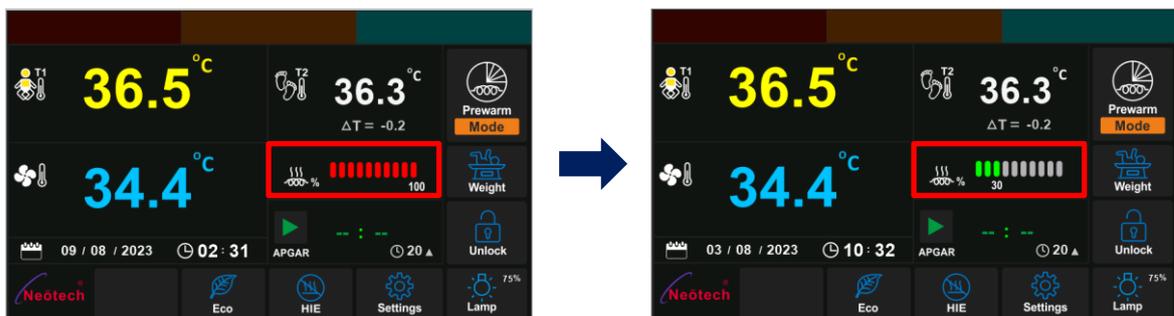
3.2.4 Pre-warm mode Operation

nice 2010, nice 2007S

- ❖ The environment temperature in bed platform area is heated or warmed before placing the Baby.
- ❖ In this mode, the temperature of the patient cannot be controlled or adjusted.
- ❖ The heater output level will be 100% by default and after 5 minutes the equipment automatically reduces the heater power to 30% output.

nice 2010 BC

- ❖ The environment temperature in bed platform area is heated or warmed before placing the Baby.
- ❖ In this mode, the temperature of the patient cannot be controlled or adjusted.
- ❖ 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.

Note: The prewarm mode should be changed to either manual mode or baby mode immediately, once the baby is placed.

3.2.5 Safe Mode Operation (except for nice 2007S)

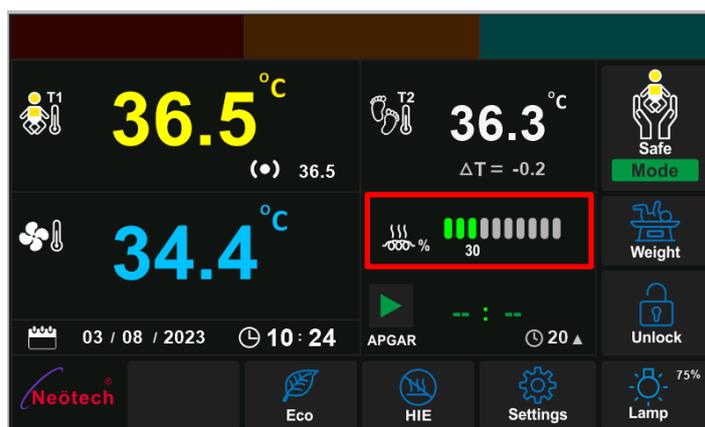
Note: The skin temperature probe must be properly attached before starting safe mode operation.

nice 2010, nice 2007S

- ❖ The user must select safe mode setting when the Infant Radiant Warmer is used in the safe mode for the first time. User is prompted to make this setting with an operator prompt tone.
- ❖ The temperature cannot be controlled in safe mode as the heater delivers a fixed rate of 40% heater output.

nice 2010 BC

- ❖ The safe mode enables the user to select required settings when the infant radiant warmer is used in the safe mode for the first time. The control panel enables the user to make this setting with an operator prompt tone.
- ❖ The temperature cannot be controlled in safe mode as the heater delivers a fixed rate of 40% heater output.



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

- ❖ Safe Mode is a servo controlled mode and the heater output get adjusted by itself (max 40%) depending on the infants temperature as against the set temperature.
- ❖ The safe mode does not cause hypothermia or chances of hyperthermia as it delivers optimal servo controlled heater output.
- ❖ Even if the probe comes off the baby – the heater output increases to only 40% thus making it a very safe mode of operation



Warning

- Verify that the patient temperature probe is securely attached to the patient. A dislodged probe does not always trigger an Audio and Visual indication

Note: A patient placed in any Infant Radiant Warmer will normally develop temperature gradients with hotter and cooler areas.

- ❖ This is an Audio and Visual indication free mode- Equipment raises an Audio and Visual indication only when the temperature exceeds 39°C
- ❖ This mode is generally used when the baby is left unattended or at night but continuous monitoring of baby is recommended.

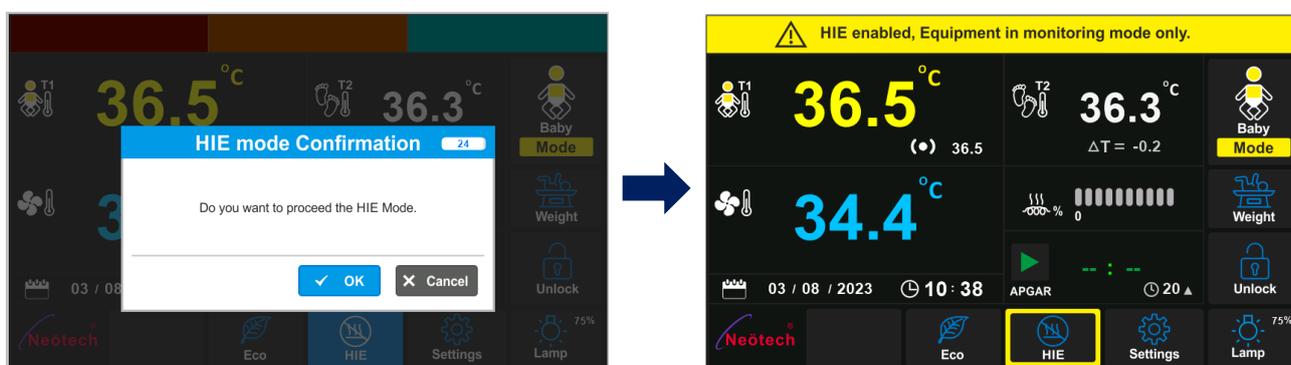
3.2.6 HIE Mode Operation

nice 2010, nice 2007S

- ❖ The HIE mode switch is enabled when long pressed for 4 seconds (HIE mode indication light blinks when the mode is pressed).

nice 2010 BC

- ❖ Press the HIE icon on the control panel to enable the HIE Mode. To disable the HIE mode press the same HIE icon on the control panel.

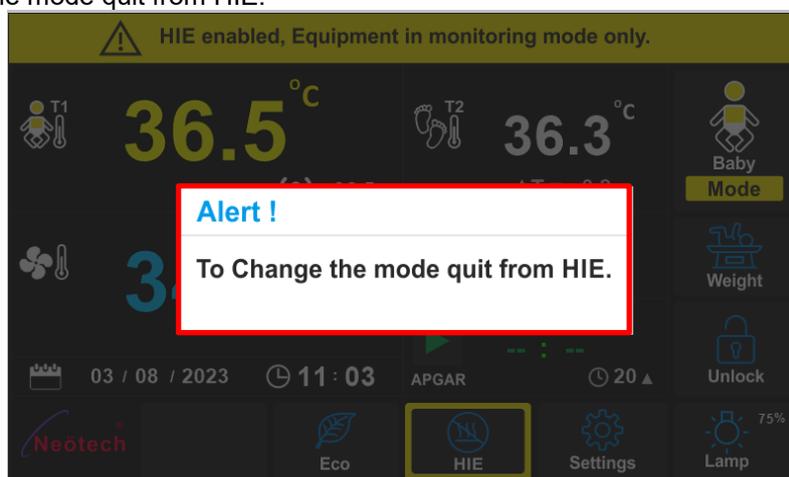


- ❖ It shows the confirmation message “Do you want to proceed the HIE Mode”, Press OK to enable this mode.

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.

Note (for nice 2010 BC): To change the mode from HIE to another mode, disable this mode; otherwise, it will display “To Change the mode quit from HIE.”



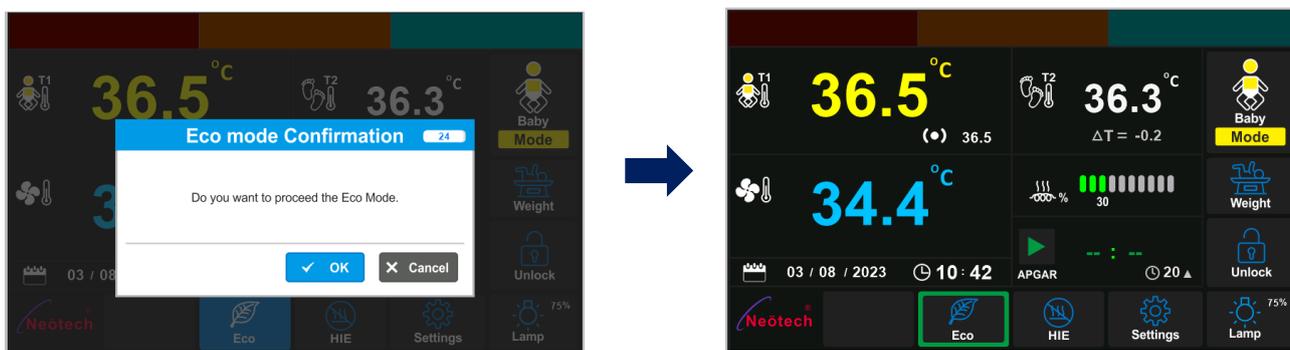
3.2.7 ECO function

nice 2010 BC, nice 2010, nice 2007S

- ❖ The control unit enables the user activate ECO function in any of the five modes of operation.
- ❖ In ECO function, the total power consumption of infant radiant warmer is optimized up to 350W.

nice 2010 BC

- Press the ECO icon on the control panel to enable the Eco Mode. To disable the Eco mode press the same Eco icon on the control panel.



- It shows the confirmation message “Do you want to proceed the Eco Mode”, Press OK to enable this mode.

Note: Eco mode is only used during the baby's observation time.

3.2.8 Apgar Timer in any Mode of Operation

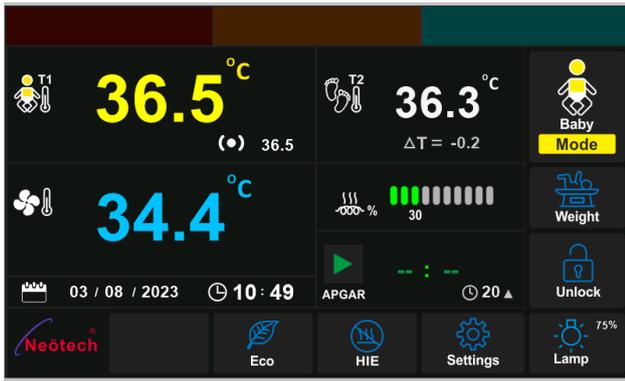
nice 2010 BC, nice 2010, nice 2007S

- ❖ In APGAR Mode, an Apgar timer can be set between 1 – 59 minutes.
- ❖ In APGAR Mode, 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 eg. 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. Skin/Air/Manual to set the APGAR Timer again, uses the APGAR key again.

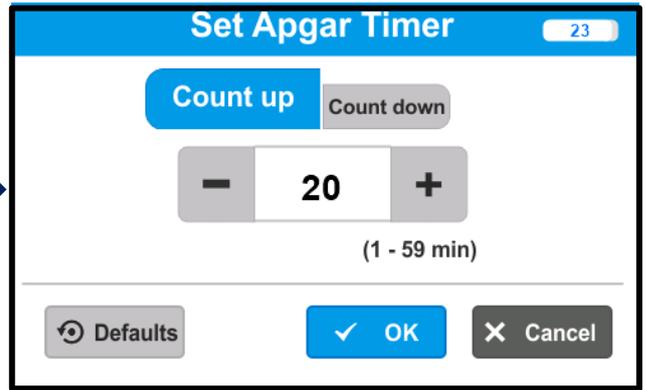
nice 2010 BC

- ❖ APGAR Timer Count up – a forward counting from zero to fixed unit of time.
- ❖ APGAR Timer Count down – a backward counting from fixed unit of time to zero.

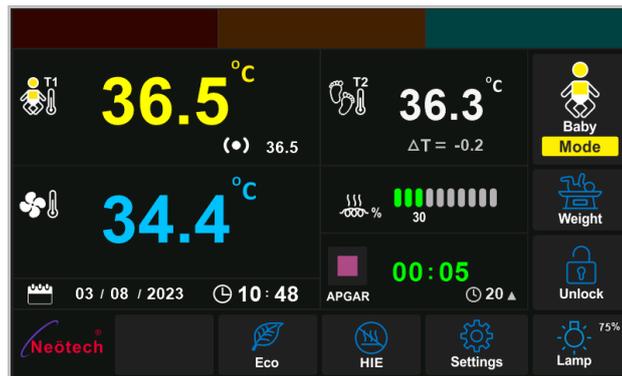
Select the APGAR timer in the control panel



Select the APGAR timer count up/ count down



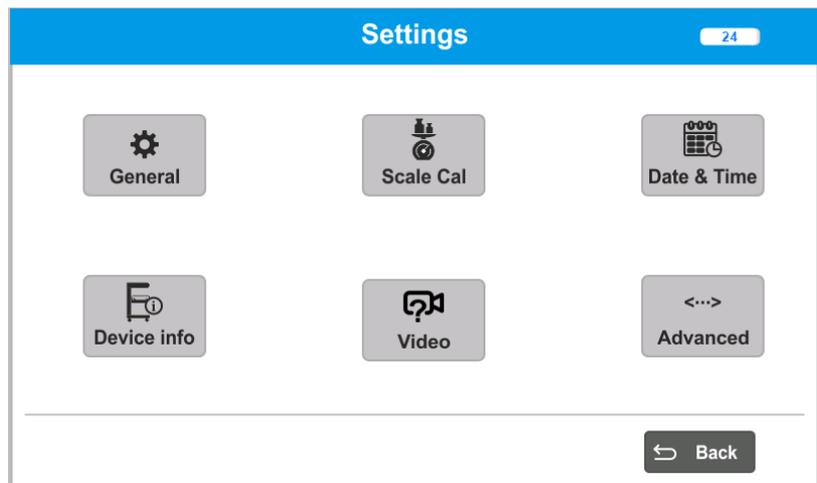
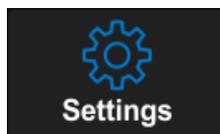
After setting APGAR Timer, it displays



3.3 Settings

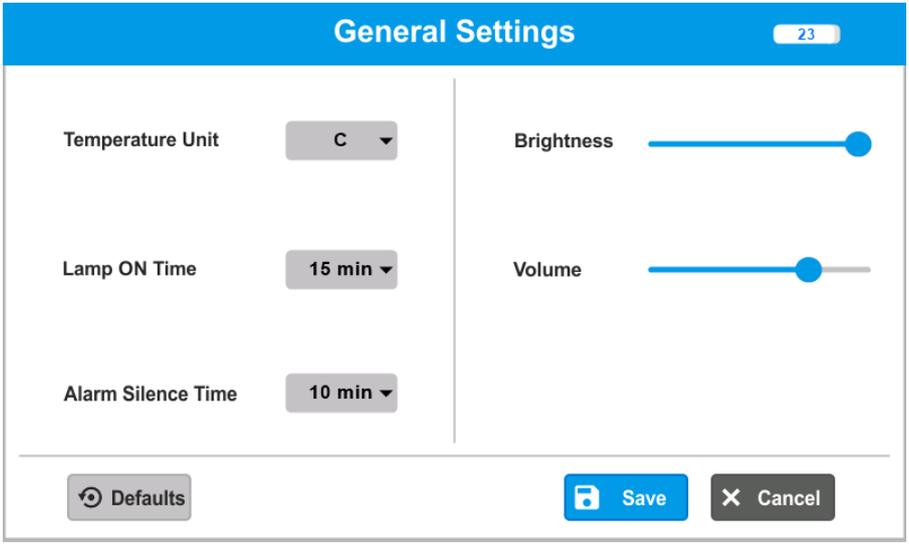
The settings instructions of nice 2010 BC are given here:

Select **Settings** in the control panel



3.3.1 General settings

The general settings contains the following:



Temperature Unit: Centigrade (°C) or Fahrenheit (°F)

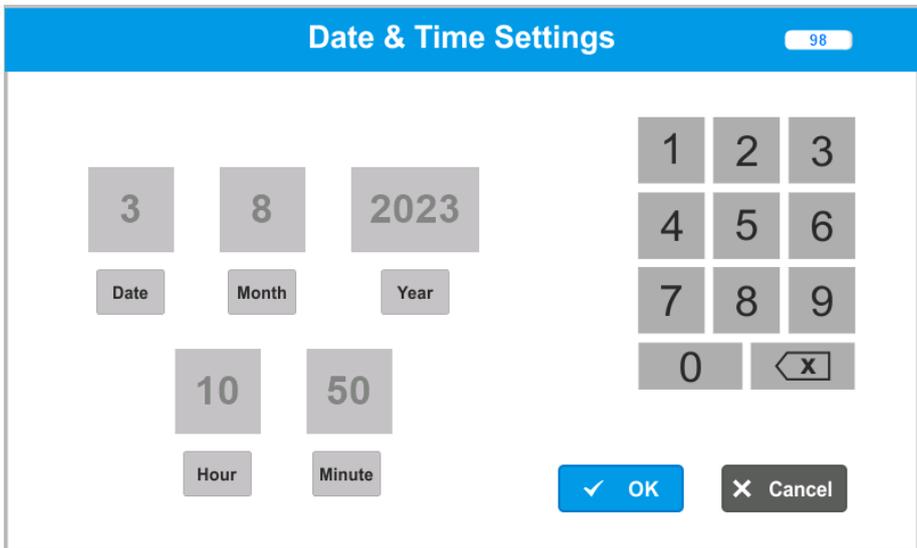
Lamp ON Time: The observation lamp timer can be selected by the user to switch ON the lap for 15 or 30 or 45 or 60 minutes.

Alarm Silence Time: The alarm pause can be selected by the user for 10 or 15 minutes.

Brightness: We can adjust the brightness of the screen.

Volume: We can adjust the volume level of audible indications.

3.3.2 Date & Time settings



Date and Time can be set before starting the operations in the Infant Radiant Warmer. It will be helpful in tracing the parameters of the patient in order for the treatment to be given.

3.3.3 Device Information settings

The device information settings contains the following:

Device Information			
Model No.	IRW454644		
Serial No.	5646554354		
CB Serial No.	YG6200		
MCU Version	1.01	Working Hours	24
GUI Version	1.01	Heater ADC	550
<input type="button" value="↶ Back"/>			

3.4 Bed Platform Operation (except 2010)

1. nice 2010 BC



Picture 84



Picture 85

- ❖ Press the bed platform tilting key in the pillar to tilt the bed platform to Trendelenburg and Reverse Trendelenburg positions.
- ❖ The bed platform tilts upto 15° in both sides.

2. nice 2007 S



Picture 86

- ❖ The bed platform tilts for Trendelenburg and Fowler 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.

3.5 Side Panel operation (except for 2010)

1. nice 2010 BC



Picture 87

- ❖ 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.

2. nice 2007 S



Picture 88

- ❖ 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 X-ray Procedures (except for nice 2010)

1. nice 2010 BC



Picture 89

- ❖ 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.

2. nice 2007 S



Picture 90

- ❖ 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 Neotech 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.

3.7 Heater rotation

1. nice 2010 BC



Picture 91

- ❖ The heater box can be rotated $\pm 90^\circ$ on both sides and check for smooth movement of heater box.

2. nice 2007 S



Picture 92

- ❖ Release 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.

3.8 Shut down Procedure

nice 2010, nice 2007S

- ❖ Remove the baby from the mattress of Infant Radiant Warmer.
- ❖ Ensure switching OFF the Flow meter and Suction.
- ❖ Switch OFF the Infant Phototherapy switch in the front panel.
- ❖ Switch OFF the observation lamp in the heater module.
- ❖ Switch OFF the Infant Radiant Warmer switch in the front panel.
- ❖ Switch OFF the green color main switch at the back side of the Infant Radiant Warmer.

nice 2010 BC

- ❖ 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.

3.9 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.

3.10 Accessories

nice 2010, nice 2010 BC, nice 2007S

S.No	Accessory Name	Single use / Reuse	Part no.	Intended use	Picture
1.	Skin Temperature Probe	Reusable	50-05-239	Intended to measure the skin temperature of patient	
2.	Air Temperature Probe	Reusable	20-05-160	Intended to measure the ambient temperature	

nice 2010 BC, nice 2007S

S.No	Accessory Name	Single use / Reuse	Part no.	Intended use	Picture
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1.	Mattress	Reusable	87-00-126	Intended for the placement of patient (baby) under Infant radiant warmer during treatment.	
2.	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.



Warning

- Use only the Reusable nice Neötech skin temperature probe to monitor the patient's skin temperature. Use of other manufacturer's probes 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.



Caution

- 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 Side Panels, Mattress, X-ray tray for cleaning

Follow the reverse process of Installation for cleaning:

Side Panels:

- For 2010 BC – refer 2.2.2.5
- For 2007 S – refer 2.5.2.6

Mattress:

- For 2010 BC – refer 2.2.2.6
- For 2007 S – refer 2.5.2.7

X-Ray:

- For 2010 BC – refer 2.2.2.9
- For 2007 S – refer 2.5.2.11

4.1.2 Cleaning and disinfection of Infant Radiant Warmer

During cleaning the Infant Radiant Warmer, the processing shall comply with ISO 17664-1:2021 for reusable of the device:

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



Caution

- 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 probe or other material being cleaned.
- Do not autoclave or gas sterilize the mattress.

4.1.3 Cleaning and disinfection of Temperature Probe

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

1. Physically clean the skin probe with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. When the equipment is not in use, temperature probe cable surfaces should be cleaned daily with an antiseptic solution like 2% glutaraldehyde and leave for 3 minutes.
3. Then rinse the temperature probe by wiping using water damp cloth
4. Dry temperature probe using dry towel or cloth



Caution

- Do not autoclave or gas sterilize the skin temperature probe.
- Do not immerse the probe in liquid cleaner. Avoid placing excessive strain on the probe lead. Always remove the probe by grasping the plug at the panel. Do not pull on the probe lead. These precautions will help avoid damage to the probe.

- After every treatment, detach the temperature probe 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 probe connector.

4.1.4 Cleaning and Disinfection of Mattress, X-ray tray, Mattress frame, Pillar, Heater box, Acrylic door, Mayo tray, Cabin, IV rod, Tilting box

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.

4.1.4.1 Removal of Side Panels

- For 2010 BC – refer 2.2.2.5
- For 2007 S – refer 2.5.2.6

4.1.4.2 Removal of mattress

- For 2010 BC – refer 2.2.2.6
- For 2007 S – refer 2.5.2.7

4.1.4.3 Removal of X-ray tray

- For 2010 BC – refer 2.2.2.9
- For 2007 S – refer 2.5.2.11

4.2 Life time of product

Since the product is classified under programmable medical electrical system and in case 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

nice 2010, nice 2007S

Mains Voltage	~230V/50Hz/5A
Rated Power	700 VA
Fuses	15 amps
Micro Processor Design Controls	Prewarm, Manual, Servo Skin, Servo Air & Safe (except nice 2007S) and HIE mode
Modes	Prewarm, Manual, Servo Skin, Servo Air, Safe (except nice 2007S) and HIE mode
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
Timed Acknowledged Time	15 minutes
Heater Output	0% to 100%, increment 5%
Skin Temperature Sensor	Thermistor based, Interchangeable with Accuracy $\pm 0.2^{\circ}\text{C}$
Air* Temperature Sensor	Thermistor based, Interchangeable with Accuracy $\pm 0.2^{\circ}\text{C}$
Sensor Interchangeability	Accuracy $\pm 0.2^{\circ}\text{C}$
Heater	Quartz heating element 600 W; Maximum heater power 600W $\pm 10\%$
Observation Lamp	1 W LED x 6 Dual LED lamp with dimming facility
Heater Module	$\pm 90^{\circ}$ to the side to facilitate X-ray procedures.
Bed Head Up / Down Facility	$\pm 15^{\circ}$ Trendelenburg and Reverse Trendelenburg
Safety Features	Safety Cut Offs & Comprehensive Indications If Temperature $> 39^{\circ}\text{C}$ in any mode
APGAR Timer	1 min – 59 minutes (selectable)
Temperature Probe Sensor	Thermistor
Temperature Probe Accuracy	$\pm 0.2^{\circ}\text{C}$ @ 30°C to 40°C (Calibration not required)
Audio & Visual Indication	
Skin Temperature High	If skin temperature is $> 1^{\circ}\text{C}$ from set temp.
Skin Temperature Low	If skin temperature is $< 1^{\circ}\text{C}$ from set temp.
Air* Temperature High	If skin temperature is $> 1^{\circ}\text{C}$ from set temp.
Air* Temperature Low	If skin temperature is $< 3^{\circ}\text{C}$ 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° , system fail alarm is triggered.
Over Temperature	If skin/air temperature is $> 39^{\circ}\text{C}$ in any mode with skin probe
Heater Fail	If the heater is disconnected or fails
Power Fail	If the power supply is disconnected or fails

Display	
Temperature conversion	Centigrade / Fahrenheit
Baby temperature Display	10 – 50°C
Air* Temperature Display	10 – 50°C
Resolution	0.1°C
Calibration	Not required
Castors	4” castors – 4 No (2 with brake, 2 without brake)
IV Pole	maximum load: 1.5 kg
Monitor Tray	maximum load 3 kg
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	36.5°C
Heater Percentage in Manual Mode	30%
Air* Control Temperature	34.0°C
Apgar Time	20 Minutes Count-up
Observation lamp	50%

nice 2010 BC

Electrical Characteristics	
Supply Mains	~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
Physical Characteristics	
Height	188 cm

Depth	120 cm
Width	930 cm
Mattress Platform height Adjustment	81 – 101 cm
Castors	4-inch Castors (2 nos with brake in front) .
Heater Rotation	±90° to the side to facilitate X-ray procedures.
Mattress platform tilting	±15° Trendelenburg and Reverse Trendelenburg.
Side panels	Transparent acrylic
IV Pole max. Load	1.5 kg.
Mayo Tray max. Load	3.0 kg.
Mattress max. Load	10.0 kg.
X-ray tray max. Load	1.5 kg.
Storage cabinet Load	3 kg.
System Characteristic	
Display	7 inch TFT-LCD with Touch screen
Battery Backup	5 minutes for display only.
Infant Radiant Warmer	
Mode	Baby, Manual, Prewarm, Safe, HIE Mode & Air
Temperature Display Range	10.1 – 50.1°C
Temperature Display Accuracy	± 0.2°C (25 – 40°C)
Skin Set Temperature Range	32 – 38°C
Air Set Temperature Range	20 - 38°C
Heater Output set range in Manual Mode	0 – 100 % in 5% Increment
Prewarm Mode	100% Heater power for 5 minutes then 30%
HIE Mode	No heater power
Safety Features	Safety Cut Offs & Comprehensive Indications If Temperature > 39°C in any mode, i-sense technology, Check-sensor alert
Temperature Sensor Interchangeability	Accuracy ± 0.2°C
Temperature Sensor Calibration	Not required
Apgar Timer	1 – 59 min, Count up/Count down
Observation Lamp	Dimmable 6W White LED light, 2000 lux @ center of mattress
	Colour Temperature: 4000 – 4500 K
Thermostat	Autoreset 90°C ± 5% in normally closed
Infant Radiant Warmer Alarms	
Skin temperature High	If baby skin temperature (T1) is > 1°C from set temp.

Skin temperature Low	If baby skin temperature (T1) is < 1°C from set temp.
Axillary temperature High	If baby axillary temperature (T2) is > 1°C from set temp.
Axillary temperature Low	If baby axillary temperature (T2) is < 1°C from set temp.
Air temperature High	If ambient air temperature is > 1°C from set temp.
Air temperature Low	If ambient air temperature is < 3°C from set temp.
Skin temperature >39°C	If baby's skin is > 39°C in any mode of operation.
Skin temperature Sensor disconnected	If baby skin temperature (T1) Sensor is removed.
Air temperature Sensor disconnected	If air temperature Sensor is removed.
Axillary temperature Sensor disconnected	If baby's axillary temperature (T2) Sensor is removed.
Skin temperature Sensor defect	If baby skin temperature (T1) Sensor is damaged.
Air temperature Sensor defect	If air temperature Sensor is damaged.
Axillary temperature Sensor defect	If baby's axillary temperature (T2) Sensor is damaged.
Manual mode alert	Activates every 15 minutes once in Manual mode of operation.
Power failure	Activates when power supply to the equipment is cut-off.
Heater Fault	If Heater is disconnected or fails
Alarm Algorithm	
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
Low Priority	Visual - Blue
Sound Pressure Level	High Priority Alarm - 69 dB, Medium Priority Alarm – 67 dB
Factory Default Setting	
Mode of operation	Baby Control (Servo Skin) Mode
Baby Set Temperature	36.5°C
Heater Percentage in Manual Mode	30%
Air Set Temperature	34.0°C
Apgar Time	20 Minutes Count-up
Temperature Unit	°C
Lamp ON Time	30 minutes
Alarm Silence Time	15 minutes

Dimensions	
nice 2010	118 cm (L) x 82 cm (W) x 194 cm (H)
nice 2007s	191 cm (H) x 131 cm (L) x 76 cm (W)
nice 2010 BC	131 cm (L) x 92 cm (W) x 187 cm (H)
Mattress	30x20x2 INCH
Weight	
nice 2010	65 kg
nice 2007S, nice 2010 BC	69 kg
Environmental Specifications	
Operating Conditions	
Temperature range	10°C to 30°C
Humidity range	15 – 90% RH, non-condensing
Altitude	Sea level to 1.9 miles (3Kms)
Atmospheric Pressure Range	50 – 106 Kpa
Pollution degree	2
Transport and Storage conditions	
Temperature range	-10°C to 60 °C
Humidity range	50% - 90% RH, non-condensing

IEC 60601-1 Specifications	
Type of Protection against electric shock	Class 1
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
Product Classification	Class II b

Quality Test Approval	
Quality	ISO 13485:2016
Electrical Safety	IEC 60601-1
Product Safety	IEC 60601-2-21
EMC Safety	IEC 60601-1-2
Alarm	IEC 60601-1-8
Graphical Symbol	ISO 15223-1:2021

Power Cord	
Technical Specifications	
Plug	3 Pin, 16A/250VAC/50 Hz
Connector	3 x 1.5 mm ² /1100VAC
Type of Cord	3 m
Max. Rated Current	16A

Optional Accessories	
O ₂ Driven Slow Suction	
Electrical Slow Suction	
Manual Respirator (Ambu Bag)	
X-ray Tray	
Cabinet (nice 2007S)	
Air probe	
Auxillary probe	

Section 6: Warranty

6.1 Conditions

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

nice 2010, nice 2007S

SI. 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.

nice 2010 BC

SI. No	Problems	Possible Causes	Recommendation
1	Power failure indication displayed	Power failure	Check the unit is plugged in to main supply
			Check the mains are switched ON.
			Otherwise contact nice Neötech
2	Can't move the machine	Brakes may be applied on the castors.	Release the brake.
		Castors damaged	Change the Castors
3	Unable to tilt the heater module	Heater module may be struck	Slightly shake and rotate the heater module
			Contact nice Neötech

7.2 System Fault Infant Radiant Warmer

SI. 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 Timed Acknowledged is ON.
		Otherwise contact nice Neötech
5	Baby temperature display shows “S-O” with continuous audio indication (S-O: Sensor Open) Display shows “Skin sensor disconnected” (for nice 2010 BC).	Check if skin temperature sensor is disconnected from the machine.
		If skin temperature sensor is defective, replace new sensor
		Otherwise contact nice Neötech
6	Air* temperature display shows “S-O” with continuous audio indication (S-O: Sensor Open) Display shows “Air sensor disconnected” (for nice 2010 BC).	Check if air* temperature sensor is disconnected from the machine.
		If air* temperature sensor is defective, replace new sensor
		Otherwise contact nice Neötech
7	Display shows H - F (H-F: Heater Failure) Display shows Heater Failure (for nice 2010 BC)	Check heater connection
		Other wise contact nice neötech
8	Over temperature indication (ie. Temp. > 39 ° C) Display shows “Skin Over Temperature”. (for nice 2010 BC)	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

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

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

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

Replacement of Power failure Battery

- Only service personnel should replace the battery. Remove the 9V Dry Battery from the battery connector by pulling from the back side of the pillar. Replace new battery by pressing the cap. Always use Hi Watt branded battery to minimize the down time.

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

7.4 Disposing of the Unit

- At the end of its Service life Dispose of the equipment in accordance with National waste Disposal 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	20-05-069	PCB Assembly	1	No.
2	20-05-108	PCB power supply assembly – nice 2010	1	No.
3	20-05-107	PCB control assembly – nice 2010	1	No.
4	20-05-121	Heater connector PCB assembly	1	No.
5	20-05-123	Observation lamp PCB assembly	2	No.
6	20-05-129	Observation lamp assembly	2	No.
7	90-00-100	Power cord 16A	1	No.
8	20-05-125	Main connector PCB assembly	1	No.
9	20-05-130	Visual alarm indicator assembly	1	No.
10	20-05-131	Speaker assembly	1	No.
11	20-05-132	Infant radiant warmer Transformer assembly	1	No.
12	99-00-183	Mayo Tray	1	No.
13	20-05-079	Access Panel Assembly FR/RR	2	No.
14	20-05-080	Access Panel Assembly LH/RH	2	No.
15	20-05-073	Skin Probe Assembly	1	No.
17	87-00-126	Mattress, 27.95 (L) x 20.7 (W) x 2 (TK) inch with plywood - IRW	1	No.
18	91-00-223	Circuit breaker 20A	2	No.
19	91-00-172	DPST switch non illuminance	1	No.
20	91-00-034	Lamp IR Heater 600W	1	No.
21	91-00-073	Thermostat,90 Dec NC	1	No.
22	91-00-051	Battery 9V, unchargeable	1	No.
23	93-00-015	CASTOR 4 INCH JAINSONS JM - 1 BRAKE	2	No.
24	93-00-016	CASTOR 4 INCH JAINSONS JM - 1 WO BRAKE	2	No.
25	98-00-009	Silicon Bush IR Lamp	2	No.
26	91-00-005	Switch	1	No.
27	91-00-018	Connector Wago Side Piece 260-301	3	No.
28	91-00-034	Lamp IR Heater 600W	1	No.
29	91-00-040	Transformer, Electronic 12V,150	1	No.
30	91-00-041	Transformer 11V 50W	1	No.
31	91-00-048	Fan 3" 230V	1	No.
32	91-00-073	Thermostat,90 Dec NC	1	No.
33	91-00-086	Fan Grill 3"	1	No.
34	94-00-017	Spring, Halogen Lamp	1	No.
35	96-00-089	X Ray Cassette Tray	1	No.
36	93-00-028	Castor 3 inch thread type with brake	2	No.
37	93-00-029	Castor 3 inch thread type without brake	2	No.
38	20-05-148	PCB Control assembly – nice 2010	1	No.
39	50-05-185	Lifting Column and Actuator PCB	1	No.
40	91-00-225	SMPS(RPS-65-24)	1	No.
41	20-05-024	Mayo Tray	1	No.
42	50-05-211	Cabinet	1	No.
43	20-10-114	Movable IV Column	1	No.
44	20-10-115	IV Hook – V type	1	No.
45	30-05-037	Air Probe assembly	1	No.
46	20-05-239	Skin Probe Assembly	1	No.

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			

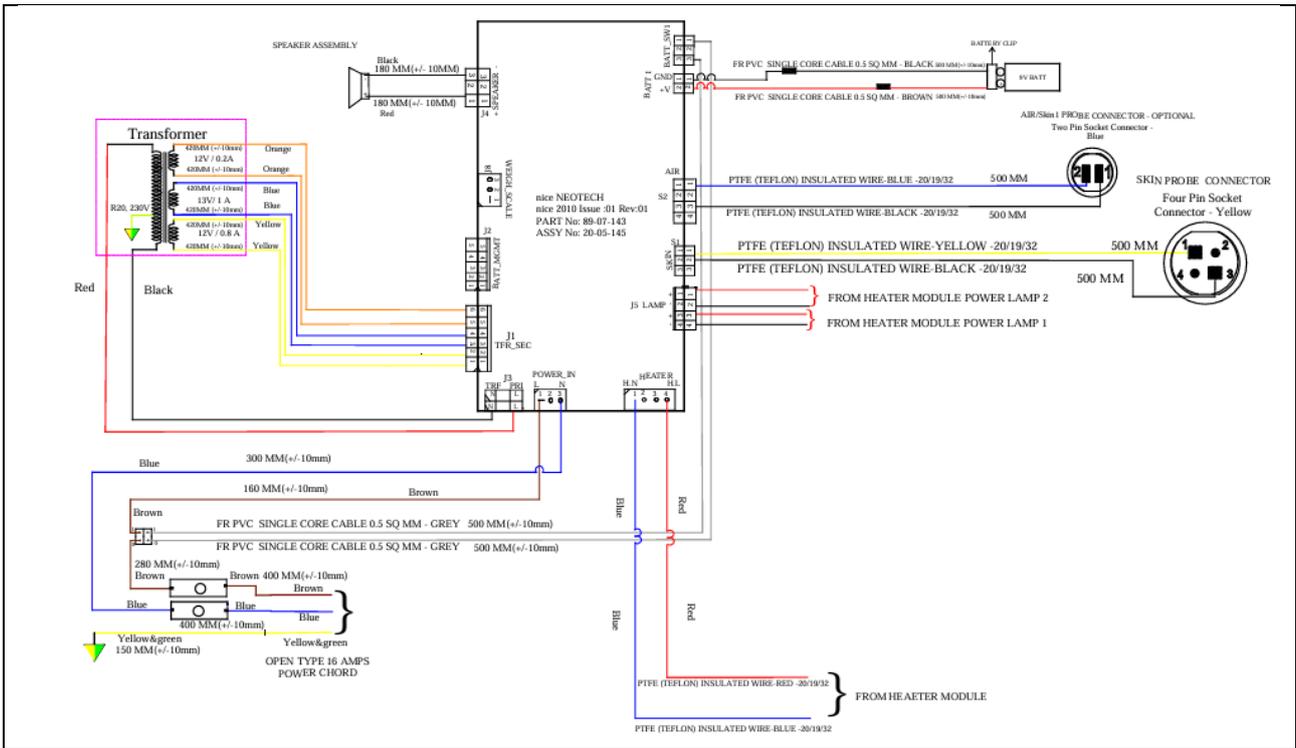
The Infant Radiant Warmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant Radiant Warmer should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted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

Acceptance criteria

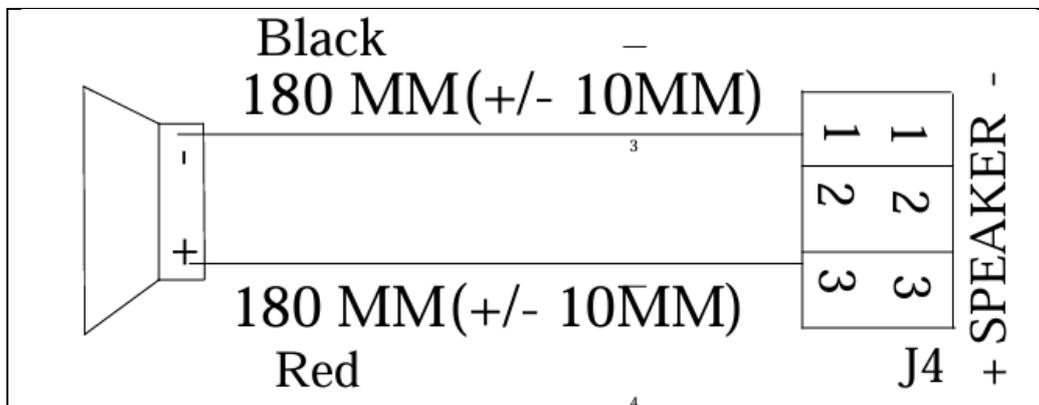
Performance criteria	Description
A	Normal performance within limits specified by nice Neötech
B	Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention
C	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

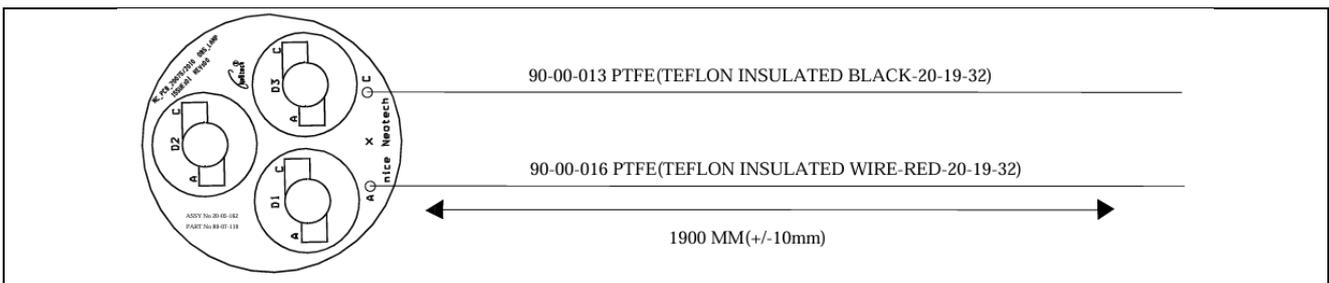
2. nice 2007s & nice 2010



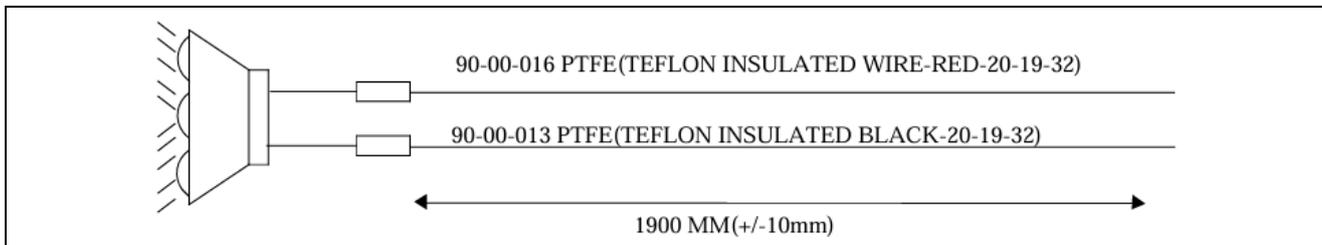
Pillar Assembly



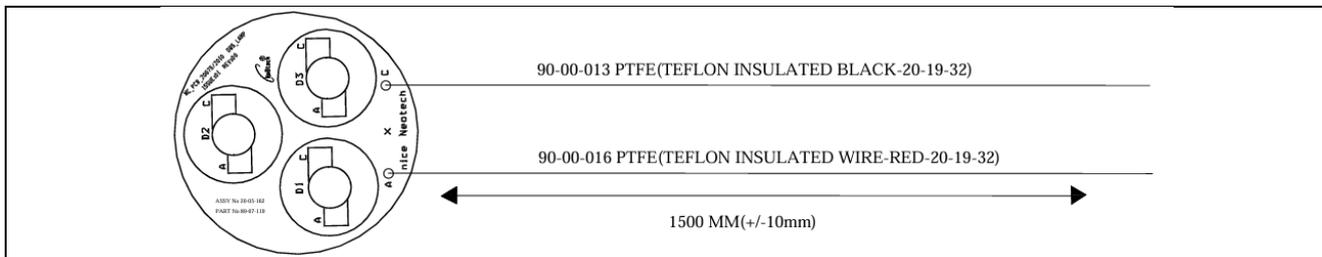
Speaker Assembly



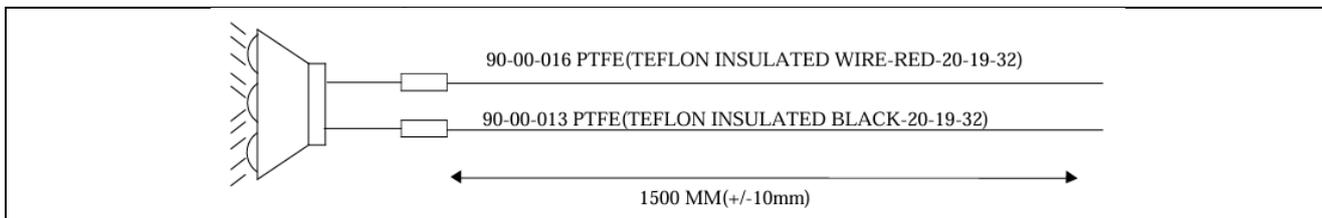
Observation Lamp MC_PCB-FR



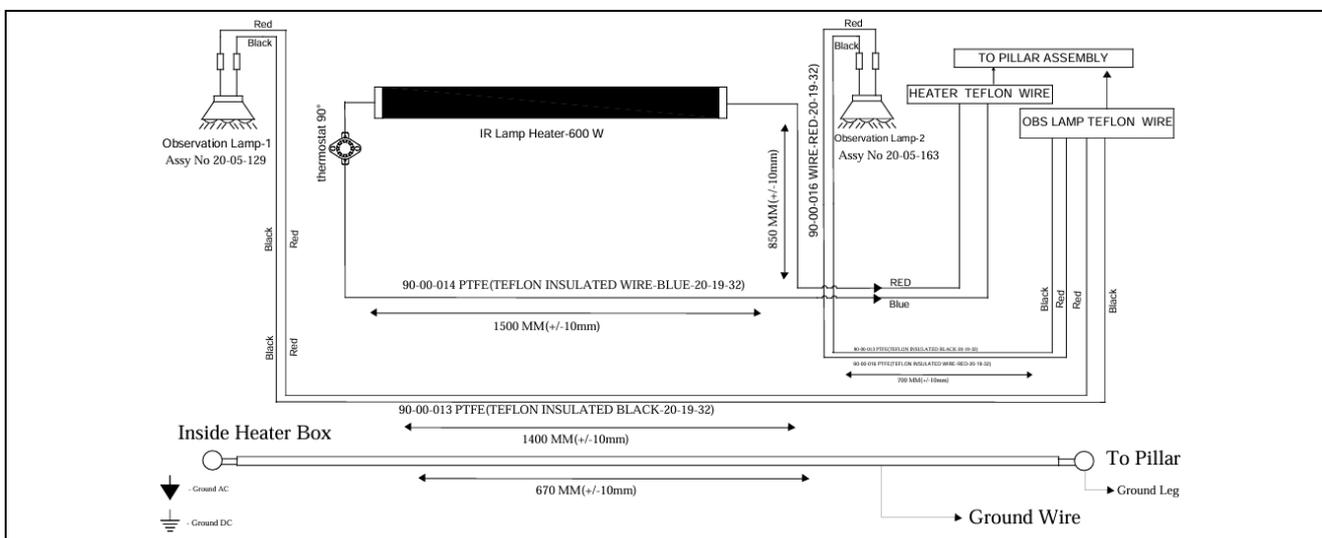
Observation Lamp-FR



Observation Lamp MC_PCB-RR



Observation Lamp-RR



Heater Module Assembly

Note: Weighing scale and Air probe is optional

3. nice 2010 BC

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:	<input type="checkbox"/> Complaints <input type="checkbox"/> Adverse Events <input type="checkbox"/> Comments <input type="checkbox"/> 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,
Mettukuppam, Vanagaram, Chennai-95,
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	EU Authorized Representative	Competent Authority
<p>nic Neötech Medical Systems Pvt. Ltd. No. 85 - 86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai-95, 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</p>	<p>Amstermed B.V Located in Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. Mr. Mike Vermin Tel: +31 23 565 6337 info@amstermed.nl www.amstermed.nl SRN: NL-AR-000001971</p>	<p>Ministerie van Volksgezondheid, Welzijn en Sport Address:P.O. Box, 20350, The Hague, Netherlands Country:Netherlands Email: medicaldevices@minvws.nl Tel:+31 70 340 79 11</p>

Section 12: EC certificate Notified Body

Name:

PCBC – POLSKIE CENTRUM BADANI CERTYFIKACJI

Notified body number:

1434

Address:

02-844 Warsaw,
469 Pulawska Street,
Poland.

Ph: +48 22 46 45 200
email:pcbc@pcbc.gov.pl