Operah plus

Neötech®
HEALTH CARE EXCELLENCE

Infant Radiant Warmer with T-Piece Resuscitator and Phototherapy

nice 5000 RP

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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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. Operator is positioned 1m approx from the front panel of the device. The device should be placed leaving space upto 1m from the wall to access the device backside easily. 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.

Model Descriptions

nice 5000 RP Operah plus provide a controlled source of radiant heat, treatment of hyperbilirubinaemia, provide the controlled suction and oxygen based manual resuscitation facilities necessary for infants and peadiatric patients along with T-Piece Resuscitator system and monitoring pulse co-oximetry parameter using Masimo rainbow SET pulse co-oximeter. The control system uses a microprocessor and provides four modes of operation. nice 5000 RP is a superior model, designed with all features.

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 User.

c. **Skin temperature**: The temperature measured from the skin surface by a temperature probe.

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

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

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

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

h. **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.

i. **Phototherapy:** Phototherapy was discovered by chance when a nurse in a hospital nursery noticed that the infants placed closer to the windows were less "yellow" than those who were not. This observation led to the application of phototherapy in the treatment of neonatal hyperbilirubinimia.

   Phototherapy is the process of using light to eliminate bilirubin in the blood. These light waves are absorbed by baby's skin and blood which change bilirubin into products that can pass through the baby's system.

j. **New Born Jaundice:** The buildup of bilirubin in the blood is called hyperbilirubinimia or new born jaundice. Because bilirubin has a pigment or coloring, it causes a yellowing of the baby's skin and tissues. Before birth bilirubin is removed efficiently by the placenta. Immediately after birth the relatively immature neonatal liver provides the sole excretory pathway and is easily overwhelmed. This condition can be treated with phototherapy.

k. Some chemical substances react to light. When a new born with jaundice is exposed to phototherapy, the bilurubin absorbs light and changes form, it breaks down and become water soluble, it is then excreted mainly in the bile and to some extent in the urine.

l. When light is used therapeutically three specifications are of importance – wavelength, irradiance and duration of exposure.

m. **Wavelength** - Solar irradiance that reaches the earth's surface consists of ultraviolet irradiation from 290 – 380nm (the ozone layer of the earth's atmosphere filters out ultraviolet of less than 290nm), the visible spectrum between 380 – 770nm and the near infrared from 770 – 1000nm. At midday sunlight has peak intensity in the blue-green region 450-500 nm.

   Wavelength is defines as the property of a wave in which the distance between the identical points between the two successive are calculated.

n. **Irradiance** is a measure of radiant flux impinging on a unit area or flux density. Irradiance is expressed as watts per square meter or milli watts per square centimeter. Irradiance is measured by a spectro radiometer.

o. **Duration of Exposure:** The product of duration of exposure and irradiance will give a measure of the total radiant energy to which the subject has been exposed.

p. **Load cell:** Load cell is a weight measurement device to display the accurate weight of the baby in digits.

q. **Oxygen saturation (SpO_2):** Oxygen saturation is the fraction of oxygen-saturated hemoglobin relative to the total hemoglobin in the blood. It is measured in percentage. The normal range of SpO_2 is 95% - 100%.

r. **Perfusion index (Pi):** The perfusion index (PI) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. The measurement range is 0.02 to 20%.

s. **Pulse Rate (PR):** Pulse rate is the number of times the heart beats per minutes (bpm). A normal resting heart rate should be 60-100 bpm, but it can vary from minute to minute.

t. **Timed Acknowledged Key:** Timed Acknowledged pause alarm for a defined duration, The Timed Acknowledged feature, temporarily pause specific alarms, operates with preset time durations of either 10 or 15 minutes. For Masimo Alarm conditions, Timed Acknowledged key initiates a 2-minute pause of the audio alarm.

u. **SpMet (Optional)**: Pulse CO-Oximetry is a continuous and non-invasive method of measuring the levels of methemoglobin concentration (SpMet) in arterial blood.

v. **SpHb (Optional)**: Pulse CO-Oximetry technology, monitoring typically refers to continuous, noninvasive monitoring of total hemoglobin levels in the bloodstream.

w. **Pleth Variability Index (PVi) Monitoring (optional):** The Pleth Variability Index (PVI) is a measure of the dynamic changes in the perfusion index (PI) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI is displayed as a percentage (0-100%).

Points to note:

i. **LED Light source** – Bilirubin absorbs light of 460 nm.

ii. **Hazards of Phototherapy:**

- The non-usage of eye pad (protection) during the phototherapy treatment may cause damage to the retina of the infant's eye.
- The phototherapy light may impact the heat supply in thermotherapy devices (radiant warmers, or heated mattresses) and the patient's body temperature.
- Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area.

The use of eye pad on the patient will possibly avoid Retinal Damage possible due to the intensity of the phototherapy lamps.

Definition of Warning Indication

Three levels of warning indication are used throughout this manual and on the unit. They are defined as follows,

A **DANGER** notice indicates an immediately hazardous situation which, if not avoided, will result in death or serious injury, serious damage to property such as total loss of use of equipment, and a fire.

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

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

Section A: Warnings

- Before using the nice Neötech Infant Radiant Warmer, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the risks and benefits of this type of device.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- To avoid the risk of electric shock, Infant Radiant Warmer must only be connected to a supply mains with protective earth.
- Overloading the shelves can affect the stability of the unit. Limit the load to 3 kg per instrument shelf.
- Limit the load placed on the x-ray cassette tray to 1.5 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.
- Explosion hazard: Do not use the equipment in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- 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.
- Proper installation of the Operah plus may require two people.
- 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 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.
- 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 pre-use check instructions (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 pre-use check instructions 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 a 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 baby mode of operation be used. When an indication is Paused, close monitoring of the patient's condition is required.

- Use the baby mode unless the manual mode. While all four modes require patient monitoring, the manual mode requires constant attention.

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

- 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 sensor lead as far away as possible from electrosurgical cables.

- Do not allow excess electrical cables to be laid on the bed platform. Use of electrosurgical units or other instruments which radiate electrical fields can cause indirect heating, by several tenths of a degree of the skin temperature 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, masimo sensors 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 sensor should be located on the patient's skin in an area which is directly in the path of the radiant heat. It should not be attached to an area which is shielded from the radiant heat or between the patient and the mattress. Large temperature gradients and very long servo response times will result from improper sensor placement.

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

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

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

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

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

- The nice 5000 RP 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.

- The nice 5000 RP 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 nice 5000 RP 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.

- The nice 5000 RP 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 reloacating 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).
- Ensure the oxygen supply is turned on and functioning correctly before placing a patient into the unit for resuscitation process. Failure to verify the oxygen flow can result in insufficient oxygen delivery, leading to severe hypoxia or death. Continuous monitoring of the oxygen supply is essential throughout the resuscitation process.
- Incorrect use of the light, or the use of parts and accessories that are not manufactured or supplied by Neötech, can damage the light, and may cause injury to the patient and/or user.
- 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.
- Switch ON the Phototherapy when it's required and Switch OFF after usage.
- **Eye Protection:** Do not look directly into the LED Lamp. During treatment, always protect the baby's eyes with eye patches or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection. Patients adjacent to the light may also need to be protected with eye patches or equivalent.
- **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.
- **Heat Supply:** The phototherapy light may impact the heat supply in thermotherapy devices (radiant warmers, or heated mattresses) and the patient's body temperature.
- **Ambient Conditions:** Varying ambient conditions, such as the ambient temperature and/or different radiation sources, may adversely affect the patient. Please refer to your hospital phototherapy policy and procedure regarding appropriate ambient conditions.
- **Operator Safety:** Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area. Using the Neötech LED Phototherapy Unit in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects.
- **Photoisomers:** Bilirubin photoisomers may cause toxic effects.
- **Diffuser:** Do not use the light if the diffuser is missing or damaged. The diffuser panel is a plastic shield that provides more uniform illumination. The diffuser panel also protects the baby and the unit from incidental debris or fluids.
- **Photosensitive drugs:** The light generated can degrade photosensitive medications. Do not place or store any drugs near or in the illuminated area.
- **Combustible gases:** Do not use the light in the presence of gases that support combustion (for example, oxygen, nitrous oxide, or other anesthetic agents).
- **Disconnect electrical power:** Always switch off the power and disconnect the power cord when cleaning the light.
- Blue light can hinder clinical observations by masking skin color changes, such as cyanosis.
- Do not store drugs and infusion liquids under the radiation area.

- Reliable protection against electric shock will only be achieved if the equipment is connected to an earthed power supply system. Do not use extension cables or adaptors.
- The effect that this resuscitator is intended for first responders to a breathing emergency only and that patient must be transferred to a transport and emergency ventilator.
- Incorrect operation of the resuscitator can be hazardous.
- If use in hazardous or explosive atmospheres, the resuscitator entrains or permits the patient to inhale gas from the atmosphere, its use in contaminated environments can be hazardous unless entrainment is prevented or appropriate filtration is provided.
- If a part which can be temporarily fitted or selected, to filter or prevent the entrainment of a contaminated atmosphere, affects the resuscitator performance, that such part is only to be used when essential and must be removed for all other uses, that may cause increased risks associated with its use.
- Resuscitator is not to be used on unattended patients.
- A recommendation that an alternative means of ventilation should be available (e.g. That training should include mouth to mouth ventilation, with or without a protective barrier).
- Breathing system filter is necessary to prevent cross-contamination of parts of the resuscitator that cannot be disassembled for cleaning and disinfection.
- Phototherapy Eye pad should be disposed after single use.
- Packing materials should be disposed after single use.
- Periodically check the irradiance level of Phototherapy lamp for effective therapy.
- Periodically check PIP/PEEP value with calibrated pressure gauge.
- To protect against injury, follow the directions below:
    - Avoid placing the device on surfaces with visible liquid spills.
    - Do not attempt to sterilize the device.
    - Use cleaning solutions only as instructed in this operator's manual.
    - Do not attempt to clean the device while monitoring a patient.
- Sterilize resuscitation accessories using Ethylene Oxide (EO) only prior to clinical use.
- Do not use steam, gamma, or other sterilization methods, as they may damage the circuit and compromise safety.
- Do not use the resuscitation accessories until aeration is complete.
- Ensure adequate aeration before patient contact.
- Do not use the accessories beyond the expiry date. Material degradation may compromise safety and performance.

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 hide or block the alarm sound way on the heater module. It may reduce or nullify the alarm sound.
- 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 sensor lead. Always remove the probe by grasping the plug at the panel. Do not pull on the sensor lead. These precautions will help avoid damage to the sensor.
- Do not use damaged sensors. Do not use a sensor with exposed optical or electrical components. Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof). Do not sterilize by irradiation, steam, autoclave or ethylene oxide unless otherwise indicated in the sensor directions for use. See the cleaning instructions in the directions for use for all masimo reusable sensors.
- Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize by irradiation, steam, autoclave or ethylene oxide.
- 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 45°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 shows incorrect reading while using the defibrillator.
- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance.
- The maximum load on

IV Pole	: maximum load: 1.5 kg.
Mayo Tray	: maximum load: 3 kg.
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.

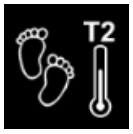
- **Other equipment**: Do not attach other equipment to the Neötech heater module or place anything on top of the heater module. The pedestal stand and heater module are not designed to support additional equipment.

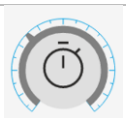
- The use of eye shields on the patient will possibly avoid Retinal Damage possible due to the intensity of the LED phototherapy lamps.
- If the external acrylic lens of the phototherapy LED has poor clarity, replace it immediately. The lens should be clean and clear.
- Do not use phototherapy equipment with flammable solution.
- 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.
- Continuous exposure of phototherapy treatment may cause water loss of the patient.
- Continuous Exposure of phototherapy may cause increase the skin temperature. Periodically monitor the skin temperature.
- 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. The LED based Phototherapy System is designed for mounting on the nice 5000 RP and consists of two lamp housings, two mounting kits and two dedicated power supply cables.
- Isolation from the Supply mains is separable Plug provided.
- **Important:** Maintain a distance of 73 cm between the light enclosure and the infant to achieve optimal light intensity.
- 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.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse co-oximeter.
- Do not attempt to resterilise resuscitation accessories after use.
- Ensure proper handling to avoid contamination after EO sterilization of resuscitation accessories.

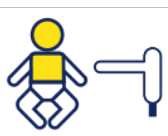
Section C: Symbols and Labels

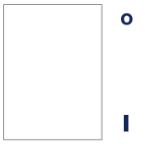
Mark	Title
Manufacturer	
	Manufacturer – Indicates the medical device manufacturer
	Date of Manufacture – Indicates the date when the medical device was manufactured.
	Country of manufacture – To identify the country of manufacture of products
	Authorized representative in the European Community/ European Union – Indicates the authorized representative in the European Community/ European Union
	Catalogue number – Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial Number – Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Batch code – Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Use-by date – Indicates the date after which the medical device is not to be used.
	CE Mark European Conformity - Signifies European conformity (CE) mark Indicates manufacturer declaration that the product complies with applicable European regulations.
Sterility	
	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process.
	Do not use if package is damaged and consult IFU - Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
Storage	
	Fragile, handle with care - Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep dry - Indicates a medical device that needs to be protected from moisture.
	Temperature limit - Indicates the temperature limits to which the medical device can be safely exposed.

	Humidity limitation - Indicates the range of humidity to which the medical device can be safely exposed.
	Do not keep near fire – Do not keep the package near fire
	Maximum stackable limit – Pay attention to numbers on the stacked boxes icon. Some stacks will have top boxes marked with an X (number)
	This way up – For the duration/ delivery, the carton should face upright.
Safe use	
	Warning - 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.
	Caution - Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Refer Instruction for use – Indicates the need for the user to refer instructions for use given by the manufacturer
	Do not re-use - Indicates a medical device that is intended for one single use only
	Consult instructions for use or consult electronic instructions for use - Indicates the need for the user to consult the instructions for use.
On Device	
	General Prohibition sign
	Do not step on surface
	Do not lean on warmer
	Use no oil
	Warning - Hot Surface area – Protective grill
	General mandatory action
	Alternating current
	Direct Current

	Off (Power: disconnection from main)
	On (Power: connection to the main)
	Type BF Equipment
	Type B (Mattress)
	Caution, Eye Protection to be worn by infants
	Wi-Fi
	Battery percentage
	Skin temperature
	Set skin temperature
	Set temperature value
	Auxiliary temperature
	Baby Mode
	Safe mode
	Manual mode
	Prewarm mode

	HIE Function
	Heater power output
	Heater output setting
	APGAR timer start
	APGAR timer stop
	APGAR timer Start/Stop
	APGAR Count Up
	APGAR Count Down
	Timer
	Phototherapy Irradiance levels
	Phototherapy Light ON
	Phototherapy Light OFF
	Observation Lamp
	Lock
	Unlock
	Menu

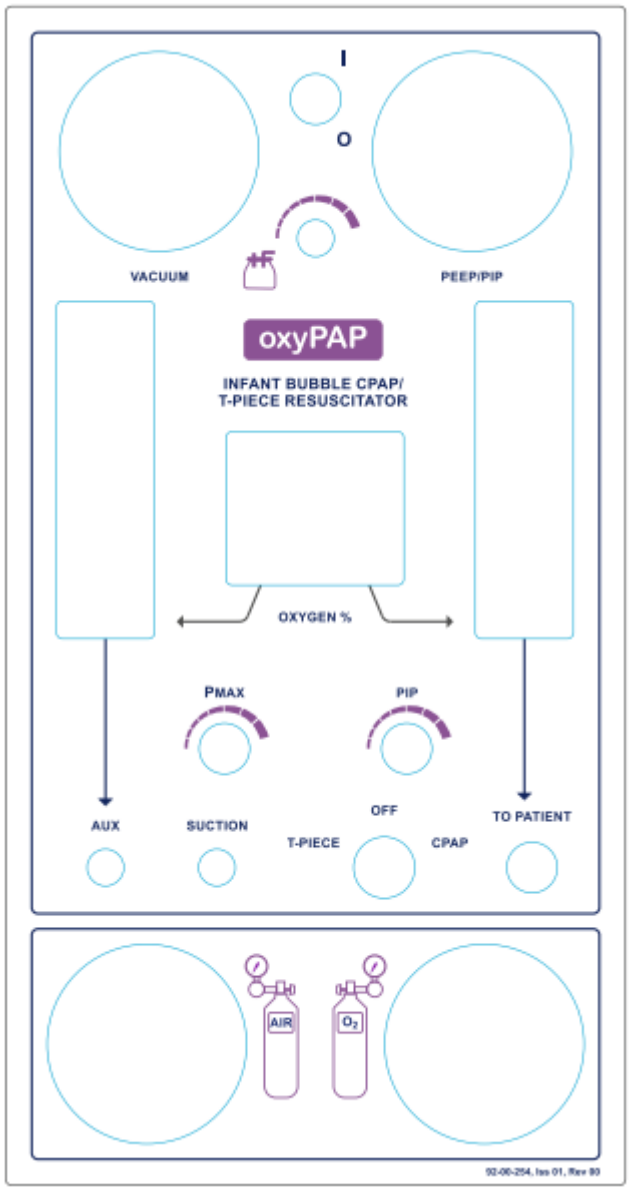
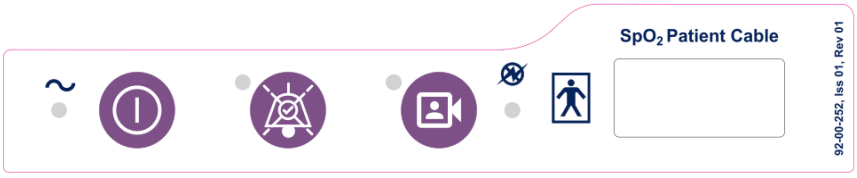
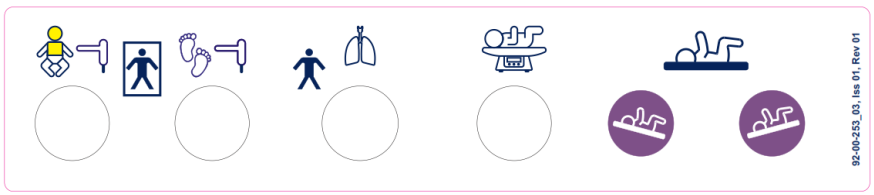
	Increase key
	Decrease key
	Calendar
	Time navigation backward (Trend settings)
	Time navigation forward (Trend settings)
	Back
	Exit (observation lamp settings)
	Volume
	Home/ Exit
	Defaults
	OK
	Cancel
	Save
	Screen timer
	Skin temperature probe

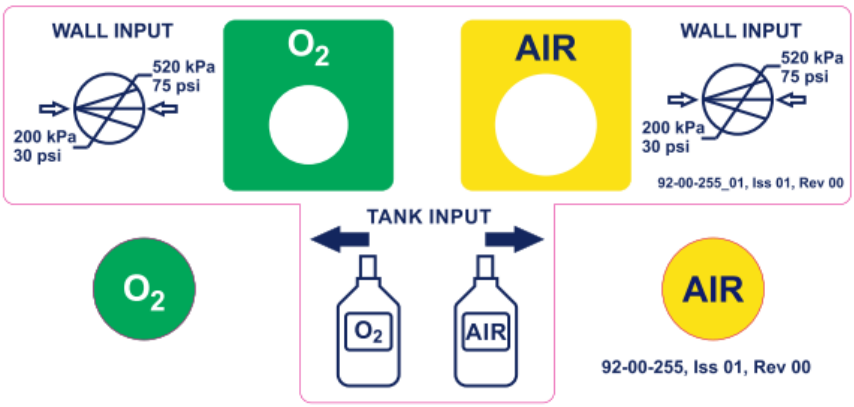
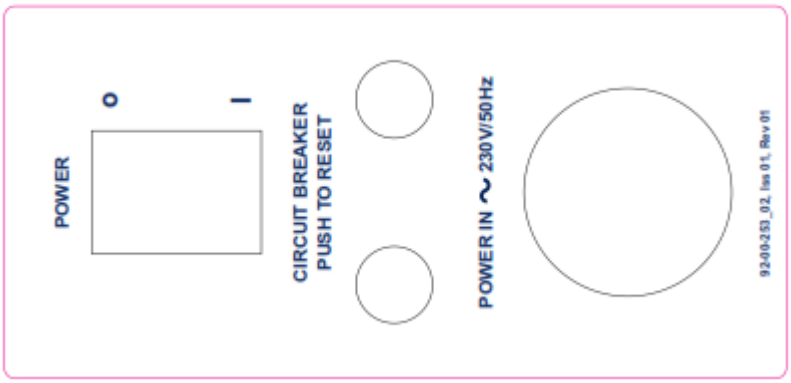
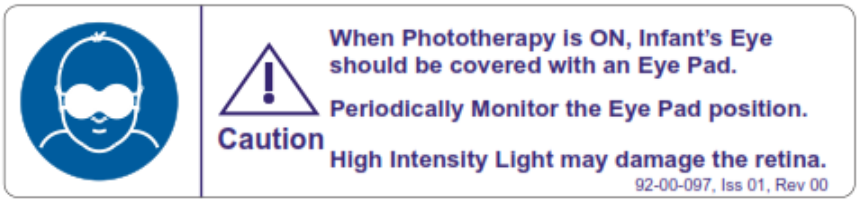
	Auxiliary temperature probe
	Bed tilting
	Bed tilting up/down
	Air inlet
	Oxygen inlet
	Main switch
	ON/OFF key
	Timed Acknowledged key
	Pedal switch - Upward pedal switch
	Pedal switch - Downward pedal switch
Others	
	Medical Device - Indicates the item is a medical device
	Type BF Equipment – Indicates that the applied part is electrically connected to patient but not directly to heart.
	WEEE Complaint - The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. The WEEE marking must appear on any electrical and electronic equipment placed on the EU market.

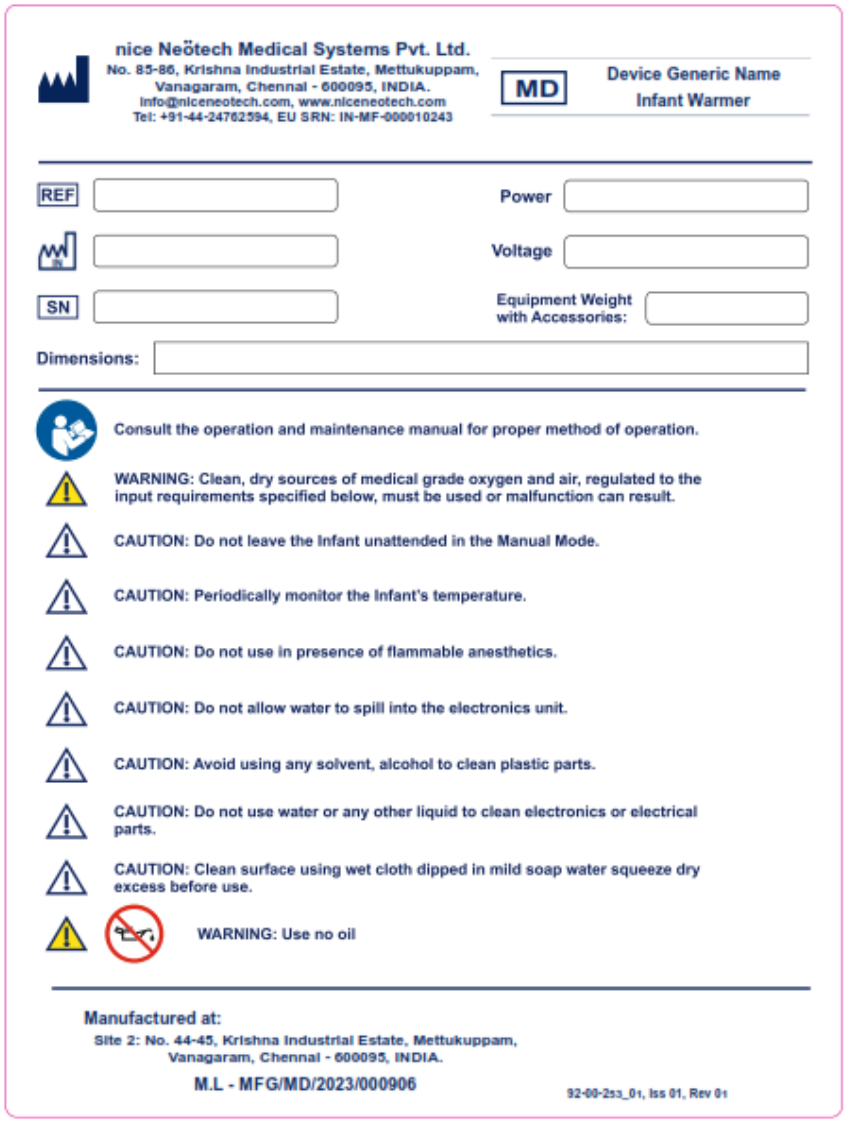
	Recyclable Package – The product can be recycled or it was made from recycled materials.
	Phthalate free – Indicates that the product does not contain the phthalate plasticizers DEHP, BBP and DBP.
	Indicates the absence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device
	Use trolley for transportation – Used for heavy products that are difficult to carry by hand, even if you have multiple people.
	RoHS Complaint – RoHS (Restriction of Hazardous Substances) Indicates that no hazardous substances have been used in the product
	Unique device identifier - Indicates a carrier that contains unique device identifier information

Labels

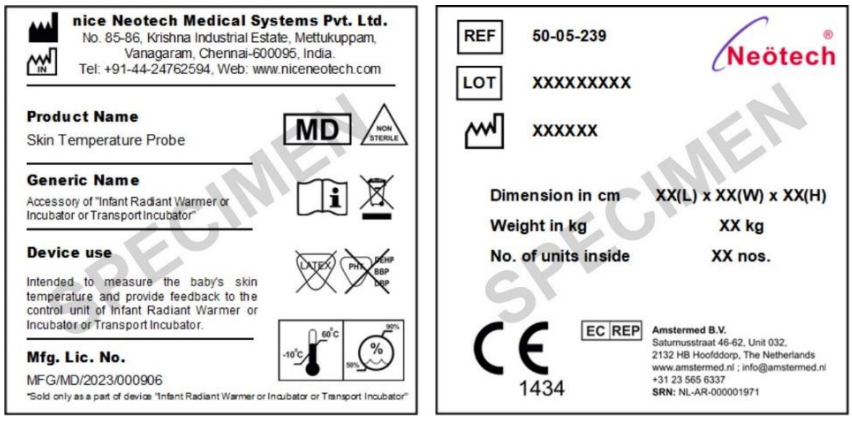
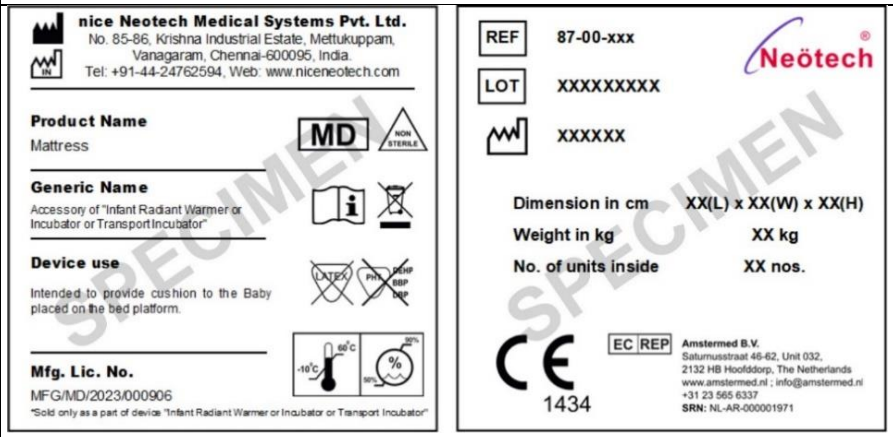
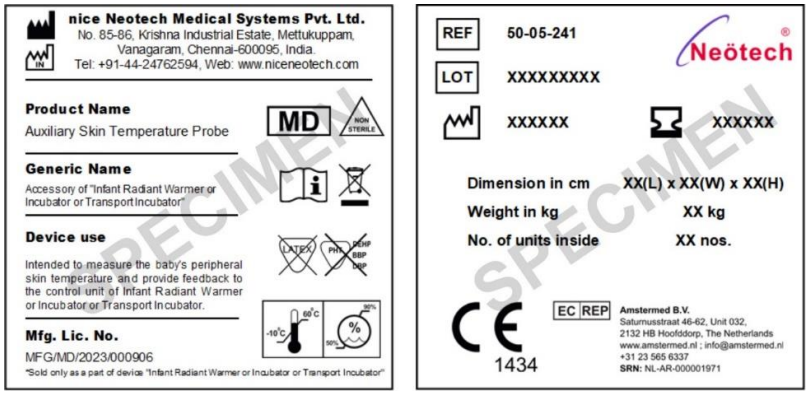
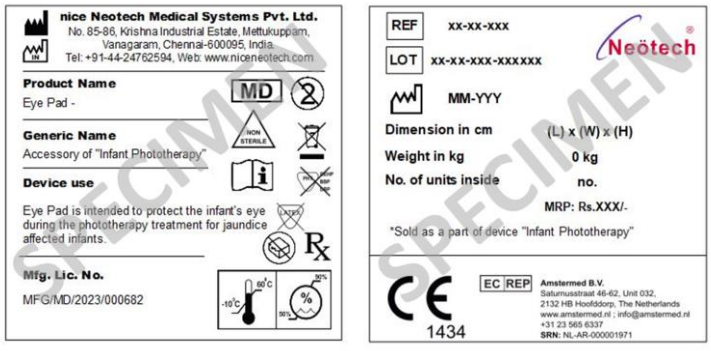
S. No	Label	Part Number	Label Description
1.		92-00-239	Max weight 1.5kg
2.		92-00-239	Max weight 3kg
3.		92-00-239	Safety sign, Hot surface
4.		92-00-239	Safety sign, Do not step on surface
5.		92-00-239	Safety sign, Do not lean on warmer

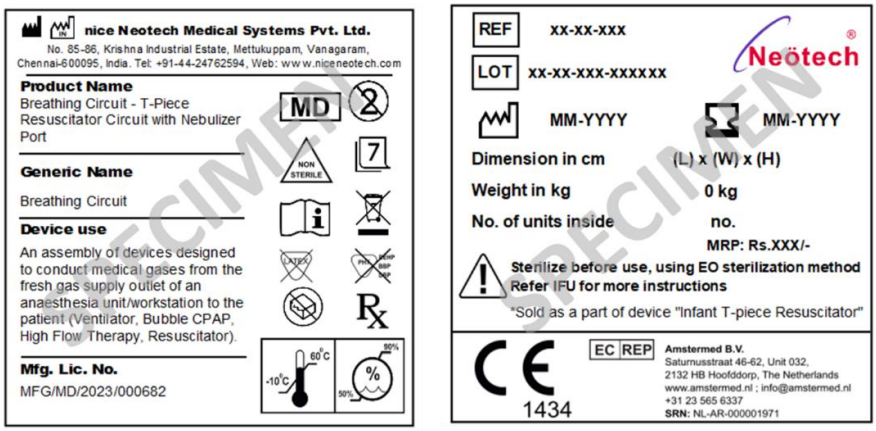
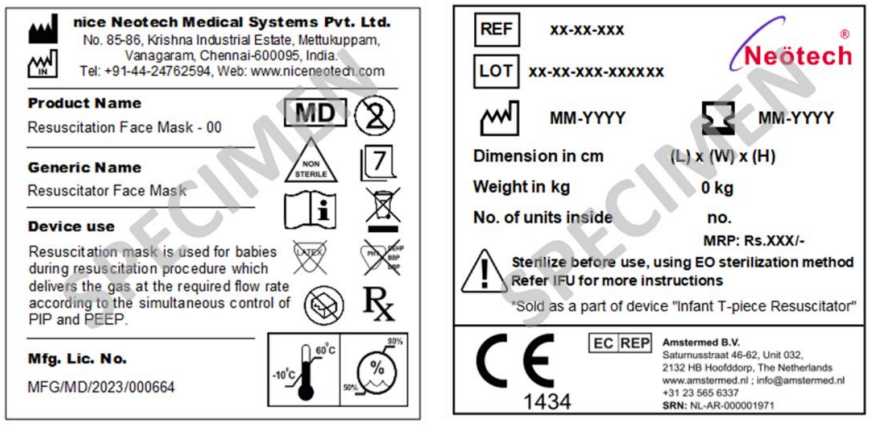
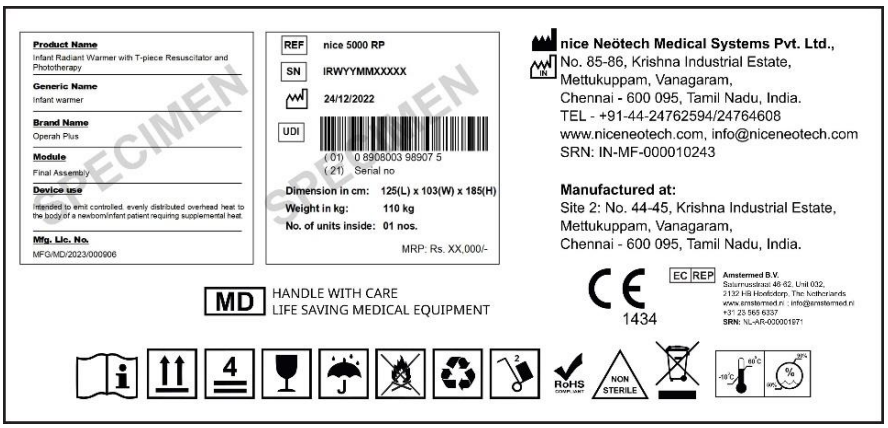
6.		92-00-254	Resuscitation
7.		92-00-252	Front panel switches (Keypad)
8.		92-00-253_03	Probe connector & keys

9.		92-00-255	Gas input
10.		92-00-253_02	Power switch, Power IN & Circuit breaker
11.	CLOSE THE DOOR IF OPENED	92-00-018	Access Door (Close the door)
12.		92-00-240	Skin temperature probe cable tag
13.		92-00-097	Eye Pad

14.		92-00-239_01	Mattress
15.		92-00-253_01	Marking plate & Information
16.		92-00-002	Neotech Logo (In pillar)

17.	Neötech®	92-00-272	Neotech Logo (In heater box)
18.	Operah plus	92-00-253	nice 5000 RP Brand Label
19.	MASIMO SET® rainbow	92-00-253	Masimo brand label
20.	REF SN	92-00-253	Reference and Serial Number
21.	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. 92-00-253_04, Iss 01, Rev 00	--	Device Use
22.	UDI (01) 0 8908003 98907 5 (21) IRW230200898	--	UDI Label
23.	CE 1434 EC REP Amstermed B.V Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. www.amstermed.nl; info@amstermed.nl Tel:+31 23 565 6337. SRN: NL-AR-000001971. 92-00-253_4, Iss 01, Rev 01	92-00-253_4	CE marking and EC REP details
24.	92-00-098 Rev 00 TOLL FREE 1800-425-2594 (INDIA only) Email: service@ niceneotech.com	92-00-098	Toll free

25.		--	Packing label – Skin Temperature Probe
26.			Packing Label - Mattress
27.			Packing label - Auxiliary Skin Temperature Probe
28.		--	Packing label - Eye Pad

29.		--	Packing label – Resuscitation Accessories (T-Piece Resuscitator circuit)
30.		--	Packing label – Resuscitation Accessories (Resuscitation face mask)
31.		--	Packing box –Transport and Storage instruction

Section 1: Description

1.1 Intended Use

The Model nice 5000 RP has Infant Radiant Warmer with T-piece resuscitator and Phototherapy for warming pre-mature babies, neonates and infant with a body weight of up to 10 Kg to maintain the body temperature at the desired level; designed to provide light of suitable wave-length and intensity for the treatment of hyperbilirubinemia and also to provide the controlled suction and oxygen based Manual resuscitation facilities necessary in helping the new born baby with breathing difficulties survive the immediate post- natal period.

1.2 Medical Indication/Conditions

- To Maintain baby's Body temperature
- For the treatment of neonatal Hyperbilirubinemia
- For Resuscitation support

1.3 Contraindication

- Hypoxic Ischemic Neonatal Encephalopathy
- Conjugated hyperbilirubinemia
- Subjects with lung immaturity

1.4 Side-effects

- Infant Radiant Warmer may affect insensible water loss and can also induce rapid drying of the skin surface.
- Phototherapy may affect insensible water loss, retinal damage, rashes.
- Resuscitator may affect the infant's ribs livers, lungs, and heart, however these risks may be accepted if resuscitation is necessary to save the infant's life.

1.5 Intended Patient Population

Premature babies, Neonates and Infants with a body weight up to 10 Kg body.

1.6 Device Intended User:

Neonatologist and Healthcare Professionals.

1.7 Working Principle

Infant Radiant Warmer:

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

T-piece Resuscitator:

T-Piece Resuscitators are typically gas powered, and capable of delivering a pre-set, consistent and controlled peak inspiratory pressure (PIP) and positive end-expiratory pressure (PEEP), helping to protect the lungs from injury and also establish and maintain functional residual capacity (FRC). FRC is the volume of air that remains in the lungs following a typical expiratory phase. The T-Piece connects to a face mask or other interface to deliver a flow regulated, pressure limited gas supply to the infant, enabling application of controlled initial inflation breaths. PIP is the maximum inspiratory pressure required to improve oxygenation without causing adverse effects. Delivering a controlled PIP is important as uncontrolled PIP that is too high may lead to lung injury, while under-inflating the lungs may not provide adequate gas exchange. PEEP is the pressure in the lungs above atmospheric pressure (the pressure outside the body) that exists at the end of the expiration and is used to optimize oxygenation by preventing alveolar collapse.

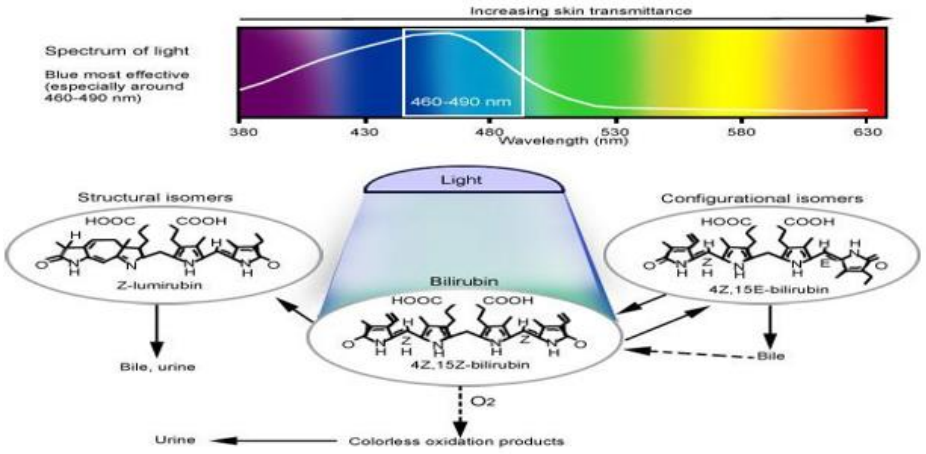
A device consists of a maximum pressure relief valve, an inspiratory pressure control valve, and a manometer connected to an external gas (O2 cylinder flow meter/air O2 blender flow meter/centralised oxygen flow meter). The required PIP can be adjusted and set using the PIP valve from -20cmH2O to 80cmH2O. The PEEP can be adjusted and set on the breathing circuit exhalation port knob of PEEP knob. The factory setting of Maximum Pressure Relief is 40 cmH2O and can be adjusted from 5-74 cmH2O. A manometer is provided to monitor the delivered PIP and PEEP. A flow rate of 5–15 LPM is given to the patient from the gas source. Depending on the set input pressure level in the external supply gas (50-60 psi), pressure gets expelled when it exceeds the set pressure level. The PEEP knob is used for varying the PEEP for say, from 1 to 10 cmH2O at
7 LPM input flow, and it helps in the inspiration (1 to 66 cmH2O) and expiration cycles of gas to the neonates by using the thumb operation.

Phototherapy:

Some “normal” jaundice will disappear within a week or two without treatment. Other babies will require treatment because of the severity of the jaundice, the cause of the jaundice, or how old the baby is when jaundice appears.

Light in the blue region of the spectrum, near 460 nm, is most strongly absorbed by bilirubin. However, only light that penetrates the skin and is absorbed by bilirubin provides the needed photochemical effect. Tissue penetration increases as the wavelength of the light increases. Thus, one must balance the use of a higher wavelength of light, which more readily penetrates tissue, with the use of a wavelength that is more readily absorbed by bilirubin, which may penetrate less deeply. With this in mind, light in the 450-465 nm wavelength is used phototherapy.

Spectral irradiance is measured in watts per centimeter, or microwatts per square centimeter per nanometer (mW/cm2 per nm) over a wavelength band. Spectral power increases as the amount of skin exposed to phototherapy increases. Infants receiving phototherapy should be left only in their diaper, allowing adequate surface area exposure for phototherapy.



The dose of phototherapy, in mW/cm2 per nm, should be measured during phototherapy using a radiometer. These devices typically measure the spectral irradiance of phototherapy in the 425-475 or 400-480nm band wavelength. Measurements of spectral irradiance can differ greatly depending on where on the infant the measurement is made, taking several measures in different locations on the infant and averaging the values is important.

Masimo Pulse Co-oximeter:

Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).

The amount of arterial blood in tissue changes with your pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well. The Masimo rainbow set pulse co-oximeter uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, and blood plasma.

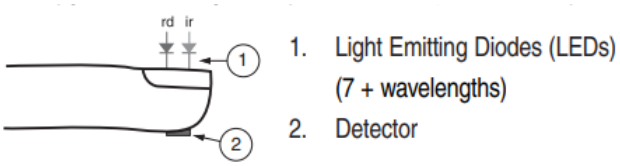


Figure 4

The Masimo rainbow set utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to a diode (detector). Signal data is obtained by passing various visible and infrared lights (LEDs, 500 to 1400nm) through a capillary bed and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the Radical-7 for calculation.

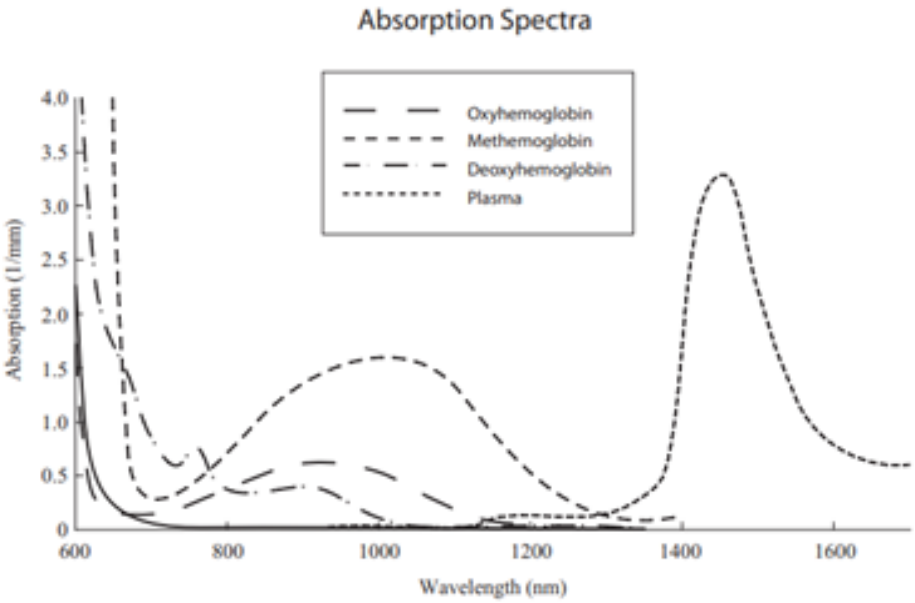


Figure 5

Once the Masimo Rainbow SET receives the signal from the sensor, it utilizes signal extraction technology to calculate the patient's functional oxygen saturation (SpO_2 (%)),methemoglobin (SpMet* (%)), Total Hemoglobin concentration (SpHb* (g/dl)) and pulse rate (PR (BPM)). The SpMet* and SpHb* measurements rely on a multiwavelength calibration equation to quantify the percentage of carbon monoxide and methemoglobin and the concentration of total hemoglobin in arterial blood. In an ambient temperature of 35º C the maximum skin surface temperature has been measured at less than 106º F (41º C), verifi ed by Masimo sensor skin temperature test procedure.

NOTE: When a Masimo Rainbow Sensor is properly connected to the patient, the instrument normally goes through a 20-30 second sensor calibration/pulse search routine and then displays numeric values for SpO_2, SpMet, SpHb, Pulse rate (PR), Perfusion Index (PI) and Pleth Variability (PVI). It also provides graphical displays for plethysmographic waveform, Signal Identification and Quality Indicator (Signal IQ). However, if the sensor calibration/pulse search routine is unsuccessful for Rainbow parameters/measurements, the instrument automatically switches to a "SpO_2 Only Mode" to provide SpO_2 , PR, PI and PVI* parameters/measurements for the user.

SpMet*, SpHb*, PVi* - Optional features

1.8 Device Description

The model nice 5000 RP Operah Plus Infant Radiant Warmer with T -Piece Resuscitator, Phototherapy and accessories designed to provide warming for new-born and pediatrics patients; designed to provide a light of suitable wavelength and intensity for the treatment of hyperbilirubinemia; and also to provide the controlled suction and oxygen based Manual resuscitation facilities necessary in helping the new born baby with breathing difficulties survive the immediate post- natal period.

Operah Plus provide a controlled source of radiant heat by Infant Radiant Warmer, blue light by Phototherapy, resuscitation by T-Piece Resuscitator for infants and pediatric patients and Masimo rainbow pulse co-oximeter. monitors SpO_2 , PR and Pi for patients And Optiona Feature (SpHb,PVI,SpMet).

Operah Plus comes with a integrated touch display as a control system built using microcontroller. Patient temperature along with set temperature, phototherapy lamp functions and pulse co-oximeter functions are controlled and displayed in the TFT display. A complete audio and visual indication system is included on the display panel.

1.8.1 Mechanical Layout

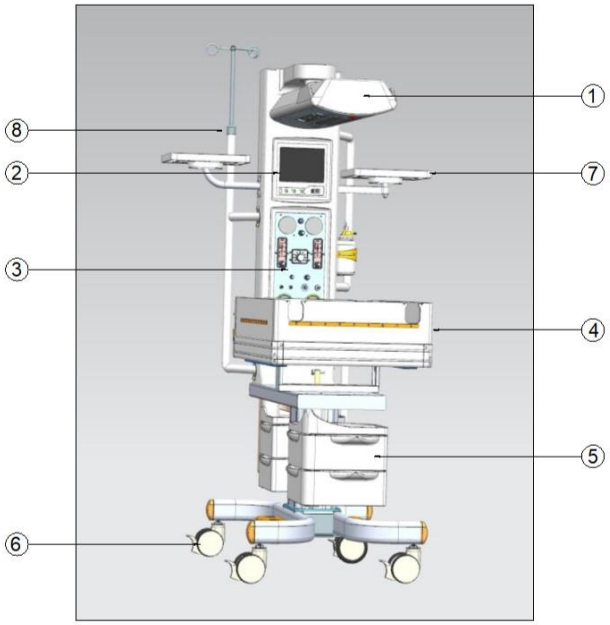


Figure 1

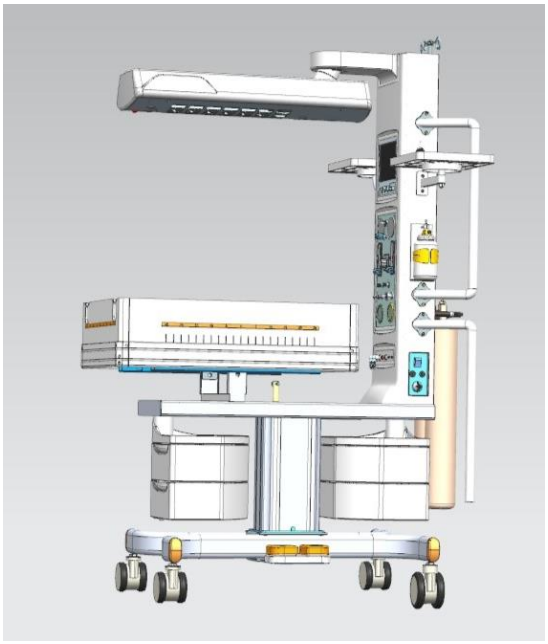


Figure 2

S.No	Parts
1.	Heater Module
2.	TFT touch control panel
3.	Resuscitation assembly
4.	Mattress platform
5.	Storage cabinet
6.	Height adjustment pedal
7.	Mayo tray
8.	IV hook

The heat loss in some new-born babies is rapid; hence, infant radiant warmers provide artificial support to keep the body temperature constant. The four operating modes for infant radiant warmers are Baby mode, manual, Prewarm, and safe. Both the patient temperature and the preset temperature are digital for ease of reading. A complete visual signaling system is located on the heater module and audio in pillar side. To protect the baby from hyperthermia (body temperature above 37.5°C), Neötech uses i-sense technology, which can automatically detect a drop in temperature and reduce the heater's output by 50%. If the baby's temperature falls below the set temperature, the microcontroller will transmit feedback to the heater, which will raise the heater output until the temperature exceeds the set temperature, after which the heater output will be lowered. Operah Plus enables the priority of audio and visual indications to alert the doctor/clinician promptly when an error arises, or attention is required. Observation lamp control with intensity adjustment in the control panel.

Infant Radiant Warmer with Bed includes a mattress and transparent side panels, and an X-ray cassette tray (located beneath the bed), allows X-rays to be taken without moving the patient. The height between the bed platform and heater module can be adjusted using motorized pedal operation.

1.8.2 Heater Module Structure

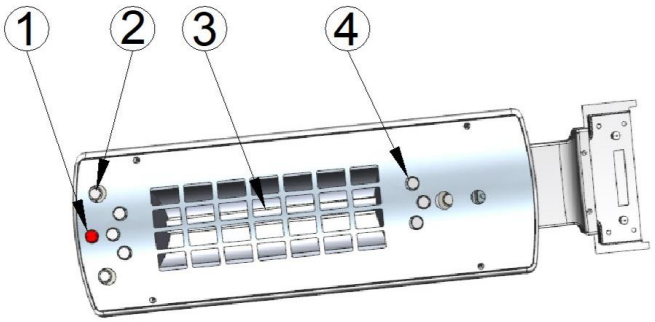


Figure 3

S.No	Parts
1.	Visual alarm indicator(Visual indicator)
2.	Blue LED for phototherapy
3.	Heater
4.	Observation Lamp LED

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.

Bed-to-heater spacing which differs from the specified 80-85 cm will result in incorrect operation and may affect the patient's condition.

1.8.3 Control Unit

Operah Plus comes with a integrated TFT touch control panel to operate infant radiant warmer, phototherapy and Masimo rainbow set pulse co-oximeter.

The resuscitation panel in 5000 RP, enabling users to perform T-Piece resuscitation operations, perform suction procedures and auxiliary control functions.

The control panel allows the user to access the radiant warmer operations through four modes of operation: baby mode, safe mode, manual mode, pre-warm mode.

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 probe 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 skin temperature between 32°C to 38°C. Auxillary probe is provided optionally to monitor the skin temperature in peripheral region (foot).

Safe mode:

In safe mode of operation, the heater output power is maintained at 40% and the actual skin temperature is displayed.

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 skin temperature will still be displayed when skin temperature sensor is attached with baby.

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.

HIE Function:

HIE Function is a no warm mode, control unit enables the user to only monitor the baby skin temperature in this mode of operation.

Other control unit features:

Operah Plus enables the user to operate phototherapy by adjusting the intensity setting in the integrated control panel.

Operah Plus's integration with Masimo rainbow set pulse co-oximetry enables monitoring and alerting the parameters such as: arterial Oxygen Saturation (SpO_2), Total Haemoglobin Concentration (SpHb)* , Pulse Rate (PR), Perfusion Index (Pi), Methemoglobin (SpMet)* and Pleth Variability Index (PVi)*.

*Optional features

I-sense Technology:

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

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

Operah Plus enables the priority of audio and visual indications to alert the doctor/clinician promptly when an error arises or attention is required.

Operah Plus holds the patient trend graph with details of patient when admitted to monitor and trace the improvement of the patient.

Observation lamp control with intensity adjustment in the control panel.

1.8.4 LED Phototherapy

Operah Plus enables the treatment for hyperbilirubinemia by using 3 nos. of high power blue LED.

Control panel of Operah Plus monitors the total usage hours of the LED and lifetime of the LED is approximately 20,000 hours.

Treatment time can be enabled to automatically cut-off the phototherapy light after the set required hours for the treatment.

1.8.5 Auxililary Oxygenation System

An auxiliary oxygen system is designed to provide supplemental oxygen to individuals who require increased levels of oxygen to maintain adequate oxygenation. An oxygen outlet is provided on the pillar delivered to patient via bag resuscitator, oxygen masks or oxygen hood. The oxygen flow rate can be adjusted using the flow metre control valve provided, and the maximum supply pressure is limited by an internal pressure relief valve for safety. The Humidifier bottle in the auxiliary system provides humidified oxygen to the patient.

The oxygen flow rate can be adjusted using the flow meter control valve provided, and the maximum supply pressure is limited by an internal pressure relief valve for safety.

1.8.6 Mechanical ventilation system

1.8.6.1 T-piece Resuscitator

An outlet is provided on the front panel to enable PIP (Positive Inspiratory Pressure) to be administered, it will be necessary for the user to manually occlude the knob of a T-Piece attached to the baby's face mask / endotracheal tube to achieve mechanical ventilation.

The oxygen flow rate can be adjusted using the flow meter control valve provided, and the maximum airway pressure can be adjusted using the variable pressure relief valve and the airway pressure gauge to monitor PIP and PEEP value. An internal pressure relief valve is also included to limit the maximum system pressure for safety.

1.8.7 Masimo rainbow set pulse co-oximetry

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a hand or foot for neonates. The sensor is connected to the Pulse CO-Oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument.

The instrument displays the calculated data in following ways:

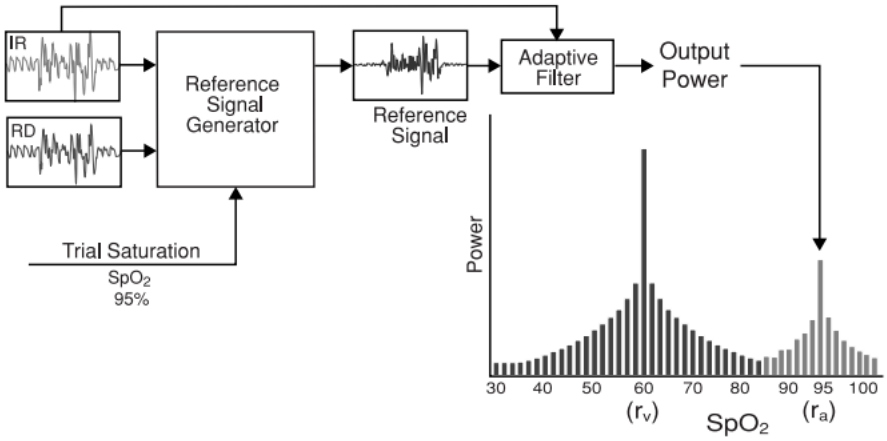
1. As a percent value for arterial oxygen saturation (SpO_2)
2. As a pulse rate (PR)
3. As a plethysmographic waveform
4. As a percent value for methemoglobin concentration (SpMet)*
5. As a percent value for total hemoglobin (SpHb)*
6. As a percent value for perfusion index (Pi)
7. Pleth Variability Index (PVi)*

*Optional features

Description

Conventional pulse oximetry works under the assumption that by looking at only the pulse and normalizing the pulsating signal over the non-pulsating signal, oxygen saturation (SpO_2) can be measured without calibration. Although this was a big step forward in the evolution of pulse oximetry, it has one major flaw–it assumes the only pulsating component is arterial blood. Unfortunately for conventional pulse oximetry, venous blood moves every time the patient moves or breathes. This causes conventional pulse oximeters to display false low or high SpO_2 and pulse rates–resulting in false alarms as high as 90% in ICUs and recovery rooms.

Masimo Signal Extraction Technology's signal processing differs from that of conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the venous blood also moves, causing conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise). Masimo SET pulse oximetry utilizes parallel engines and adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. The Masimo SET signal processing algorithm, Discrete Saturation Transform (DST), in parallel with Fast Saturation Transform (FST), reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.



1.8.8 Suction system

The suction system is designed to collect the secretion of fluids like excess mucus, saliva, or amniotic fluid from the respiratory and oral passages of infants. This helps to maintain a clear airway and prevent the risk of aspiration. Suction is achieved using an oxygen activated venturi slow suction system in the control module. This is connected to a suction bottle, mounted on the bassinet support, via a tubing adaptor on the front panel. A bacterial filter is included in the suction tube to isolate the bottle from the control system. The level of suction can be adjusted using a control knob on the front panel, and a vacuum gauge is provided to indicate the degree of suction achieved. It has a level mark to indicate the level of fluid collection to allow medical personnel to monitor the suctioned fluids easily. It is equipped with a cap to secure the collected contents and prevent spillage.

To minimize setting-up time an on/off switch is also provided. The level of suction required can be pre-set before resuscitation is necessary and the system switched off until required for use.

An internal pressure relief valve is also included to limit the maximum suction pressure for safety.

1.8.9 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.

Motorized tilting of bed platform allows Trendelenburg and Reverse Trendelenburg positioning. The system for the tiltable bed provides a smooth motion to avoid disturbing the patient.

Height between the bed platform and heater module can be adjusted by using motorized pedal operation.

1.9 UDI Carrier

This UDI system consists of Device Identifier (DI) and Production Identifier (PI). The same is incorporated and followed throughout the device life cycle. The UDI is placed on the device itself or on the packaging labels (for all packaging levels) as applicable.

Device Variant	Device Identifier (DI)	Production Identifier (PI)
nice 5000 RP	08908003989075	IRWYMMXXXXX IRW- Product Code YY – year MM – Month XXXXX – serial No

UDI label


Section 2: Installation

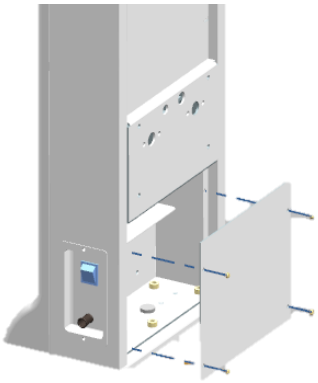
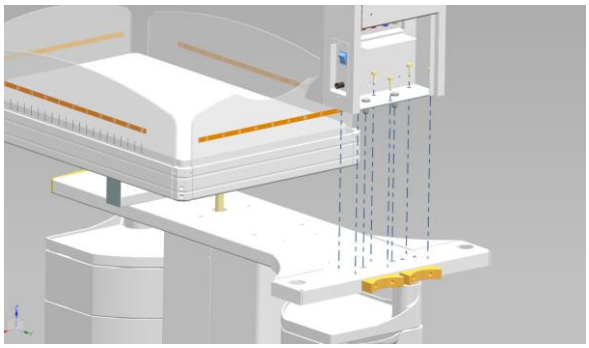
2.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of Operah Plus.
- 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.

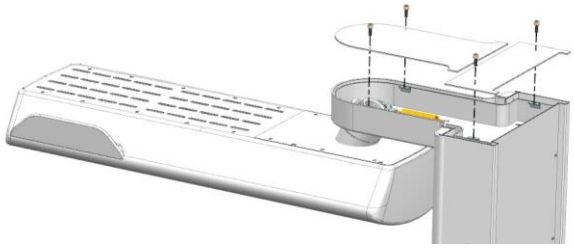
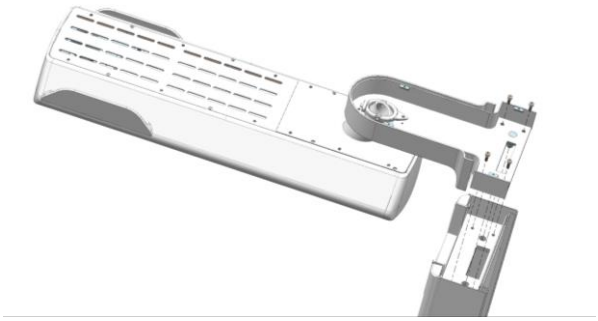
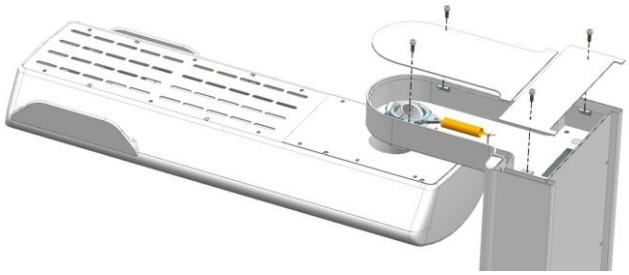
Do not use the equipment, if it appears or is suspected to be damaged.

2.2 Installation of Pillar to Base assembly

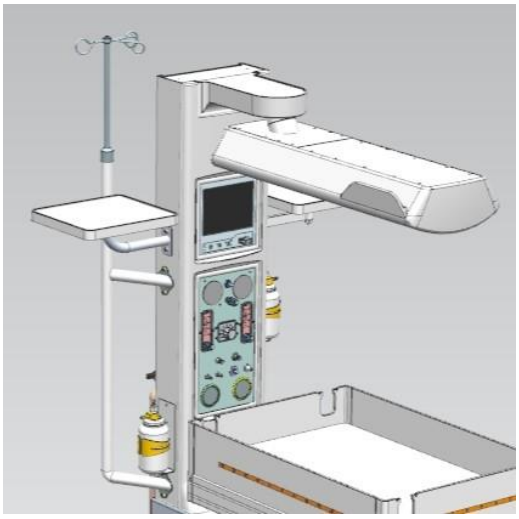
 Picture 1	• Open pillar cover, by unscrewing the M4PNPL screw as shown in the figure.
 Picture 2	• Install the pillar assembly to the base, by locating the pin on the pillar to the base. • Then screw the M10 Allen bolt as shown in the figure below.

 Picture 3	• Perform the wiring as per the drawing. • Then close the pillar cover using M4PNPL screw as shown in the figure.

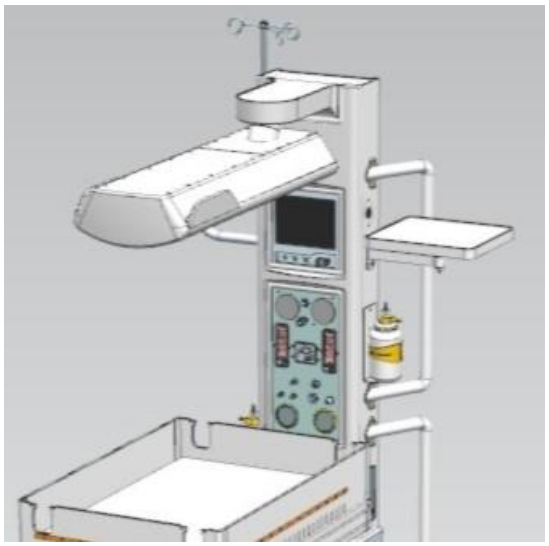
2.3 Installation of Heater to Pillar assembly

 Picture 4	• Open heater cover, by unscrewing the M3PNPL screw as shown in the figure.
 Picture 5	• Install the heater assembly to the pillar, by locating the pin on the heater assembly to the pillar. • Then screw the M10 Allen bolt as shown in the figure below.
 Picture 6	• Perform the wiring as per the drawing. • Then close the heater cover using M3PNPL screw as shown in the figure.

2.4 Installation of IV poles along with IV hook and Mayo tray



Picture 7



Picture 8

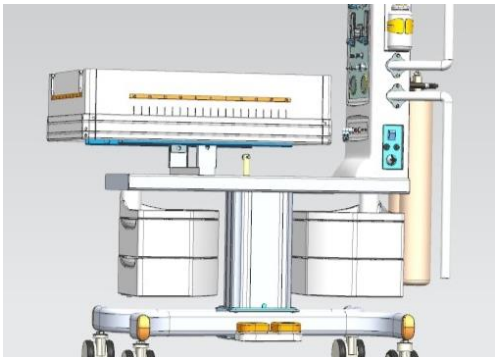
- Install the IV pole to the groove provide in the bed platform, screw the clamp as shown in the figure.
- Then insert the IV hook or Mayo tray as shown in the figure and then put the pole bush along with top of the hetear module.

2.5 Resuscitation Assembly Setup

2.5.1 Fitting the suction and humidifier bottle

Picture 9

Place the Suction Bottle and humifidier Bottle in the Suction Bottle Mounting Bracket and the humifidier Bottle Mounting Bracket on the right and left side of the pillar.



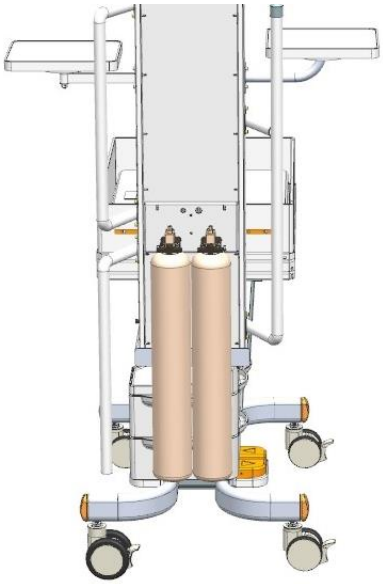
Picture 10

Push the Suction Tube Adaptor into the Suction Connector and Humifidier Tube Adaptor into the Auxilary Connector respectively on the Resuscitation Module Control Panel and hand the Patient Tube over the bottle.

2.5.2 Fitting the air and oxygen cylinder (optional)

Picture 11

A yoke assembly is provided at the back of the pillar to connect the air and oxygen cyclinder.

 Picture 12	Fix the oxygen cylinder in the yoke assembly and lock it. It is tightened using the knob provided in the yoke assembly.
 Picture 13	In the same way, the other cylinder is placed in the other yoke assembly.

2.5.3 Fitting wallmount air and oxygen supply

 Picture 14	Air and Oxygen DISS fitting are provided at the back of the pillar. Here the wallmount supply for air and oxygen can be given.

2.6 Pre-use Check Instructions

2.6.1 Mechanical Pre-use Check Instructions

- Before using the nice Neötech Infant Radiant Warmer, read this entire manual. Attempting to use this device without a thorough Understanding of its operation may result in patient or user injury.

Warning

- Do not perform the Pre-use Check Instructions (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 Pre-use Check Instructions it must be removed from use and repaired.

2.6.1.1 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 Pre-use Check Instructions

- 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.

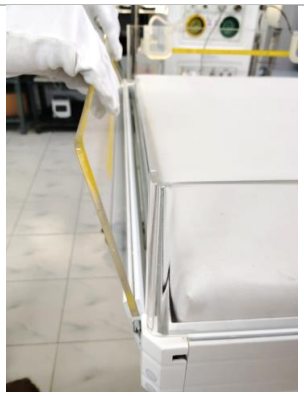
2.6.1.2 Heater Assembly Rotation

Picture 15

- Tilt the heater box to both sides.
- Check if the heater box locks at 90° angle (approx.) on both sides.

2.6.1.3 Side Panels

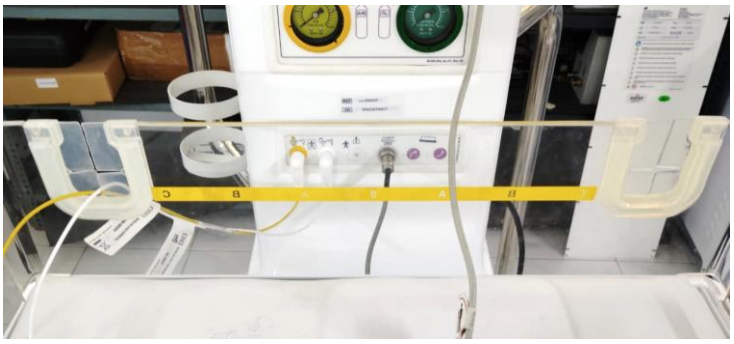
- Lift the side panels and show its way out from the hook.
- The panel must swing freely after removing from its hook; all panels can be operated in the same way.



Picture 16

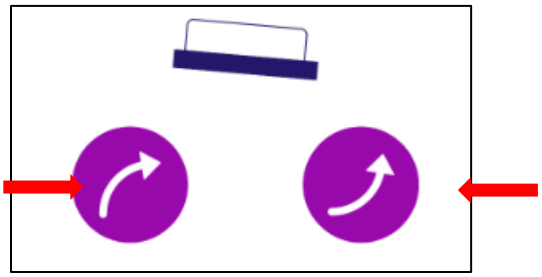
Picture 17

- Grommets are provided in side pannel.



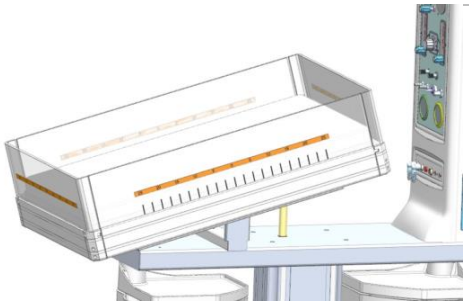
Picture 18

2.6.1.4 Tilting Mechanism

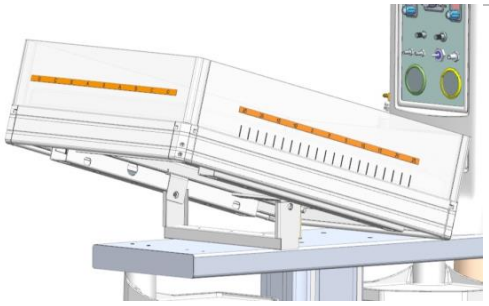


Picture 19

- Press the bed platform tilting key in the pillar to tilt the bed platform to Trendelenburg and Reverse Trendelenburg positions.



Picture 20



Picture 21

- Check the operation of the tilt mechanism. Verify that the bed platform operates smoothly and locks in normal, Trendelenburg and Reverse Trendelenburg positions.

Caution

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

2.6.1.5 Height adjustment

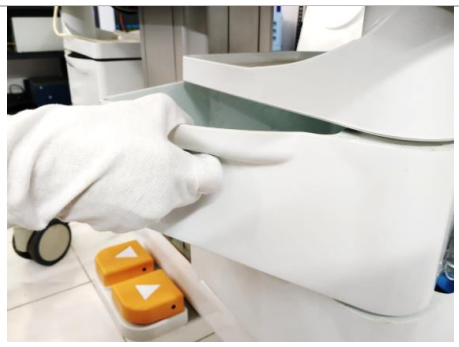
Picture 22

- Press the increase and decrease pedal switch on the base to check the height between the bed platform and heater module is changing accordingly

➔ **Upward pedal switch**

➔ **Downward pedal switch**

2.6.1.6 Storage cabinet



Picture 23

- Check whether all the 4 cabinets can be accessed easily by pull and push operation .

2.6.1.7 Accessory Checks

- Perform these checks if they are applicable.
- Check that all accessories are mounted securely and that the load limits mentioned in the labels are not exceeded.
- Check that all gas accessories are installed and operating properly.
- Where applicable, perform the Pre-use Check Instructions 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:

IV Pole	: maximum load: 1.5 kg
Mayo Tray	: maximum load: 3 kg
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

2.6.2 Control Unit Pre-use Check Instructions

- Do not perform the Pre-use Check Instructions (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 Pre-use Check Instructions it must be removed from use and repaired.

2.6.2.1 Control Unit Check

Connect the Infant Radiant Warmer power cord to an appropriate power source. Refer to the rating label on the Infant Radiant Warmer for the proper voltage needed.

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

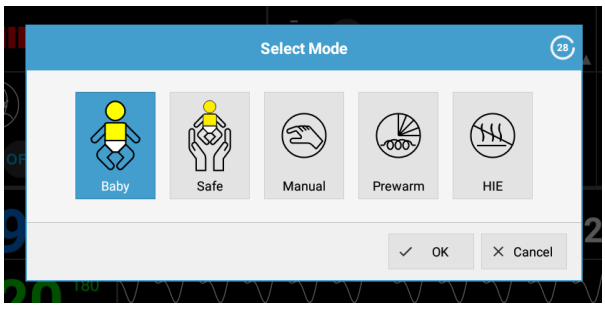
- Check that the control panel switches ON with Neotech logo followed by Operah Plus displayed on the screen.
- Check that the system initializes on self check mode, verify pink light on the Visual alarm indicatorin the heater module.

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 3.4 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 probe to check that the Baby sensor fail indication lits up with both audio & visual indication.
- Press the Timed Acknowledged key to check that the audio indications are paused for certain time duration.
  (*Refer to Section 3.4 for full information on operation*)
- Press the lamp icon on the control panel and check that all the 6 observation lamps lit up.

- Select the APGAR timer and select the desired time and check that the timer is displayed on the control panel.

2.6.2.2 Phototherapy Unit Check

- Switch ON the phototherapy lamps by going through the MENU option in the control panel and press LED PT option, check that all the phototherapy lamps lit up. Also check whether the lamps go off when LED PT option in the MENU is pressed again [*Refer to Section 3.7 for full information on operation]*

- Check that irradiance level is at least 25-30 µW/cm^2/nm of the phototherapy lamp from the center of the bed by using any standard irradiance meter. (e.g. Neötech-irradiance meter, Minolta / Air-Shields Fluoro-Lite Meter / International lights)

- If a lamp or unit fails to light correctly check for the possible cause and rectify before the system is put into service.

2.6.2.3 Masimo Rainbow SET Pulse Co-oximetry Pre-use Check

1. Connect a patient cable or a direct cable sensor to the Patient Cable Connector in the right side of pillar of Operah Plus. Make sure it is a firm connection and the cable is not twisted, sliced or frayed.
2. Select a sensor that is compatible with the Pulse CO-Oximeter before connecting it to the patient cable or instrument. See section 3.22, Sensors and Patient Cables. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the detector are properly aligned. Remove any substances that may interfere with the transmission of light between the sensor's light source and detector.
3. Attach the sensor to the patient. Refer to the Directions for Use of the sensor Section 3.22.2.
4. Switch ON the device and control panel of Operah Plus.
5. Make sure the display window is free of alarm and system failure messages (see Section 3.10, Audio and Visual indication)
6. On the display, verify:
    - The high and low alarm limits for SpO_2, PI and pulse rate.
    - The readings for SpO_2 , PI and pulse rate.

NOTE:

- "- - -" initially shows in the numeric display fields for all the parameters/measurements when the Radical-7 is turned on. As the system starts monitoring, the numeric display fields update (refresh). The numeric display fields for the parameters/measurements begin to show numbers during the refresh cycles even though the numbers have not stabilized; during this period, the measurement label will flash to indicate that the measurement value is being processed. When the flashing stops, the number has stabilized (less than 15 seconds for SpO_2 , PI and pulse rate.

7. Verify that the patient alarms are functional by setting the high and low SpO_2, PI, and pulse rate alarm limits beyond the patient readings.
    - An alarm tone sounds.
    - The violated alarm limit and reading flash on the display.
    - The red alarm indicator flashes on the Pilot lamp.
8. Verify the sensor alarms are functional by removing the sensor from the sensor site or patient cable or instrument.
    - "Sensor Off" appears in the message area of the graphic display.
    - The alarm tone sounds.
    - The alarm indicator flashes.
9. Verify alarm Pause operation.
    - Create an alarm condition by lowering the SpO_2 or pulse rate high alarm limits beyond the patient readings.
    - Press the Timed Acknowledged button.
    - The alarm tone ceases for the displayed amount of time.

2.6.3 Resuscitation Assembly Pre-use Check Instructions

2.6.3.1 General

- Check that the Suction System is clean, undamaged and correctly assembled.
- Check that an Oxygen Cylinder is fitted for their emergency standby user operation as applicable.
- Check that adequate supplies of sterile Endotracheal Adaptors, Oxygen Tubing, Y - piece Connectors, Suction Catheters, etc, are available for use.
- If a Bag Resuscitator or similar equipment is to be used check that it is clean and undamaged and that the Manufacturer's operating instructions are available and consulted before use.
- If the elapsed time from start of resuscitation is to be recorded, check that a suitable Clock or Timer is available, and that it is operational in accordance with the Manufacturer's instructions.
- Carry out a Functional Test to ensure operational integrity before placing an infant on the nice 5000 RP. This may be done while the nice 5000 RP is being warmed up prior to use.

2.6.3.2 Functional test

a) Check that both flow meters are turned off (clockwise) and the Suction Control Switch is OFF.

- Do not use excessive force when closing a control valve or damage to the valve set and leakage may occur.

b) Check that a Tubing Adaptor Stem is fitted in the auxiliary and Manual ventilation outlet connectors.

- To fit the adaptor, push the plain end firmly into the connector.
- If an oxygen supply hose is fitted, remove the sensor from the pipeline terminal.

c) Check the Oxygen Cylinder supply pressure. If two cylinders are fitted check each separately.

  - Open the valve on one oxygen cylinder two full turns anti-clockwise and listen for any sound of gas leakage.
  - open and close a flow meter valve to vent the system, and then note the operating pressure on the cylinder pressure on the cylinder pressure gauge.
  - For satisfactory operation the pressure should be in excess 35 bar. A full cylinder/ will indicate approximately 137 bar.
  - Close the cylinder valve again/then repeat with the second cylinder if applicable.
  - If two cylinders are fitted, place an IN USE' label on the cylinder indicating the lower pressure and keep the other for standby.

- If an Oxygen Supply Hose is fitted, connect the probe to a suitable pipeline terminal to continue testing.

IMPORTANT - Keep the oxygen cylinder valves closed when a pipeline supply is used or cylinder valves closed when a pipeline supply is used or cylinder gas may bleed into the system and result in an exhausted cylinder when required for emergency use.

d) Check the Auxiliary Oxygen System.

- Turn on the Flow meter and set the flow to 3 Liters / min.
- Occlude the outlet stem and check the internal pressure relief valve is hard to operate. This will limit the maximum pressure achieved to between 36 and 44 cmH_20.
- Turn off the Flow meter and check that flow ceases.

e) Check the Manual Ventilation System.

- Check manometer reads zero with no gas flow.
- Connect oxygen supply to gas inlet port using gas supply line.
- Connect patient supply line and patient T-piece to the gas outlet port.
- connect test lung to patient T-piece (before use, inspect test lung for signs of damage such as discolor)
- Adjust gas supply to desired flow rate between 5 and 15 LPM.
- To check Maximum Pressure, Occlude PEEP cap and turn PIP control fully clockwise adjust maximum pressure control knob clockwise or counterclockwise to set desired maximum pressure.
- To set PIP, while still occluding the PEEP cap, turn PIP control knob counter-clockwise until the desired peak inspiratory pressure is set.
- To set PEEP, adjust PEEP cap to the desired PEEP level.
- Occlude the PEEP knob and, this will limit the Peak Inspiratory pressure achieved between set PIP Value.
- Turn off gas supply and remove test lung from patient T-piece.
- Ensure that the rigid plastic connector of the test lung is also removed from the T-piece before attempting to connect a mask or endotracheal tube. Failing to do so may cause unacceptable delays during patient resuscitation.

f) Check and set up the Suction Control System (venturi slow suction).

- Switch ON the suction system then occlude the patient suction tube outlet.
- Turn the suction control knob anti-clockwise and check the suction can be increased to the maximum permitted by the system 0-150 mmHg.
- Set the approximate level of suction required for use, then switch OFF the system and check that suction cases.

➢ If the oxygen cylinder supply was used for testing, check the cylinder operating pressure again, then close the cylinder valve (clockwise) to prevent leakage. Always keep the oxygen cylinder valve closed when not in use.

➢ If any part of the test fails, rectify the fault or contact a qualified Service Engineer before using the equipment.

➢ For valuable information on the physiology and management of birth asphyxia, a publication entitled 'A guide to Resuscitation of the Newborn infant".

Note: Market available disposable patient circuit, mask can be used.

2.7 Sterilization Instructions

2.7.1 Preparation

- Visually inspect the breathing circuit and Resuscitation face mask. Do not use if it is damaged.
- Do not remove circuit from package prior to sterilization.
- Place an EO indicator tape on the outside of each sterilization pack.
- Ensure labeling and lot tracking are applied according to hospital or facility policy.

- Sterilize using Ethylene Oxide (EO) only prior to clinical use.
- Do not use steam, gamma, or other sterilization methods, as they may damage the circuit and compromise safety.

2.7.2 Sterilization Process

Use a validated EO sterilization cycle appropriate for your equipment and load configuration. A general guideline is as follows:

Parameter	Recommended Range
EO Concentration	450 to 1200 mg/l
Temperature	40 to 60°C
Chamber Humidity	60 to 80%
EO Exposure time	1 to 6 hours

- Avoid overloading the chamber.
- Ensure adequate space for EO circulation.

2.7.3 Aeration (EO Residual removal)

To reduce EO residuals, perform aeration immediately after sterilization as given general guidelines below or follow facility's validated aeration protocol.

Method	Aeration conditions
Heated Aeration	12–24 hours at 50–55 °C in a dedicated aeration cabinet
Ambient Aeration	7 days at room temperature (≥20 °C)

- Do not use the product until aeration is complete.
- Ensure adequate aeration before patient contact.

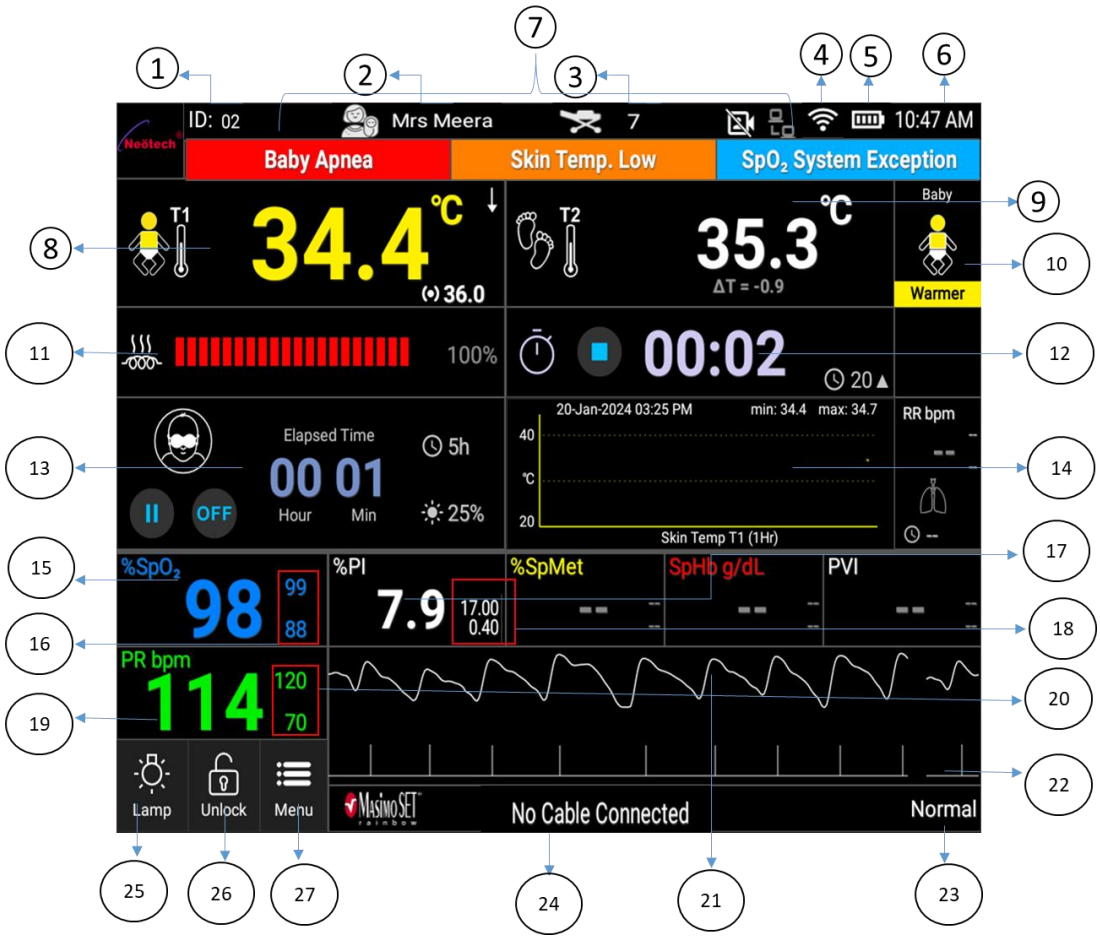
2.7.4 Post-Aeration Release

- Verify package integrity and indicator color change.
- Ensure the sterilization cycle was completed successfully (review cycle records).
- Do not use the product if:
  - Packaging is compromised
  - Indicator fails to show sterilization
  - Required aeration has not been performed

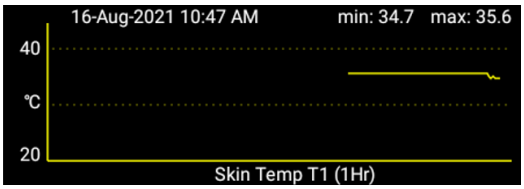
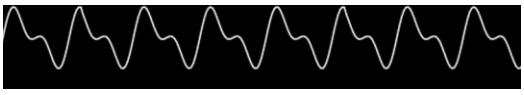
- Do not attempt to resterilize after use.
- Ensure proper handling to avoid contamination after EO sterilization.

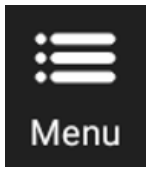
Section 3: Operation

3.1 TFT Touch Control Panel Display

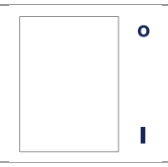


S.No.	Control panel icons/displays	Display names	Description
1.		PATIENT ID	Patient ID is displayed on top of the screen
2.		MOTHER'S NAME	Mother's name is displayed
3.		BED NUMBER	Bed no. is displayed
4.		Wi-Fi	Wi-Fi icon is displayed when Wi-Fi is enabled
5.		BATTERY PERCENTAGE	The TFT display's battery percentage is indicated
6.		TIME	Curent time is displayed
7.		ALARM INDICATION PANEL	Indicates the audio and visual alarm. 3 indications at a time.
8.		SKIN TEMPERATURE (T1) & BABY SET TEMPERATURE	Baby's temperatue and the baby set temperature is displayed
9.		AUXILIARY TEMPERATURE (T2)	The auxiliary temperature of the baby is displayed
10.		MODE SELECTION	Used to select modes such as baby mode, safe mode, manual mode, prewarm mode, HIE function.
11.		HEATER OUTPUT	The heater output is displayed as heater output percentage
12.		APGAR TIMER	APGAR timer displays time in minutes (1 - 59 mins)

13.		PHOTOTHERAPY	Phototherapy controls are displayed
14.		TREND SCREEN	The trend screen displays the trend data of the Skin temperature T1
15.		SpO_2 MEASURED VALUE	The value of oxygen saturation is displayed in percentage
16.		SpO_2 ALARM LIMITS DISPLAY	High and Low alarm limits of SpO_2 are displayed
17.		Pi MEASURED VALUE	Perfusion index indicates the pulse strength numerically in percentage
18.		Pi ALARM LIMITS DISPLAY	High and Low alarm limits of Pi are displayed
19.		PULSE RATE MEASURED VALUE	Pulse rate measured is displayed in beats per minute (bpm)
20.		PR ALARM LIMITS DISPLAY	High and Low alarm limits of PR are displayed
21.		PLETHYSMOGRAPHIC WAVEFORM	Plethysmographic waveform is displayed as a graph
22.		SIGNAL STRENGTH	Signal strength of the plethysmographic waveform is displayed
23.		SENSITIVITY MODE	The sensitivity mode of Masimo rainbow SET pulse co-oximeter: normal, maximum (MAX) and

			Adaptive Sensor Off Detection (APOD) are displayed
24.		MASIMO SET EXCEPTION MESSAGES	Exception messages of the Masimo rainbow SET pulse co-oximeter are displayed
25.		OBSERVATION LAMP	Observation Lamp function is displayed
26.		LOCK/UNLOCK	Lock/Unlock function is displayed
27.		MENU	Menu contains mode, volume, settings, admit which can be selected

3.2 Switches & Keys

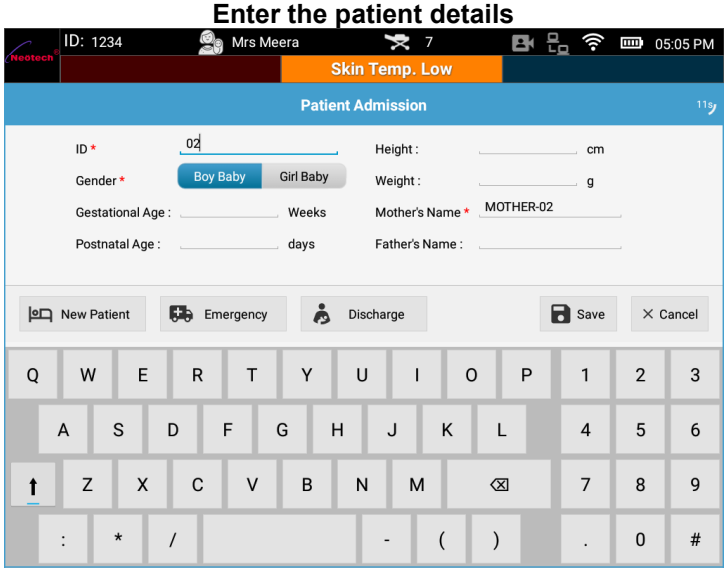
	Main switch	This switch is used to switch ON/OFF the device placed on the left side of the machine
	ON/OFF key	This key is used to switch ON/OFF the control panel
	Timed Acknowledged key	This key is used to Pause the audible indication for time duration. It Pauses indications except the power failure indication. The Timed Acknowledged indication key glows when in use.

3.3 General Control Panel Operation

3.3.1 Patient Admission

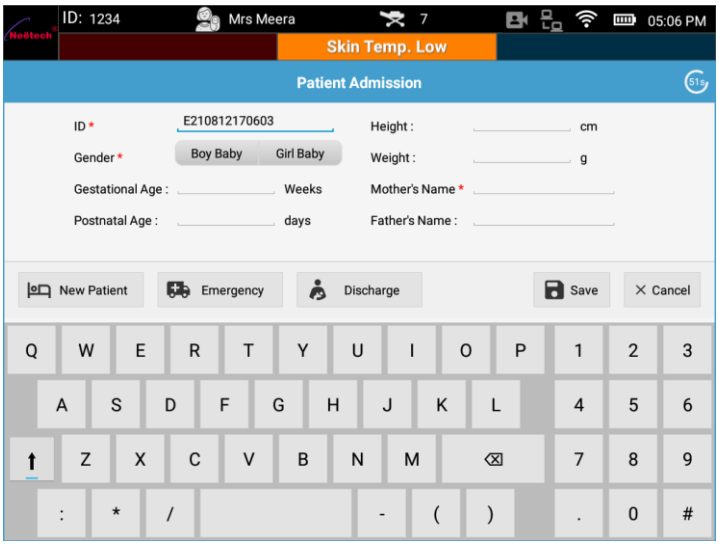
During patient admission The patient's ID, gender and mother's name fields are mandatory which should be entered. Other fields such as age, height, weight and father's name are also entered. For the trend screen to be accessed, patient admission is necessary.

Select MENU **Then select ADMIT** **Enter the patient details**



For emergency cases, emergency option can be selected where the need to fill patient details is not necessary. Here, the patient ID is automatically generated.

For emergency patients, Patient ID is created automatically.



3.3.2 Observation Lamp

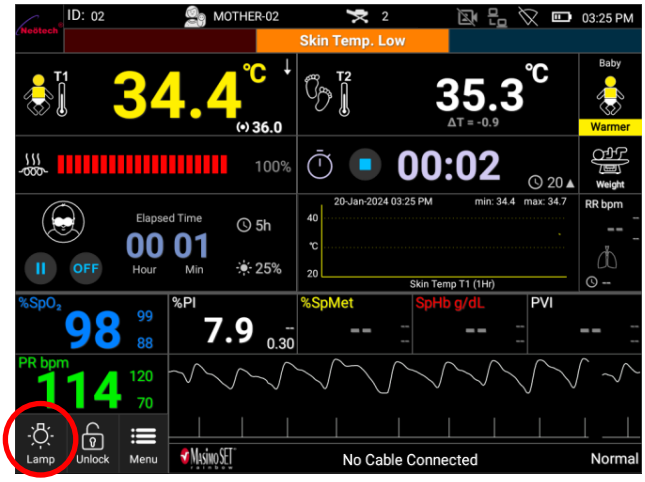
The lamp allows the plysician to observe the growth of the baby and monitor baby's heath conditions. The lamp brightness levels can be selected at 25%, 50%, 75% and 100% as required by the physician.

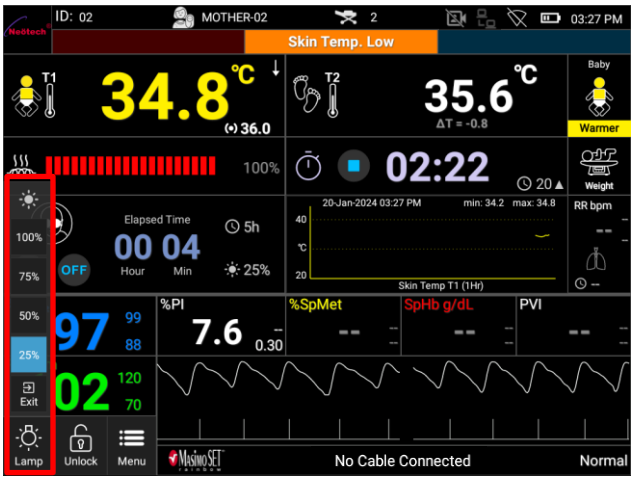
Warning

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.

To enable observation lamp, press the lamp icon on the control panel which is seen here:

- **Press the Lamp icon to enable the observation lamp function.**
- **To switch it OFF, press the same icon once.**
- **The lamp brightness can be selected as soon as the lamp is enabled ON.**





3.3.3 Lock function

The lock function in the control panel locks the control panel display from making any changes other than the user or physician. Both lock and unlock functions can be done by pressing the lock/unlock icon.

To enable the lock function, press the lamp icon on the control panel which can be seen here:

• **When the control panel is locked, the below icon is displayed.** • **Press the icon in the control panel to unlock.** 	• **When the control panel is unlocked, the below icon is displayed.** • **Press the icon in the control panel to lock.** 

Note: Only the following functions can be accessible when the Lock has been enabled:

1. Observation Lamp ON/ OFF
2. Phototherapy lamp ON/OFF
3. APGAR timer ON/OFF

Except this, all the other icons are inaccessible when lock function is enabled.

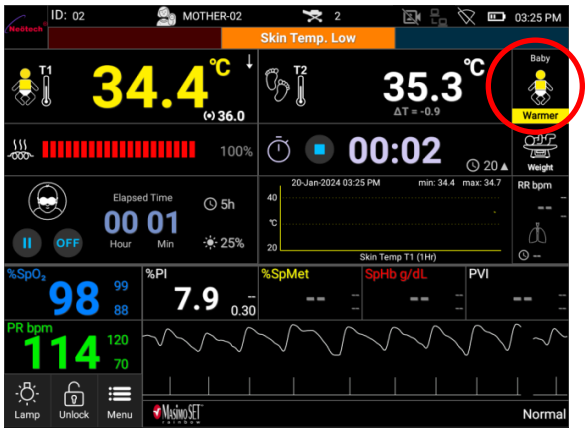
Note: A dialog box with alert message as “Unlock screen” appears when control panel is accessed with lock function enabled.

3.4 Warmer Operation

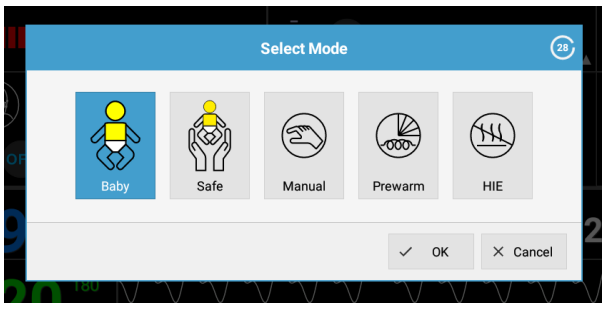
3.4.1 Mode selection

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



Note: Mode can also be selected by pressing the Menu icon.

3.4.2 Baby Mode (Skin Mode)

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

- The skin control temperature (set required temperature) enables the user to select the required settings when the Infant Radiant Warmer is used in the baby mode for the first time. The control panel enables

the user to make this setting with an operator prompt tone and the changing of the control temperature display.

- The skin control temperature is adjusted by pressing the increase (▲) and decrease (▼) touch switches. The control temperature can be adjusted from 32 to 38°C. In the baby mode, the temperature sensed by the skin temperature probe is used by the control system to modulate the radiant heat and maintain the patient's temperature at the selected control temperature.

- If the patient temperature is not reached near skin control temperature within 20 minutes, the 100% heater output will be reduced to 30% for 10 minutes to avoid over heating. After 10 minutes the heater output return to 100% for normal mode of operation and vice versa.

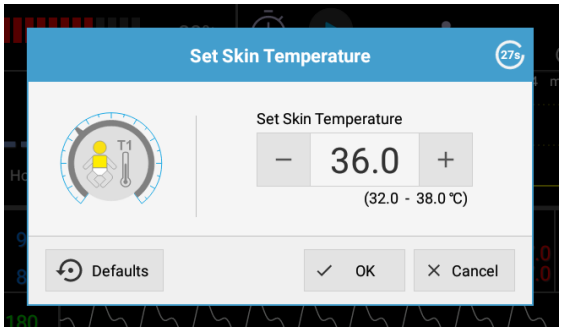
- After reaching skin control temperature, if a sudden reduction is found in patient temperature, the heater output is reduced to 50% instead of 100%. When the patient temperature comes to near skin control temperature the heater output returns to 100% for normal mode of operation.

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 ancillary thermometer.

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

Select Skin temperature (T1) in the control panel (red circled)

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



Warning

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.

3.4.2.1 Radiant Energy Distribution

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

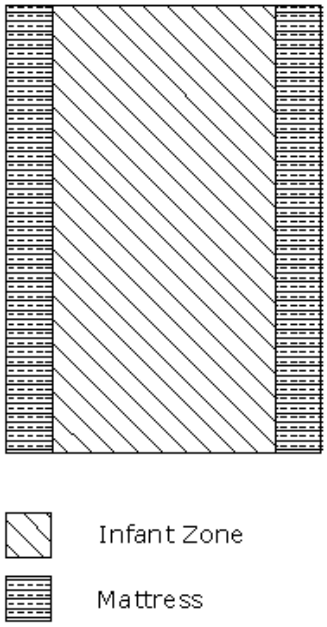


Figure 6

- Infant Zone – 400mm wide
- Irradiance Level – 25-30µW/cm^2/nm

3.4.2.2 Skin Temperature Sensor Attachment

- Use only the reusable nice neötech skin temperature sensor to monitor the baby's 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.

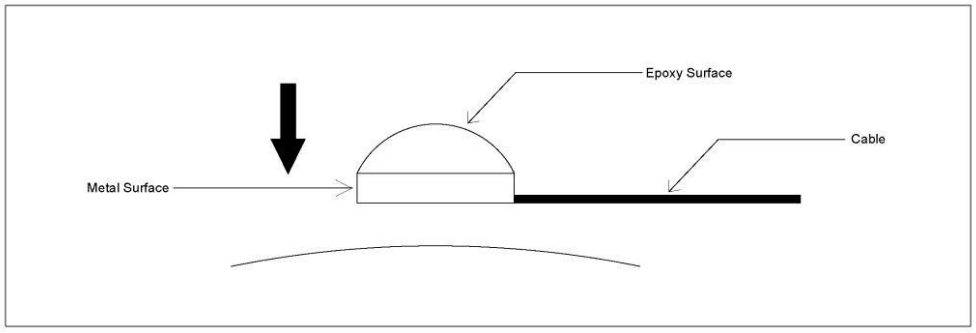


Figure 7

❖ 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. Remove the paper protecting the hypoallergenic adhesive on the heat reflective patch. Secure the skin temperature sensor to the patient's skin with the adhesive side of the patch.

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.

Intimate contact between the skin temperature sensor 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 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 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.

Always remove the sensor from the patient by grasping and removing the heat reflective patch first, and then remove the sensor from the patient or the patch. Always remove the sensor from the infant radiant warmer by grasping the plug at the panel. Placing excessive strain on the skin temperature sensor lead can damage the sensor.

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

3.4.3 Safe Mode

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

- 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 sensor comes off the baby – the heater output increases to only 40% thus making it a very safe mode of operation.

Verify that the patient temperature sensor is securely attached to the patient. A dislodged sensor 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.

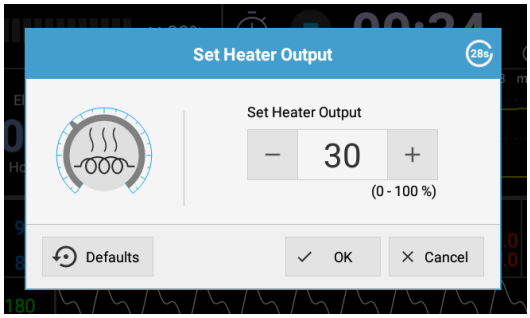
- This is an audio and visual indication free mode- equipment raises an audio and visual indication only when the temperature exceeds 39°C.
- This mode is generally used when the baby is left unattended or at night but continuous monitoring of baby is recommended.

3.4.4 Manual Mode

- 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 (red circled)

Select the desired heater output by increaing 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%

- In the manual mode the skin temperature will not automatically control.
- Use the baby 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 skin 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.

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

❖ If the heater output level is 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 mintues by pressing the Timed Acknowledged key to 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 sensor may be used to monitor the patient's temperature in the manual mode but it does not control the radiant heat energy level.

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

Manual mode alert

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

➢ The following indications appear once the warmer has an heater output above 50%:

- In the alarm indication panel, "manual mode alert" appears indicating the message
- A low priority alarm is activated along with the visual alarm indication.

3.4.5 Prewarm Mode

❖ 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 set at 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.

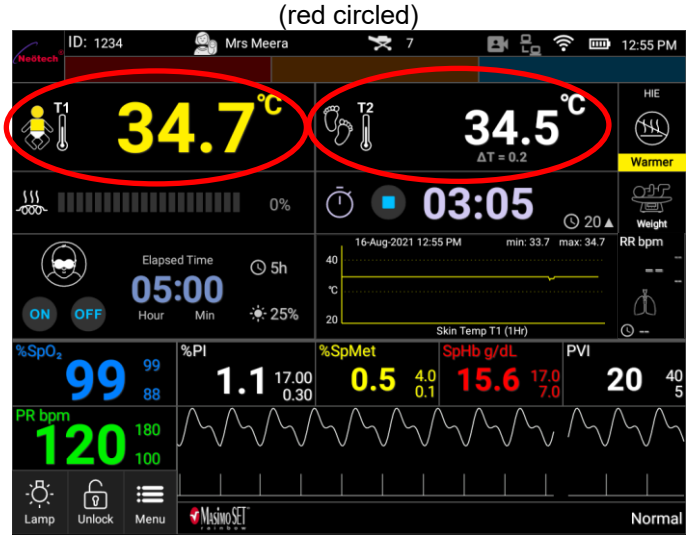
Note: The prewarm mode should be changed to either manual mode or baby mode immediately, once the baby is placed.

3.4.6 HIE Function

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.

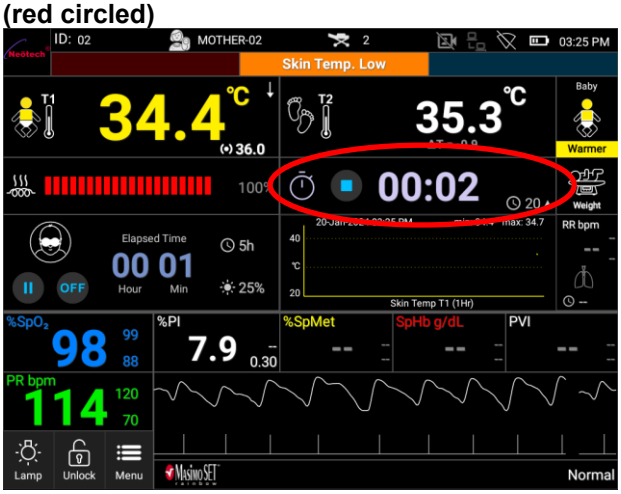
Only the skin temperature (T1 & T2) can be viewed
(red circled)



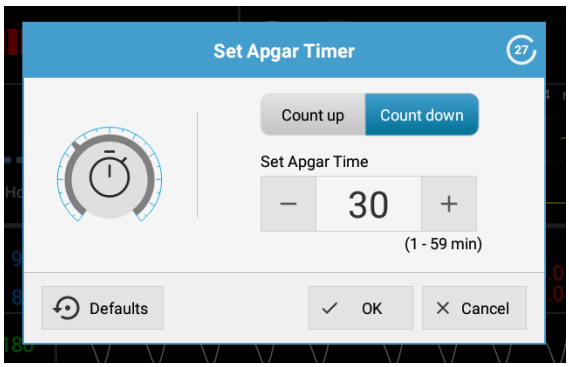
3.4.7 APGAR Timer

- In APGAR timer, apgar time can be set between 1-59 minutes in any mode of operation.
- In APGAR timer, when the set time duration is 20 minutes, the Infant Radiant Warmer will give an audio indication at 1st, 5th, 10th, 15th and 20th Minutes, to make APGAR Scores.
- Supposing, the APGAR Timer is set for a lesser duration for eg. 13 minutes, the Infant Radiant Warmer activates audio indication at 1st, 5th, 10th and the 13th Minutes.
- ➢ After the final audio indication, the Infant Radiant Warmer automatically resumes the previous mode of operation i.e. Baby/Safe/Manual/HIE to set the APGAR Timer again, uses the APGAR key again.

Select the APGAR timer in the control panel
(red circled)



Select the APGAR timer count up/ count down



3.5 Control unit back up

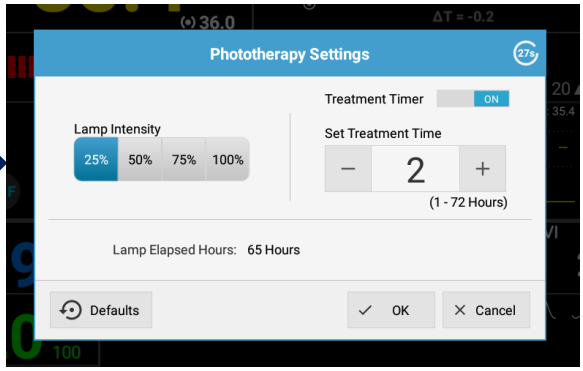
Rechargeable 12V sealed battery is provided for power fail indication and backup to control unit for 5 minutes to prevent failure when the power shuts off and it will monitor the real-time skin temperature of the baby.

3.6 Infant Phototherapy Operation

To switch ON/OFF the phototherapy, follow the instructions given below:

- **Press the Phototherapy from the control panel to enable the function.**
- **To switch it OFF, press the OFF icon.**

The lamp intensity & treatment time can be set in the phototherapy settings



In the control panel, Phototherapy ON/OFF switch is present to enable the LED light. The set treatment time, lamp intensity and lamp elapsed hours can also be seen.

Lamp Intensity: The user can select the intensity of phototherapy required by the baby's condition. 25%, 50%, 75% or 100% intensity level can be selected by the user.

Treatment Timer: The treatment timer can be switched ON/OFF.

Set Treatment Timer: The treatment timer can be set between 1 – 72 hours. The phototherapy lights will turn OFF automatically after the set time.

Lamp Elapsed Hours: The total lamp usage hours can be seen here by the user. The usage hour is automatically updated every hour. It ensures the amount of time the phototherapy has been in use.

3.6.1 Effective Treatment (Phototherapy)

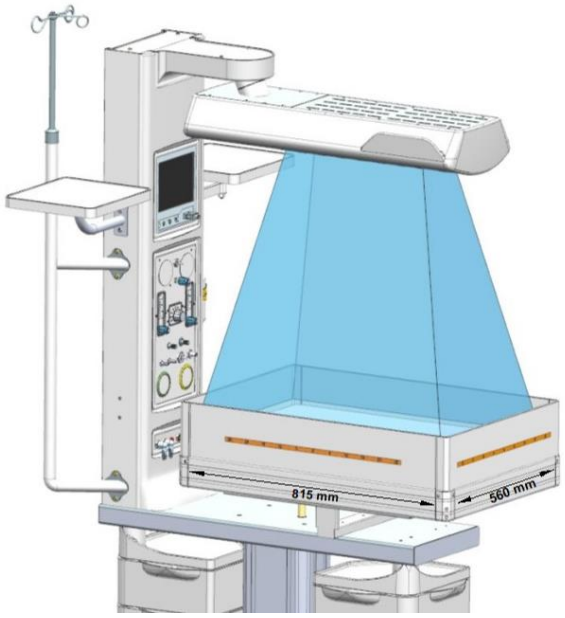


Figure 8

Caution

Keep the patient in the effective area, monitor periodically, failing which patient falling off from the effective area will result in lack of treatment.

3.6.2 Monitoring the Patient during Treatment

The following graph shows the normalized spectrum of blue lamp and the spectral sensitivity of the spectrophotometer.

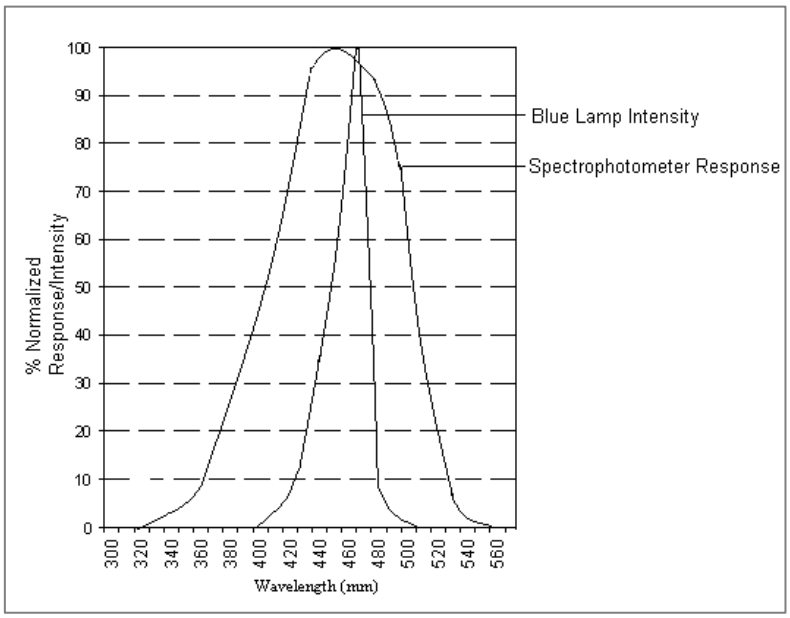


Figure 9

Calibration Curve of Phototherapy Radiometer Sensor (International Light – SCD 144)

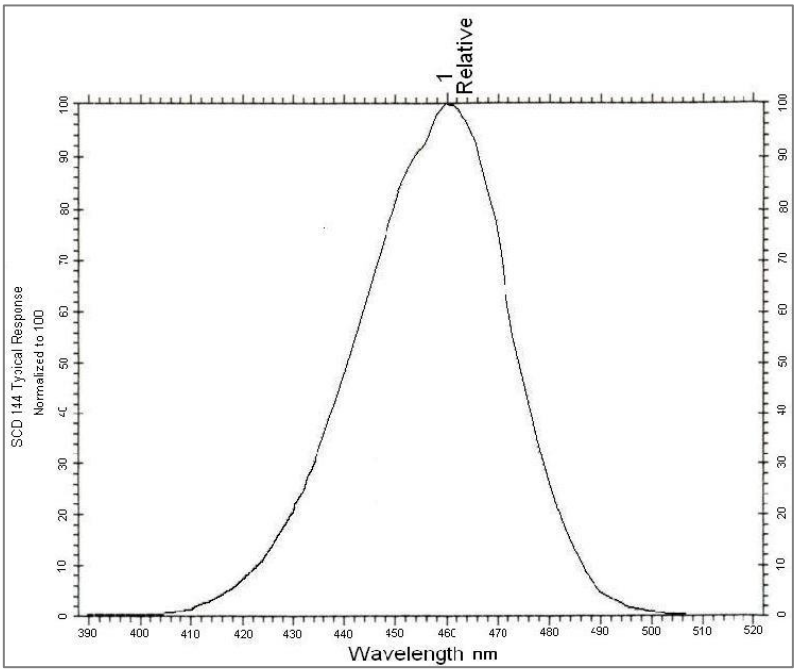


Figure 10

- Always check that the LED based units function correctly before placing a baby on the nice 5000 RP.
- Before switching on the lights close and cover the baby's eyes with a suitable eye pad to prevent possible injury to the retina from the high intensity light source.
    - Check which eye pad is held securely in place and will not become loose or obstruct respiration.
    - Ensure that other infants in the vicinity are shielded from observing the light source.

1 Remove much clothing as possible from the baby to present a large surface area for exposure to the lamps.

2 Switch ON the LED Based units by pressing the ON/OFF LED icon in the menu and follow the same for switching it OFF. Refer section no. 3.6 for phototherapy settings.

- ❖ Check that all the lamps light, and if treatment is to be recorded note the start time.
- ❖ Always keep the baby in the effective surface area. (See Figure 8)
- ❖ The effectiveness of the phototherapy treatment should be monitored by routine determination of the blood serum level. The therapeutic value will depend upon the irradiance of the lamps, and the area and duration of exposure.

- Phototherapy treatment may increase Insensible Water Loss (IWL) and measures to maintain the infant's fluid balance should be considered.
- The lamp housings will become hot during use, particularly in high ambient temperatures. Do not cover the lamp housings or obstruct air flow through the units or overheating will occur and the internal thermal cutout will operate to switch off the unit.
- If a single lamp fails during operation the unit may continue to be used safely until the Operah plus can be taken out of service but the therapeutic effect will be reduced.
- If all the lamps in a unit fail, switch off the unit and take the equipment out of service as soon as possible.
- When treatment has finished switch OFF the LED icon in the menu and if the treatment is being recorded, note the finish time.

Regular monitoring during treatment is recommended.

Use the following guidelines:

- Measure the patient's bilirubin level periodically during treatment as per Institution's procedures.
- Turn off the light when checking the baby's condition and visualizing skin color.
- Follow standard procedures for monitoring patient temperature and fluid status.
- Verify that the baby's eyes are protected and free of infection as per Institution's procedures

- There is a possibility of electromagnetic interference or other interference causes from other external equipment, the phototherapy may get in operation. Use EMC compliance Equipment to avoid the interference.
- The phototherapy may cause radio interference, in which case adequate measure may be required to prevent interference.
- **Operator Safety:** Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area. Using the Neötech LED Phototherapy Unit in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects.

- Continuous Exposure of phototherapy may cause increase the skin temperature. Periodically monitor the skin temperature
- 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
- Isolation from the Supply mains is separable Plug provided.

3.7 Masimo Rainbow SET Pulse Co-oximetry

- Do not start or operate the pulse co-oximeter unless the setup was verified to be correct as per the pre-use check instructions in section 2.6.2.
- To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.
- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse co-oximeter for proper functioning.
- Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.

- The pulse co-oximeter should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.
- The pulse co-oximeter is not an apnea monitor.
- The pulse co-oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse co-oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
- The pulse co-oximeter should not be used for arrhythmia analysis.
- Do not adjust, repair, open, disassemble, or modify the pulse co-oximeter or accessories. Injury to personnel or equipment damage could occur.

Caution

- When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.
- If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.
- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse co-oximeter is used.

NOTES:

- A functional tester cannot be used to assess the accuracy of the pulse co-oximeter.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the pulse co-oximeter to obtain vital sign readings.

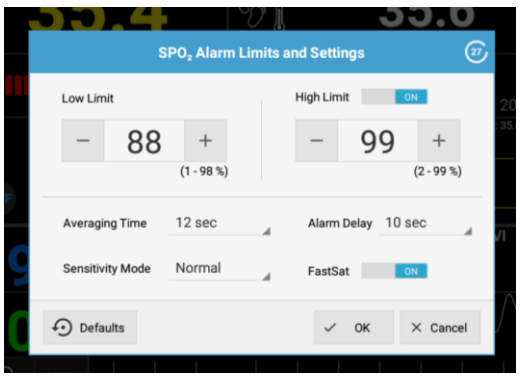
3.7.1 SpO_2 Monitoring & Setting

Stability of the SpO_2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each. The stability of the readings over time is affected by the averaging mode being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer averaging times delay the response of the oximeter and reduce the measured variations of SpO_2 and pulse rate.

To open SpO_2 settings, follow below instructions:

Select SpO_2 in the control panel

Select required settings to be adjusted or set and save the settings



SpO_2 High Limit: The SpO_2 high alarm limit can be set anywhere between 2% and 99%, then "---" with a 1% step size. In the "----" (off) setting, the alarm can be turned off completely.

SpO_2 Low Limit: The SpO_2 low alarm limit can be set anywhere between 1% and 98%, with a 1% step size.

NOTE: The low alarm limit must be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.

Averaging time: For SpO_2 reading stability can be set to: 2-4, 4-6, 8, 10, 12, 14 & 16 seconds.

Sensitivity Mode: For SpO_2 monitoring has three modes that can be enabled based on the requiements. They are as follows:

- **Normal Sensitivity –** This is the recommended mode for patients that are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).

- **Adaptive Probe Off Detection (APOD) –** This is the recommended monitoring mode where there is a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.

- **Maximum Sensitivity (MAX) -** This mode is recommended for patients with low perfusion or when the low perfusion message is displayed on the screen in APOD or normal sensitivity mode. This mode is not recommended for care areas where patients are not monitored visually, such as general wards. It is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.

Alarm Delay: The delay can be set to either 0, 5,10 or 15 seconds. The delay setting only affects saturation alarms indications

FAST SAT setting: can be enabled to activate the FastSat algorithm, the averaging time is dependednt on the input signal. In the 2 and 4 seconds averaging mode, the FastSat algorithm is automatically enabled.

NOTE: When using the Maximum Sensitivity setting, performance of the "Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental "noise" such as light, vibration, and excessive air movement.

- Inaccurate SpO_2 readings may be caused by:
  - Improper sensor application and placement
  - Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2 . When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
  - Elevated levels of bilirubin
  - Elevated levels of dyshemoglobin
  - Vasospastic disease, such as Raynaud's, and peripheral vascular disease
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Hypocapnic or hypercapnic conditions
  - Severe anemia
  - Very low arterial perfusion
  - Extreme motion artifact
  - Abnormal venous pulsation or venous constriction
  - Severe vasoconstriction or hypothermia
  - Arterial catheters and intra-aortic balloon
  - Intravascular dyes, such as indocyanine green or methylene blue
  - Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
  - Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.

- Skin color disorders

Caution

- If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
- The device must be configured to match your local power line frequency to allow for the cancelation of noise introduced by fluorescent lights and other sources.

3.7.2 Perfusion Index (Pi) Monitoring

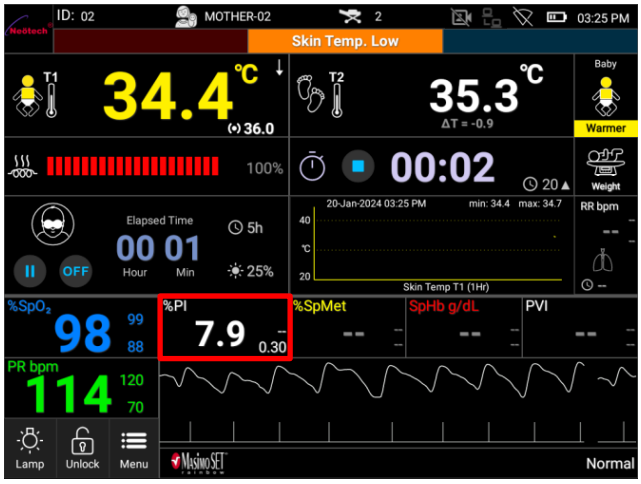
The perfusion index (PI) display provides a relative numeric indication of the pulse strength at the monitoring site. It is a calculated percentage of the pulsatile signal to non-pulsatile signal of arterial blood moving through the site. PI may be used to find the best perfused site and to monitor physiological changes in the patient. It displays an operating range of 0.02 percent to 20.00 percent. A percentage greater than 1.00 percent is desired. Extreme changes in the display number are due to motion artifact and changes in physiology and blood flow.

The PI measurement is displayed as follows:

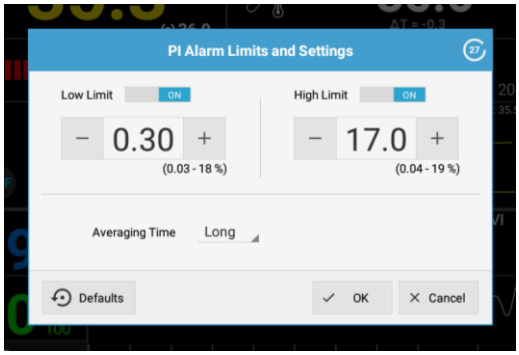
≤ 0.99 (2 decimal places)
1.0 to 9.9 (1 decimal place)
≥10 (0 decimal places)

To open PI settings, follow below instructions:

Select Pi in the control panel



Select required settings to be adjusted or set and save the settings



PI High Limit: The PI high alarm limit can be set anywhere between 0.04 and 19, then "---" with a 0.01 step size between 0.04 and 0.10, a 0.10 step size between 0.10 and 1.0, and a 1.0 step size between 1.0 and 19. In the "---" (off) setting, the PI High Alarm Limit Alarm is disabled.

PI Low Limit: The PI low alarm limit can be set as "---", or anywhere between 0.03 to 18 with a .01 step size between 0.03 and 0.10, a 0.10 step size between 0.10 and 1.0, and a 1.0 step size between 1.0 and 18. In the "---" (off) setting, the PI Low Alarm Limit Alarm is disabled.

NOTE: The low alarm limit must be set below the high alarm setting. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.

Averaging time: The signal averaging algorithm can be set to short or long.

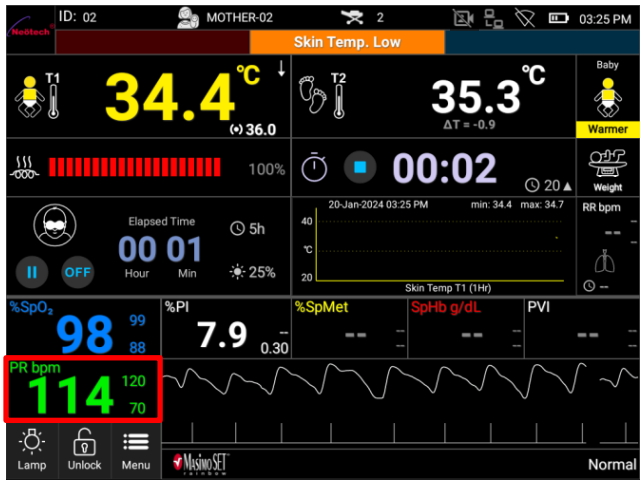
3.7.3 Pulse Rate (PR) Monitoring (bpm)

The Pulse Rate displayed in the control panel may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to

physiological changes in the patient or one of the instruments or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can cause the pulse rate displayed in the control panel to be significantly different than the ECG heart rate.

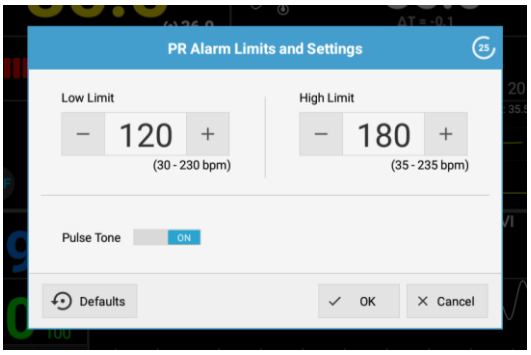
PR alarm limit can be set by following the below steps:

Select "PR" in the control panel



Select required settings to be adjusted or set and save the settings.

Pulse tone can be heard when switched ON.



PR High Limit: The pulse rate high alarm limit can be set anywhere between 35 BPM and 235 BPM, with a 5 BPM step size.

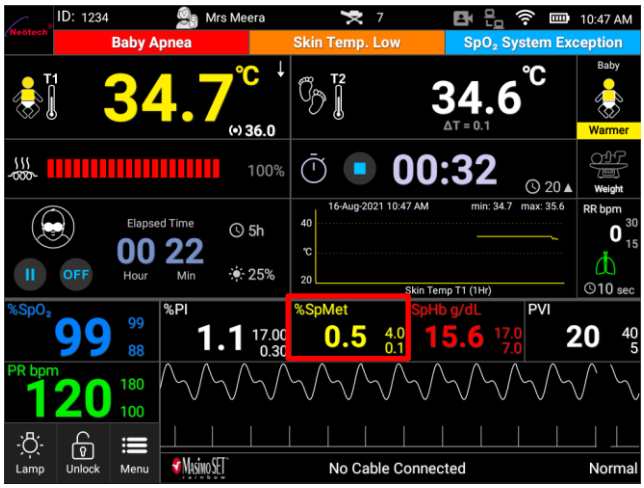
PR Low Limit: The pulse rate low alarm limit can be set anywhere between 30 BPM and 230 BPM, with a 5 BPM step size.

NOTE: The low alarm limit must be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.

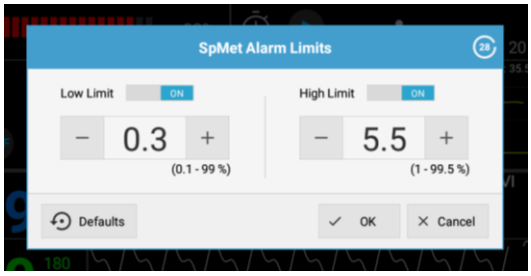
3.7.4 SpMet Monitoring (optional)

A stable SpMet reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site). Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

Select SpMet in the control panel



Select required settings to be adjusted or set and save the settings



SpMet High Limit: The SpMet high alarm limit can be set anywhere between 1.0% to 99.5%, then "---". Between 1.0% and 2.0%, the step increment is 0.1%. Between 2.0% and 99.5%, the step increment is 0.5%.

SpMet Low Limit: The SpMet low alarm limit can be set as "---", or anywhere between 0.1% to 99%. Between 0.1% and 2.0%, the step increment is 0.1%. Between 2.0% and 99%, the step increment is 0.5%. In the "----" (off) setting, the alarm can be turned off completely.

NOTE: The low alarm limit must be set below the high alarm setting. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.

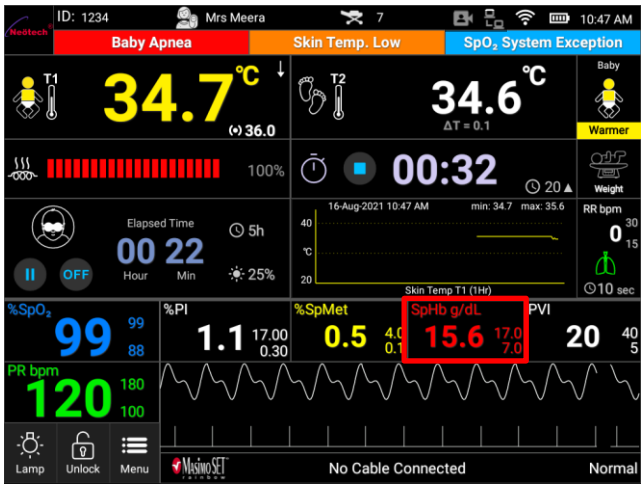
- Inaccurate SpMet readings may be caused by:
  - Improper sensor application
  - Intravascular dyes such as indocyanine green or methylene blue
  - Abnormal hemoglobin levels
  - Low arterial perfusion
  - Low arterial oxygen saturation levels including altitude induced hypoxemia
  - Elevated total bilirubin levels
  - Motion artifact

3.7.5 SpHb Monitoring (optional)

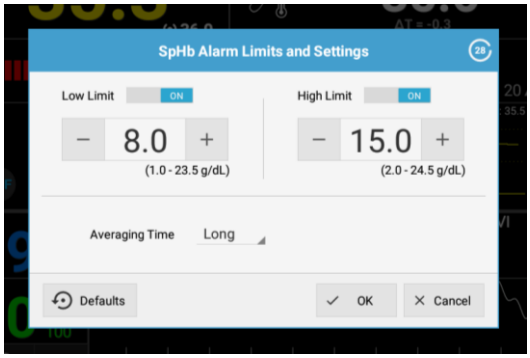
A stable SpHb reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion.

To open SpHb settings, follow below instructions:

Select SpHb in the control panel



Select required settings to be adjusted or set and save the settings



**SpHb not approved for <3 kg

SpHb High Limit: The SpHb high alarm limit can be set anywhere between 2.0 g/dl and 24.5 g/dl, then "---" with a 0.1 g/dl step size between 2.0 and 20.0, and a 0.5 g/ dl step size between 20.0 and 24.5. In the "---" (off) setting, the SpHb High Alarm Limit Alarm is disabled.

SpHb Low Limit: The SpHb low alarm limit can be set as "---", or anywhere between 1.0 g/dl and 24 g/dl with a 0.1 g/dl step size between 1.0 and 20.0, and a 0.5 g/dl step size between 20.0 and 24.0. In the "---" (off) setting, the SpHb Low Alarm Limit Alarm is disabled.

NOTE: The low alarm limit must be set below the high alarm setting. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.

Averaging time: for SpHb reading stability can be set to: Short, Medium or Long setting.

Warning

- Inaccurate SpHb readings may be caused by:
  - Improper sensor application
  - Intravascular dyes such as indocyanine green or methylene blue
  - Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
  - Elevated PaO_2 levels
  - Elevated levels of bilirubin
  - Low arterial perfusion
  - Motion artifact
  - Low arterial oxygen saturation levels
  - Elevated carboxyhemoglobin levels
  - Elevated methemoglobin levels
  - Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
  - Vasospastic disease such as Raynaud's
  - Elevated altitude
  - Peripheral vascular disease
  - Liver disease
  - EMI radiation interference

Caution

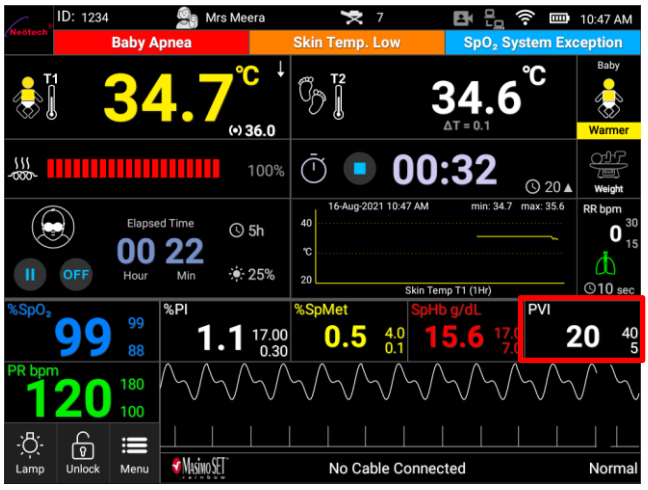
Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory devices prior to clinical decision making to completely understand the patient's condition.

3.7.6 Pleth Variability Index (PVi) Monitoring (optional)

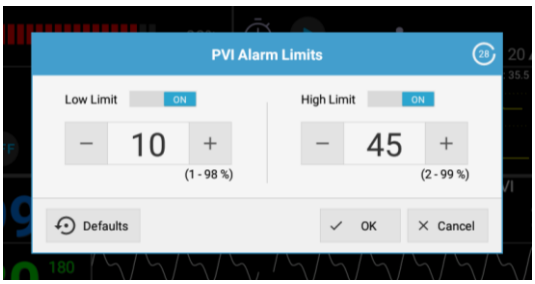
The pleth variability index (PVI) is a measure of the dynamic changes in the perfusion index (PI) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI is displayed as a percentage (0-100%).

To open PVI settings, follow below instructions:

Select "PVI" in the control panel



Select required settings to be adjusted or set and save the settings

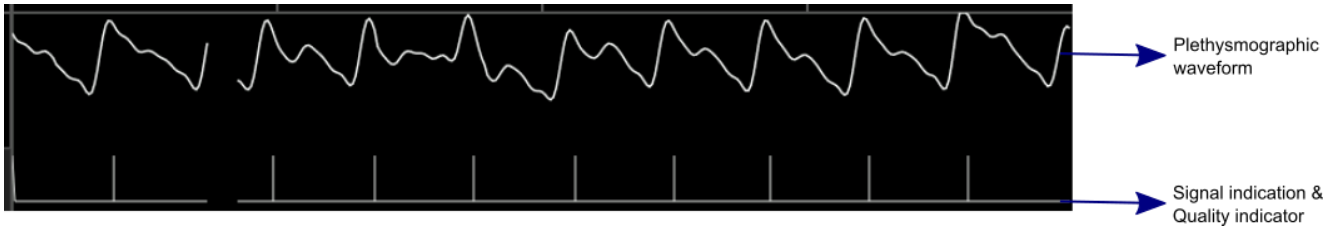


PVI High Limit: The PVI high alarm limit can be set anywhere between 2 and 99, then "---" with a 1 step size between 2 and 99. In the "---" (off) setting, the PVI High Alarm Limit Alarm is disabled.

PVI Low Limit: The PVI low alarm limit can be set as "---", or anywhere between 1 and 98 with a 1 step size. In the "---" (off) setting, the PVI Low Alarm Limit Alarm is disabled.

NOTE: The low alarm limit must be set below the high alarm setting. If the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.

3.7.7 Signal Indication and Quality Indicator (SIQ)



The Pulse CO-Oximeter display provides a visual indicator of the plethysmogram signal quality and an alert when the displayed SpO_2 values are not based on adequate signal quality. The signal quality indicator displayed on the Pulse CO-Oximeter is called the SpO_2 SIQ. The SpO_2 SIQ can be used to identify the occurrence of a patient's pulse and the associated signal quality of the measurement.

With motion, the plethysmographic waveform is often distorted and may be obscured by artifact. The SpO_2 SIQ, shown as a vertical line, coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Pulse CO-Oximeter locates the arterial pulsation. The pulse tone (when enabled) coincides with the vertical line of the SpO_2 SIQ.

The height of the vertical line of the SpO_2 SIQ indicates the quality of the measured signal. A high vertical bar indicates that the SpO_2 measurement is based on a good quality signal. A small vertical bar indicates that the SpO_2 measurement is based on data with low signal quality. When the signal quality is very low the accuracy of the SpO_2 measurement may be compromised, and a "Low SpO_2 SIQ" message is displayed in the message area on the Pulse CO-Oximeter display. When the Low SPO_2 SIQ message appears, proceed with caution and do the following:

- Assess the patient.
- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site for the Pulse CO-Oximeter to maintain accurate readings. Also, misalignment of the sensor's emitter and detector can result in smaller signals and cause erroneous readings.
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or an episode of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site is not interrupted. Interruption, for example, may occur while lifting or crossing their legs during a diaper change.

After performing the above, if the Low SpO_2 SIQ message is displayed frequently or continuously, obtaining an arterial blood specimen for CO-Oximetry analysis may be considered to verify the oxygen saturation value.

Low SpMet SIQ

When the signal quality for SpMet is very low, the accuracy of the SpMet measurement(s) may be compromised, and a Low SpMet SIQ message is displayed in the message area on the Pulse CO-Oximeter display. When the Low message(s) appear, proceed with caution and follow the steps listed in "Actions to be taken", Signal Indication and Quality Indicator (SiQ).

Low SpHb SIQ

When the SpHb signal quality is very low, the accuracy of the SpHb measurement may be compromised. A Low SpHb SIQ message is displayed in the message area on the Pulse CO-Oximeter display, and the parameter/measurement value will display dashes ("---") instead of a number value for SpHb. In addition, an icon will appear in the Menu Icon bar where the Max/APOD icon normally is displayed. An available option is to acknowledge the Low SpHb SIQ state and display the number, with the understanding that the accuracy of the value may be compromised. To acknowledge the Low SpHb SIQ state and display the number, press the icon. A numeric value will display for SpHb. The "SpHb" parameter label will continue to flash to indicate the monitor is

in a Low SpHb SIQ state. If the user does not acknowledge the Low SpHb SIQ state, "---" will continue to be displayed instead of a number value. To access the Max/APOD button and change the Sensitivity setting in this situation when the icon is displayed, press the "next page" icon.

Note: Once the Low SpHb SIQ state is acknowledged, the icon will not be displayed again in the same monitoring session. The SpHb parameter label will still flash to indicate a Low SpHb SIQ state

Actions To Be Taken

If the SpO_2 , PI or pulse rate readings show significant differences, do the following:

- Make sure the emitter and detector are aligned directly opposite each other.
- Select a site where the distance between the emitter and detector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) for 20-30 seconds to increase perfusion. However, strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electrosurgical units or other electrical/ electronic equipment. If these solutions are not possible, operate the Pulse CO-Oximeter on battery power, or try plugging the Pulse CO-Oximeter into a different electrical outlet.
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- If possible, ensure that the sensor is placed in a location with low ambient or low strobing light. Although the Operah Plus with integrated Masimo Rainbow SET technology has significant immunity to ambient or strobing light, excessive ambient or excessive strobing light may cause readings to be incorrect.

- If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse co-oximeter for proper functioning.
- Change the application site or replace the sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
- Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

Low Perfusion

The Pulse CO-Oximeter displays a "Low Perfusion" message when there are very low amplitude arterial pulsations. It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation. This "localized hypoxemia" may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate.)

If the low perfusion message is frequently displayed, find a better-perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

SpO_2 , SpMet*, and SpHb* are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

*Optional features

3.7.8 Masimo sensors

- When a Masimo Rainbow Sensor is properly connected to the patient, the instrument normally goes through a 20-30 second sensor calibration/pulse search routine and then displays numeric values for SpO_2 , SpMet*, SpHb*, pulse rate, Perfusion Index (Pi) and Pleth Variability (PVi*). It also provides graphical displays for plethysmographic waveform, Signal Identification and Quality Indicator (Signal IQ).

However, if the sensor calibration/pulse search routine is unsuccessful for Rainbow parameters/measurements, the instrument automatically switches to a "SpO_2 Only Mode" to provide SpO_2 , PR, Pi and PVi* parameters/measurements for the user.

Note: When a Masimo alarm condition arises, the system initiates an audio alarm to alert the user. This audio alarm can be temporarily paused by utilizing the Timed Acknowledged key for a duration of 2 minutes. After this 2-minute period, the audio alarm automatically reactivates, serving as a continued indication to the user.

- If a Masimo Rainbow Direct Connect Reusable Sensor is being used and "SpO_2 Only Mode" appears on the display screen, perform one of the following steps to reset the instrument:
  - Remove the sensor from from patient (recommended).
  - Remove the cable connector from instrument.
  - Turn the power Off and On at the instrument.

- If a Masimo Rainbow Adhesive Sensor is being used and "SpO_2 Only Mode" appears on the display screen, perform one of the following steps to reset the instrument:
  - Disconnect sensor cable connector from the patient cable connector (recommended).
  - Remove patient cable connector from instrument.
  - Turn the power Off and On at the instrument.
  - Remove the sensor from the patient.

SpMet*, SpHb*, PVi* - Optional features

Use only Masimo sensors for pulse oximetry or pulse CO-Oximetry measurements.

- Do not use damaged sensors. Do not use a sensor with exposed optical or electrical components. Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not waterproof). Do not sterilize by irradiation, steam, autoclave or ethylene oxide unless otherwise indicated in the sensor directions for use. See the cleaning instructions in the directions for use for all masimo reusable sensors.
- Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize by irradiation, steam, autoclave or ethylene oxide.

NOTE: Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.

NOTE: Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).

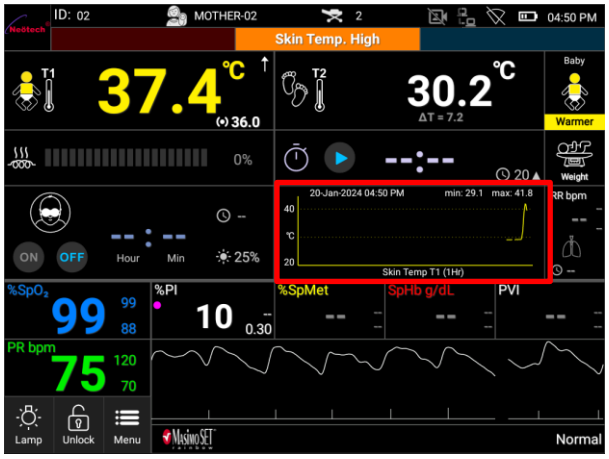
NOTE: Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

3.8 Trend Screen

- The trend screen displays the trend of each physiological parameter or measurement in the form of graph displayed as time versus scale range.
- T1, T2, SpO_2 , PR, Pi, PVi*, SpMet*, SpHb* are displayed graphically with respect to time.
- The timeline reader enables the user to know the readings at any particular time. The time navigation keys (back and forward arrows) are used to select the time frame to view the parameters.
- The time picker can be selected at 30 minutes, 1 hour, 2 hours, 4 hours, 8 hours, 12 hours or 24 hours to view the trend data.

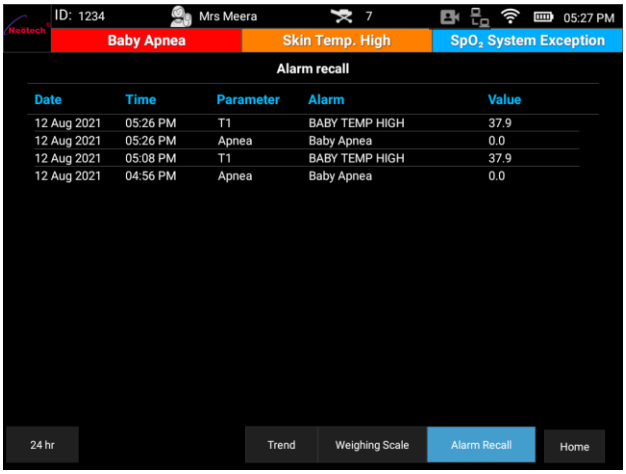
❖ Next to it, alarm recall is present which records the date & time, parameter, alarm pause conditions of each alarm during the treatment time and the values obtained.

Select Trend in the control panel (red box)



The Trend displays the readings of the selected parameters

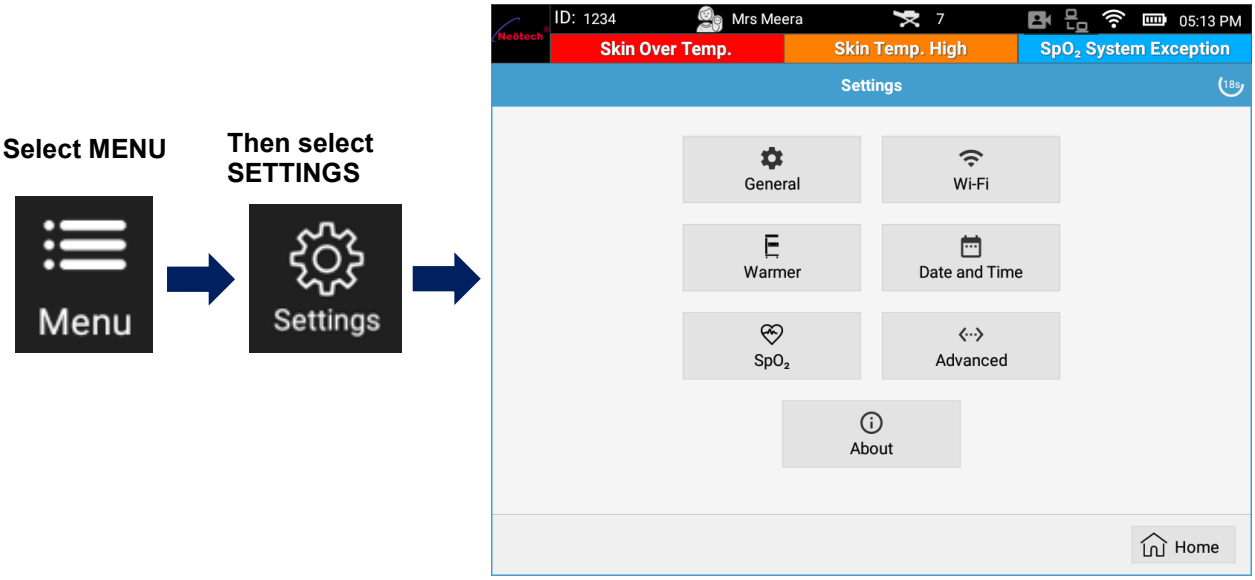
The alarm conditions are recorded for alarm recall purposes



SpMet*, SpHb*, PVi* - Optional features

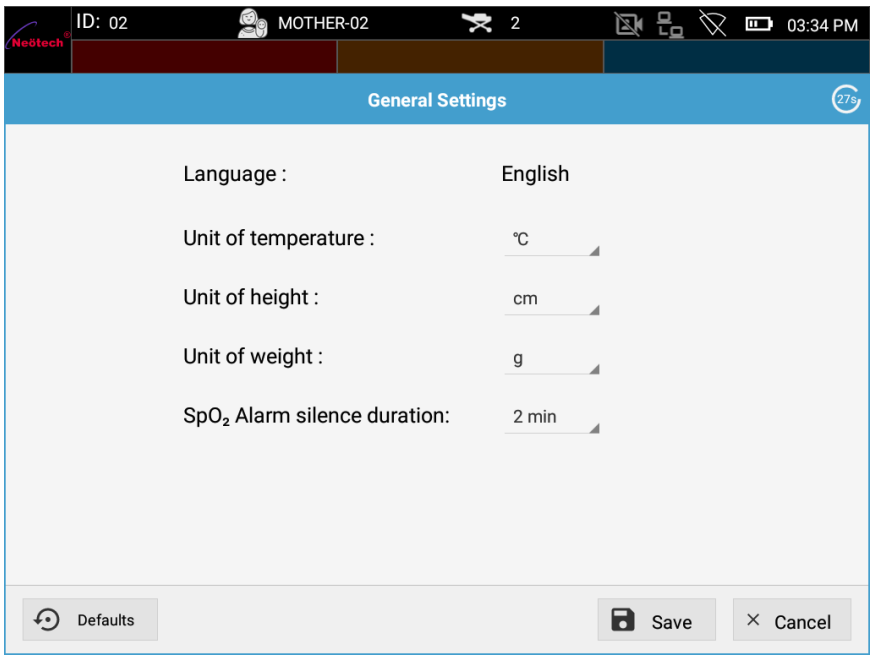
3.9 Settings

The settings instructions of nice 5000 RP are given here:



3.9.1 General settings

The general settings contains the following:



Language: English is the default language setting.

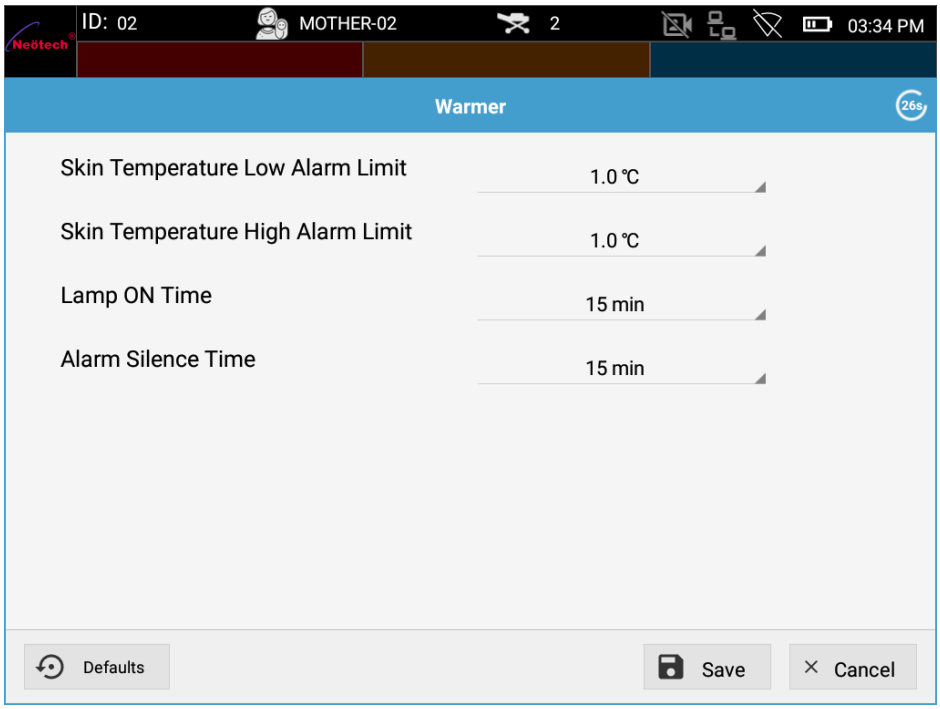
Unit of temperature: Centigrade (°C) or Fahrenheit (°F)

Unit of height: centimeters (cm) or inch

Unit of weight: grams (g) or pounds (lb).

SpO_2 Alarm silence duration: 1, 2 or 3 minutes.

3.9.2 Warmer settings



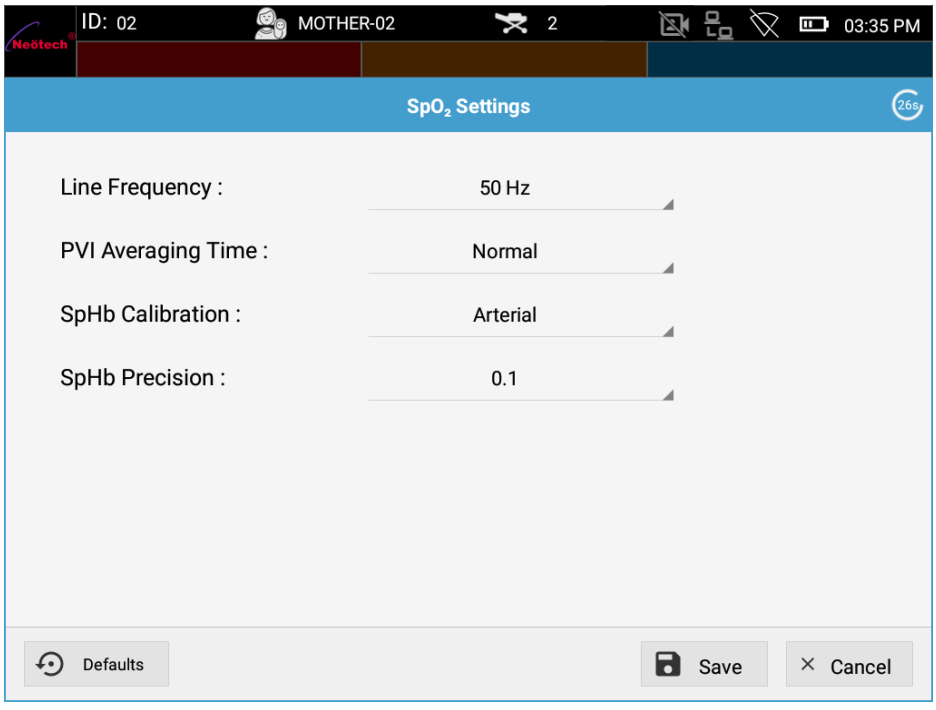
Skin temperature Low Alarm Limit: The user can select the alarm limit for low skin temperature as either 0.5°C or 1.0°C.

Skin temperature High Alarm Limit: The user can select the alarm limit for high skin temperature as either 0.5°C or 1.0°C.

Lamp ON Time: The observation lamp timer can be selected by the user to switch ON the lamp 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.

3.9.3 SpO_2 settings



Line Frequency: The line frequency can either be set at 50 or 60 Hz.

PVI Averaging time: The PVI signal averaging algorithm can be set as normal or fast.

SpHb Calibration: Arterial or Venous calibration setting. Set to SpHb or SpHbV. This feature provides an Arterial (SpHb) or Venous (SpHbV) value that displays on the main screen.

NOTE: The hemorheologic profile of arterial and venous blood samples can vary. To accommodate this difference, the Masimo rainbow SET pulse co-oximeter provides the option of displaying a SpHb parameter that is based on either Arterial or Venous SpHb laboratory blood sample data.

SpHb Precision: Set to 0 (whole numbers), 0.1 or 0.5 increments. This feature allows the user to set the decimal for SpHb.

3.10 Audio & Visual Indication

3.10.1 Alarm priorities

An audio and visual indication occurs when there is an alarm or an emergency to attend to the patient. The alarm indication occurs when it exceeds the set limit with colour codes

According to the levels of priority, color coded visual lamp indication along with alarm priority flashes indication rises. For the parameters present in the Trend screen, an arrowhead indication displays for the high and low values. Color codes for visual lamp indication and alarm priorities are explained in 3.10.2

Operah Plus unit distinguishes the following Audio & Visual Indication:

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
	Skin sensor disconnected	Activates when Primary skin temperature sensor is detached from the baby's skin in Baby mode and Safe mode
	Skin sensor defect	Activates when primary skin temperature sensor fails or is short in Baby mode and Safe mode
	Heater Fault	Activates when the heater is defected or disconnected from the equipment in any mode of operation.
	SpO_2 LOW	Activates when the saturated oxygen percentage of baby decreases then the set alarm limit for % of SpO_2 .
	PR LOW	Activates when the pulse rate of baby decreases than the set alarm limit for pulse rate in bpm.
Medium Priority	Skin temperature high	Activates when baby's skin temperature raises more than 1°C from the set required temperature in Baby mode and Safe mode.
	Skin temperature low	Activates when baby's skin temperature decreases less than 1°C from the set required temperature in Baby mode.
Low Priority	Skin sensor disconnected	Activates when Primary skin temperature sensor is detached from the baby's skin in Manual mode, Pre-warm mode and HIE Function.
	Skin sensor defect	Activates when primary skin temperature sensor fails or is short in Manual mode, Pre-warm mode and Function mode

	Manual mode alert	Activates every 15 minutres 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.
	Replace PT lamp	Activates when the phototherapy lamp lifetime of 20,000 hours is expired.
	Low Battery	Activates when the backup battery is low.
	Battery disconnected	Activates when battery is disconnected.
	SpO_2 HIGH	Activates when the saturated oxygen percentage of baby raises than the set alarm limit for % of SpO_2 .
	PR HIGH	Activates when the pulse rate of baby raises or than the set alarm limit for pulse rate in bpm.
	PI HIGH	Activates when the perfusion index percentage of baby raises than the set alarm limit for % of PI.
	PI LOW	Activates when the perfusion index percentage of baby decreases then the set alarm limit for % of PI.
	SpO_2 System Exception	Activates when pulse oximeter system exceptions messages are displayed in the control panel
	SpO_2 error	Activates when board failure and diagnostic failure codes exception messages are displayed in the control panel

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

NOTE: All the above audio alarms except power failure can be paused for certain time duration using the Timed Acknwoledged 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 either 10 or 15 minutes.
Specifically for Masimo Alarm conditions, engaging the Timed Acknowledged key results in a 2-minute pause of the audio alarm. After this pause time, the system gives alert to the user, ensuring continuous awareness of the ongoing alarm condition.

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.

3.10.2 Visual alarm indicator

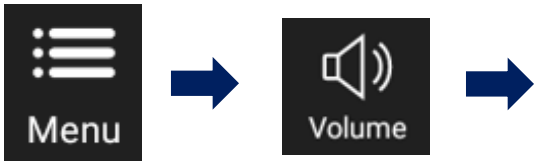
A Visual alarm indicator is fixed on the heater module to produce different audio and visual indications for low, medium and high priority alarms other than the control panel. It produces visual indications based on colors such as pink for self-test, green for normal condition, blue for low priority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

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

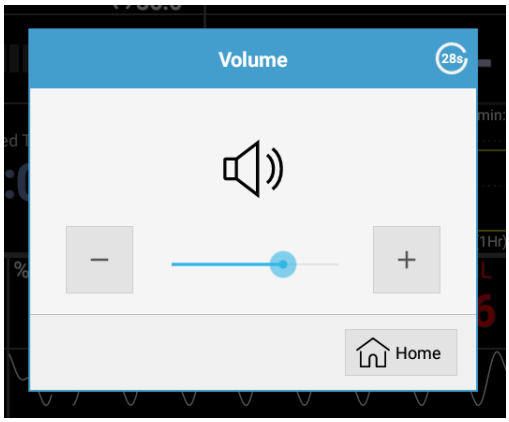
3.10.3 Setting the volume level

To set the volume of audible indications, the following instructions should be followed:

Select MENU **Select VOLUME**



After selecting VOLUME, adjust the volume level using increase and decrease key



3.11 Resuscitation module operation

nice 5000 RP module allows the user to perform Resuscitation.

Resuscitation module operation

Figure 11

1.	Auxiliary ON/OFF switch	9.	PIP control knob
2.	Suction pressure guage	10.	Auxiliary Output
3.	PEEP/PIP manometer	11.	Patient output
4.	Vaccum control knob	12.	Suction Output
5.	Auxiliary Flowmeter	13.	Resuscitator switch
6.	Primary Flowmeter	14.	Air cylinder pressure gauge
7.	FiO_2 setting	15.	Oxygen cylinder pressure gauge
8.	P_{MAX} control knob		

1. **Suction ON/OFF switch:**

   This switch is used to switch ON/OFF suction.

2. **Suction Pressure Guage:**

   The suction pressure levels can be monitored in the manometer.

3. **PEEP/PIP manometer:**

   PEEP and PIP levels along with the maximum pressure can be viewed in this manometer.

4. **Vaccum control knob:**

   The vaccum control knob helps control suction in the circuit.

5. **Flowmeter:**

   The flowmeter with resolution from 1 to 15 LPM is given for setting the flow rate during the therapy.

6. **Auxiliary Flowmeter:**

   The Auxiliary flowmeter with resolution from 1 to 15 LPM is given for setting the flow rate during the therapy.

7. **FiO2 setting:**

   The oxygen percentage can be set in the FiO2 control knob.

8. **P_{MAX} control knob:**

   The maximum pressure can be set using the P_{MAX} control knob.

9. **PIP control knob:**

   The Peak Inspiratory Pressure (PIP) can be set using the PIP control knob.

10. **Auxiliary output:**

    Auxiliary output helps to connect to the oxygen masks and head box/oxygen hood.

11. **Patient output:**

    Patient output is given to connect the breathing circuit in the connector.

12. **Suction output:**

    Suction output is given to connect the suction line in the circuit.

13. **Resuscitator switch:**

    The system includes a switch that functions to choose the desired operation. When set to T-Piece resuscitation, this operation is activated. If the switch is turned to the Off position, no operation takes place.

    Note: If none of the modes are selected, the module should be switched OFF.

14. **Air cylinder pressure guage:**

    The level of air contained in the cylinder can be monitored in the gauge.

15. **Oxygen cylinder pressure guage:**

    The level of oxygen contained in the cylinder can be monitored in the gauge.

3.11.1 Resuscitator Operation

- Oxygen is a drug and should be prescribed only by a physician.
- Exposing an infant to an elevated oxygen concentration can result in retrolental fibroplasia (RLF) and brain damage.
- Oxygen vigorously supports combustion. Exclude any source of ignition in the presence of oxygen and do not use oil or grease on oxygen equipment or spontaneous combustion may occur.
- Always carry out a functional test before use to ensure safety and operational integrity.
- If the equipment is damaged or fails to operate correctly take it out of service immediately and contact a qualified service engineer to ensure operational safety.

- 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 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).

Note: Users should refer to ILCOR / AHA / ERC guidelines to determine the suitability of different types of resuscitator for use in cardiopulmonary resuscitation.

3.11.1.1 Setting the module to Resuscitation

Picture 24

- To use the Resuscitation module in resuscitator mode, turn the switch to “T-piece”

3.11.1.2 Gas Supply Flow rate

Picture 25

- Set the flow rate at 5-15 LPM in the flow meter.

3.11.1.3 Setting the Maximum Pressure

Picture 26

- Occlude PEEP knob and turn PIP control fully clockwise adjust maximum pressure control knob clockwise or counterclockwise to set desired maximum pressure.

3.11.1.4 Setting the Peak Inspiratory Pressure (PIP)

Picture 27

- Occlude the PEEP knob, turn PIP control knob counter-clockwise until the desired peak inspiratory pressure is set.

3.11.1.5 Setting the Positive End Expiratory Pressure (PEEP)

Picture 28

- Adjust PEEP knob clockwise or anti-clockwise to the desired PEEP level.

3.11.1.6 Resuscitate with nice 5000 RP Infant T-Piece Resuscitator

- Adjust gas supply to the desired flow rate.
- Fit patient T-piece to neonatal resuscitation mask and place over the baby's mouth and/or nose. Fit patient T-piece to the endotracheal tube.
- Resuscitate by placing and removing thumb over the PEEP knob to allow inspiration and expiration.

3.11.1.7 After use

- Switch OFF the Timer if applicable and record the finish time.
- Check the oxygen cylinder pressure on the cylinder pressure gauge if used, and then close the cylinder valve.
- Disconnect the oxygen supply hose from the pipeline outlet terminal if applicable.

Note:

- Ensure the oxygen concentration of oxygen / air supply is either monitored using an oxygen analyzer, or preset using oxygen/air flow rate graphs.
- The factory setting of the maximum pressure relief is 40 cmH_2O.
- The maximum pressure relief valve acts as an overall limit on the achievable circuit pressure. resuscitation above 40 cmH_2O cannot be achieved unless the maximum pressure relief valve is adjusted.
- The infant resuscitator can be used with either single-use patient supply lines.
- Single-use patient supply lines can eliminate the possibility of cross-patient infection without requiring time consuming and expensive cleaning and sterilization procedures.
- Resuscitator set consist of patient circuit with T-piece, mask, test lung, gas supply tube & gas cylinder with pressure regulator.

- If resuscitation time to be recorded switch on the Stop Watch.
- Check that the oxygen supply hose is connected if applicable, or open the IN USE oxygen cylinder valve two full turns anticlockwise.

Note: The maximum body weight of the baby is up to 10kg.

Warning

Total dead space with the T – piece is 5ml, if add additional connectors it may be varied.

3.12 Oxygen driven venturi slow suction system (pneumatic)

Picture 29

- Fit a sterile suction catheter on the Patient Suction Tube outlet.
- Switch ON the suction system using the suction switch.
- Occlude the suction port and adjust the level of suction using the suction control knob.
- Suction may take a short time to build up as the bottle and tubing have to be evacuated first.
- Aspirate as necessary. The level of suction may be altered at any time.
- Switch OFF the suction system after use.

Warning

Only qualified clinical personnel should use the suction capability provided on infant radiant warmer. Before using the equipment, read the instructions. Failure to do so could result in patient injury.

The lining of a new born baby's mouth and airway is very delicate so do not apply suction continuously or at excessive levels and switch OFF the suction control system after use to conserve oxygen.

3.13 Auxiliary flowmeter and Auxiliary output

nice 5000 RP provides an Auxiliary flowmeter and Auxiliary output for connecting oxygen hood/ head box and oxygen masks.

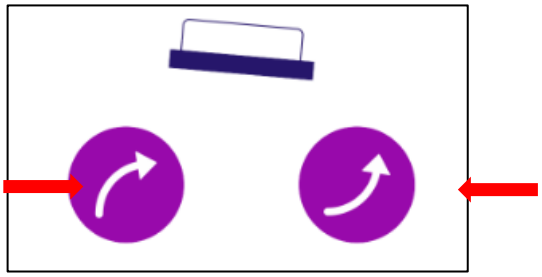
Warning

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

Note: Use “A-type” size pin indexed gas cylinders only.

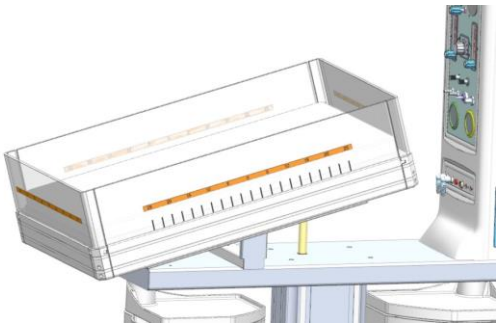
Note: Discontinue therapy while replacing cylinders.

3.15 Bed Platform Operation

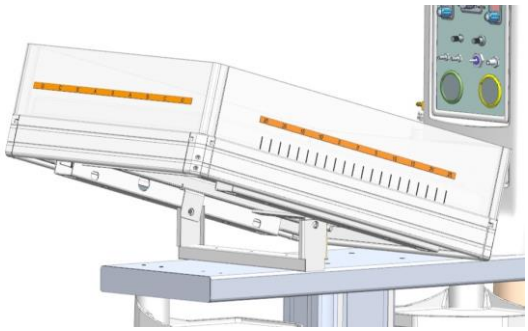


Picture 30

- Press the bed platform tilting key in the pillar to tilt the bed platform to Trendelenburg and Reverse Trendelenburg positions.



Picture 31



Picture 32

- The bed platform tilts upto 15° in both sides.

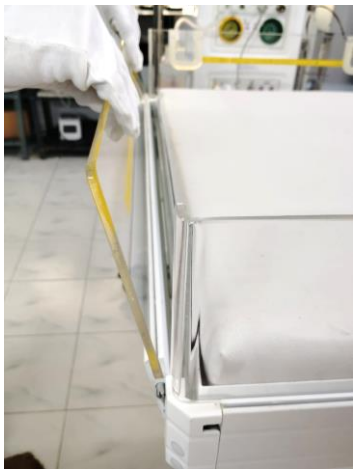
Caution

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.

3.16 Side Panel operation



Picture 33

Picture 34

- ➢ 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.

- 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.

3.17 Height adjustment

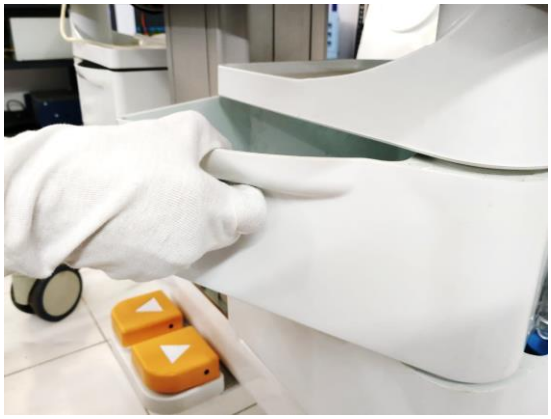
Picture 35

- ➢ The distance between the bed platform and heater in nice 5000 RP can be adjusted easily by using pedal operation.
- ➢ To increase and decrease the height, press the pedal according to the symbol denoted on the pedal.

➔ **Upward pedal switch**

➔ **Downward pedal switch**

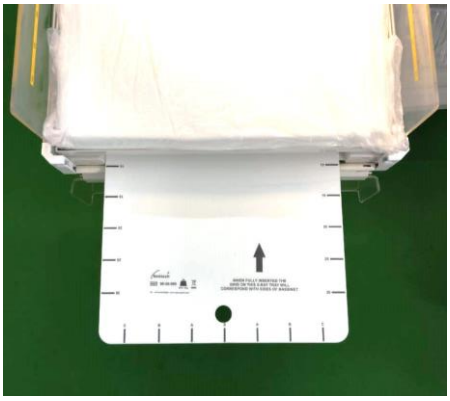
3.18 Storage cabinet



Picture 36

- There are 4 cabinets underneath the bed platform for storage purposes.
- The cabinets can be accessed easily by pull and push operation .
- Handles in the cabinets provide additional grip to the user while operating.

3.19 X-ray Casette Tray



Picture 37

- Lower FR side panel, then insert the x-ray cassette tray in the slot provided as shown in the figure.
- 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.

Warning

- The tray should not be used as a writing surface or as work space during procedures.
- Limit the load placed on X-ray tray. (1.5 Kg) to avoid a tipping hazard.
- Never place an infant on the X-ray cassette tray.
- Do not place any foreign objects on the Infant Radiant Warmer bed or in the under bed cavity while performing X-ray procedures. Incompatible materials in the path of the X-ray may adversely affect the quality of the X-ray image. Use of mattress or bedding materials other than those supplied by nice Neötech should be evaluated by a Neonatologist or Radiologist.

Caution

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

3.20 Heater rotation

Picture 38

- Heater module can be rotated on both sides.
- Heat is directed to bed even when the heater is rotated on both sides.

3.21 Shut down Procedure

- Remove the baby from the mattress of Infant Radiant Warmer
- Ensure switching OFF the Flow meter and Suction
- Switch OFF the ON/OFF switch below the control panel in the pillar.
- Switch OFF the main switch at the right side of the pillar.

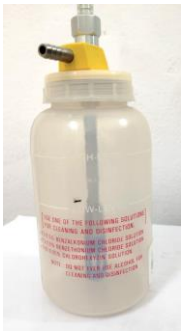
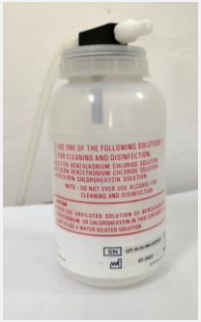
3.22 Transport/Movement details

- 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 move the Infant radiant warmer unit again.

3.23 Accessories

Standard Accessories

#	Accessory Name	Type of use	Part no.	Intended use	Picture
1.	Skin temperature Probe	Multiple-use, Non-sterile	50-05-239	Intended to measure the baby temperature.	
2.	Auxiliary temperature Probe	Reusable	50-05-241	Intended to measure the baby's temperature.	
3.	Infant Disposable T-Piece circuit	Single-use, non-sterile	50-05-154	Breathing circuit is intended to direct the flow of medical gas to the patients	
4.	Silicon Resuscitation Mask – Size 0, 00, 01	Single-use, non-sterile	98-00-124 98-00-125 98-00-126	Used for babies during resuscitation procedure which delivers the gas at the required flow rate according to the control of PIP and PEEP.	
5.	Mattress	Multiple-use, Non-sterile	87-00-126	Intended for the placement of patient (baby) under Infant radiant warmer / Phototherapy during treatment.	

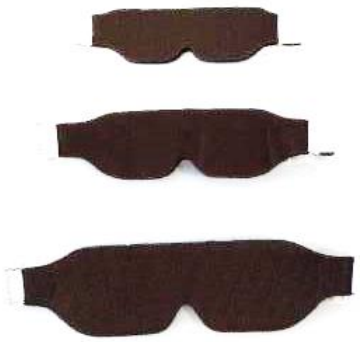
6.	Masimo RD Rainbow SET MD 20-12 Patient Cable [20 pin patient cable] P/N: 4073	Multiple-use, Non-sterile	89-16-109	Intended for use as interlink between masimo sensors and the device	
7.	Masimo Sensor [RD SET YI] P/N: 4054	Multiple-use, Non-sterile	89-16-110	Intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor)	
8.	Phototherapy Eyepad	Single-use, non-sterile	Elastic - 76-00-030 76-00-031 76-00-032 Hookable - 76-00-059 76-00-060 76-00-061	Intended to protect the baby's eye during phototherapy	
9.	Suction Bottle	Reusable	30-05-068	Suction Bottle collect the secretion of fluids like mucous and phlegm during therapy.	
10.	Humidifier Bottle	Reusable	50-05-087	Humidifier bottle adds moisture or humification oxygen that is being inspired by the patients.	

11.	X-ray Cassette Tray	Reusable	96-00-089	Intended to facilitate X-ray procedures while patients occupy the Infant Radiant Warmer bed.	

Optional Accessories

#	Accessory Name	Single use / Reuse	Part no.	Intended use	Picture
1.	Masimo Sensor [RD SET INF] Neonatal Adhesive sensors	Single-use, non-sterile	--	Intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor)	
2.	Masimo Sensor [RD SET NEO] Infant Adhesive sensors	Single-use, non-sterile	--		
3.	T-Piece Resuscitator circuit with heater wire and nebulizer port	Single use	50-05-150	Used to deliver the respiratory gases from the equipment to the patient.	

3.23.1 Instructions to use – Phototherapy Eye pad

S.no.	Picture	Size	Instruction
a)		Small Medium Large	• Select the appropriate size of Eye pad for the baby
b)			• Place the Black fabric part of eye pad over the baby's eye.
c)			• Lift the baby's head slightly and wear the elastic strap of eye pad to the back side of baby's head as shown in the image.
d)			• Ensure the eye pad is covered fully over the baby's eye.

3.23.2 Instructions to use – T-piece Resuscitator

S.No.	Picture	Instructions
1.		The T-piece resuscitator circuit with a nebulizer port is inserted in the patient output of the Resuscitation module.
2.		There are three sizes of resuscitation mask to choose from, according to the baby needs. The other end of the resuscitator is connected to the Resuscitator mask.
3.		A test lung is also provided to check the pressure of gas during the resuscitation procedure.

3.23.3 Instructions to use – Masimo Sensor [RD SET YI]

Site Selection

- Always choose a site that will completely cover the sensor's detector window.
- The site should be free of debris prior to sensor placement.
- Choose a site that is well perfused and least restricts a conscious patient's movements.
- The sensor is not intended for placement on the ear

NEONATES (1–3 kg), CleanShield Wrap / Standard Wrap / Foam Wrap

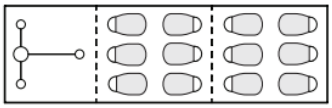
- The preferred sites are the outer aspect of the foot, under the fourth toe or the outer aspect of the palm of the hand.

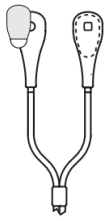
INFANTS (3–10 kg), CleanShield Wrap / Standard Wrap / Foam Wrap

- The preferred sites are the outer aspect of the foot, under the fifth toe or the outer aspect of the palm of the hand, under the fifth finger. For infants with fat or edematous feet, the great toe or thumb is recommended.

Attaching the adhesive squares to the sensor (not required for CleanShield Multisite Wrap)

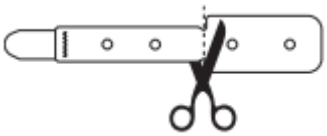
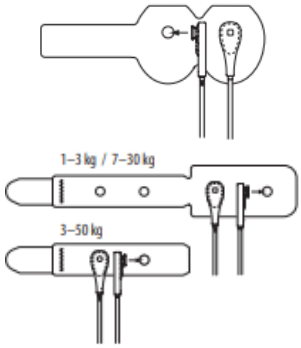
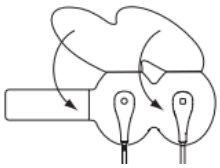
- For improved adherence of the adhesive squares to the sensor wipe the sensor pads with 70% isopropyl alcohol and allow to dry prior to attaching the adhesive squares.

S.No.	Image/Figure	Instructions
1.		• Remove the adhesive squares from the backing.

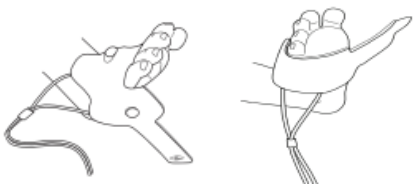
2.		• Attach one square to each window of the sensor pads (emitter and detector). Avoid touching the sticky side prior to applying to the sensor pads. • Do not remove the release liner until ready to apply the sensor to the site.

Do not use adhesive squares on fragile skin.

Attaching the sensor to the patient

S.No.	Image/Figure	Instructions
1.		• The foam wrap can be trimmed to the shorter length for smaller site applications such as a child's finger or toe or a pre-term infant's foot or hand.
2.		• Remove the backing from the adhesive wrap, leaving the backing on the tab end (CleanShield Wrap, Standard Wrap, and Standard Petite Wrap only). • Push the "button" on the emitter sensor pad (cable is marked with a red indicator) through the hole on the left and the remaining button on the detector sensor pad through the hole on the right.
3.		• For the CleanShield Wrap only, fold the upper portion of the attachment tape down over the sensor pads and remove the release liner from the folded over section of the adhesive wrap prior to applying the sensor to the site.

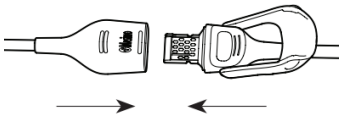
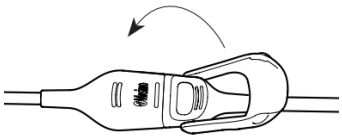
NEONATES (1–3 kg) and INFANTS (3–10 kg), CleanShield Wrap / Standard Wrap / Foam Wrap

S.No.	Image/Figure	Instructions
1.		• Direct the sensor cable toward the patient. Orient the YI on the outer aspect of the foot or hand with the center of the wrap under the 5th digit and the detector window on the fleshy portion and the emitter window (cable is marked with a red indicator) directly opposite. • Secure the small tape end and remove the remaining backing (Standard Wrap, CleanShield Wrap)
2.		• Wrap the tape loosely enough to avoid restricting circulation around the site and to maintain proper alignment of the detector and emitter windows.

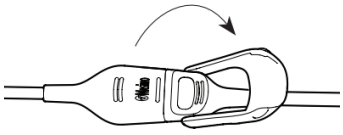
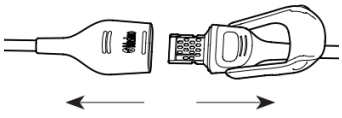
3.		• If using the Foam Wrap, secure the Foam Wrap using the hook and loop tab.

NOTE: When placing the YI on the hand, it is recommended that the EMITTER (cable is marked with a red indicator) pad be placed on the palm of the hand, under the 4th or 5th finger.

Attaching the sensor to the patient cable

S.No.	Image/Figure	Instructions
1.		• Properly orient the sensor connector and insert the sensor connector completely into the patient cable connector.
2.		• Close the protective latch cover completely.

Disconnecting the sensor from the patient cable

S.No.	Image/Figure	Instructions
3.		• Lift up the protective cover.
4.		• Pull firmly on the sensor connector to remove it from the patient cable.

NOTE: To avoid damage, pull on the sensor connector, not the cable.

- Use only Masimo sensors for pulse oximetry or pulse CO-Oximetry measurements.

- Do not use damaged sensors. Do not use a sensor with exposed optical or electrical components. Do not immerse the sensor in water, solvents, or cleaning solutions (the sensors and connectors are not

waterproof). Do not sterilize by irradiation, steam, autoclave or ethylene oxide unless otherwise indicated in the sensor directions for use. See the cleaning instructions in the directions for use for all masimo reusable sensors.

- Do not use damaged patient cables. Do not immerse the patient cables in water, solvents, or cleaning solutions (the patient cable connectors are not waterproof). Do not sterilize by irradiation, steam, autoclave or ethylene oxide.

NOTE: Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

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 with T-Piece Resuscitator system and Phototherapy into service.

- ➢ Use only the nice Neötech sensor to monitor the patient's skin temperature. Use of other manufacturer's sensors may affect the accuracy of Infant Radiant Warmer operation and the electrical safety of the patient.
- ➢ Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.
- ➢ Make sure that the oxygen supply to the radiant warmer is turned OFF and that the warmer is disconnected from the oxygen supply when performing cleaning and Maintenance procedures; a fire and explosion hazard exists when performing cleaning and/or Maintenance procedures in an oxygen-enriched environment.
- ➢ 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 heater to cool before cleaning to avoid the possibility of a burn.

- ➢ Don't keep the metal surface in wet condition it may cause corrosion and damage the part
- ➢ Use the cleaning solution sparingly on a cloth when cleaning the Infant Radiant Warmer. Do not saturate the unit - excessive solution causes damage to internal components.
- ➢ **Use of non-standard 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.
- ➢ Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.

4.1.1 Cleaning and disinfection of Infant Radiant Warmer with T-Piece Resuscitator system and Phototherapy

During cleaning the Infant Radiant Warmer with T-Piece Resuscitator system and Phototherapy and its accessories, the processing shall comply with ISO 17664-1:2021 for reusable of the device.

1. Clean the equipment with damped cloth using soap (e.g. liquid dish soap) and clean water.
2. Rinse the equipment completely with water damped cloth.
3. Disinfect the equipment by using 2% Glutaraldehyde to inactivate any remaining pathogens.

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

4. Rinse with damped cloth using sterile or clean water (i.e. water boiled for 5 minutes and cooled). Sterile water is preferred for rinsing off residual liquid chemical disinfectant from Infant Radiant Warmer with T-Piece Resuscitator system and Phototherapy 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 filtered water (i.e. water passed through a 0.2 µ filter).

5. Dry Infant Radiant Warmer with T-Piece Resuscitator system and Phototherapy using dry towel or cloth.

Disconnect the power cord of Infant Radiant Warmer from AC power before cleaning.

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

4.1.2 Cleaning and disinfection of Temperature Sensor

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

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

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

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

4. Dry temperature sensor using dry towel or cloth

- Do not autoclave or gas sterilize the skin temperature sensor.
- Do not immerse the sensor in liquid cleaner. Avoid placing excessive strain on the sensor lead. Always remove the sensor by grasping the plug at the panel. Do not pull on the sensor lead. These precautions will help avoid damage to the sensor.
- After every treatment, detach the temperature sensor and clean thoroughly on the cable surface, first by light detergent solution and then by antiseptic solution for 3 minutes.

- Some Chemicals cleaning agents may be Conductive and/or leave a residue which may permit a built-up of dust or dirt which may be Conductive. Do not permit cleaning agents to contact electrical components. Do not spray cleaning Solutions onto any of these Surfaces.
- Don’t keep the metal surface in wet condition it may cause corrosion and damage the part
- Do not apply cleaning solutions to the sensor connector.

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

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.

4.1.3.1 Cleaning TFT Display.

1. Clean the TFT Display using Dry cloth only.

- While Cleaning the TFT Display, use a dry, lint-free cloth to gently wipe the TFT Display. Ensure the cloth is free from any moisture before use.
- Do not spray cleaning solutions or pour water directly onto the TFT Display.

4.1.4 Cleaning and reuse of Masimo reusable sensors and cables

Reusable sensors and patient cables can be cleaned as per the following procedure:

1. Remove the sensor from the patient.
2. Disconnect the sensor from the patient cable.
3. Disconnect the patient cable from the monitor.
4. Wipe the entire sensor and/or patient cable clean with a 70% isopropyl alcohol pad.
5. Allow to air dry thoroughly before returning it to operation.

Carefully route patient cables to reduce the possibility of patient entanglement or strangulation

4.1.5 Reattachment of single use adhesive sensors

Single use sensors may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adhere to the skin.

Note: If the sensor fails to track the pulse consistently, the sensors may be incorrectly positioned. Reposisition the sensor or choose a different monitoring site.

- Do not attempt to reprocess, recondition or recycle any masimo sensors or patient cables as these processes may damage the electrical components, potentially leading to patient harm.
- To prevent damage, do not soak or immerse the sensor in any liquid solution. Do not attempt to sterilize by irradiation, steam, autoclave or any method other than ethylene oxide as indicated.

To avoid cross contamination only use masimo single use sensors on the same patient.

4.2 Life time of product

The lifetime of LEDs used in the equipment is up to 20000 hours and inspiratory pressure regulator is 3 years, which can be replaced if necessary without affecting the primary use of the device or does not degrade the property other critical components. Thereby, Life time of the product is five years considering the availability of microcontroller.

Service life of the device is extendable up to 1 years so, the service life of the device is six years (5 years of lifetime + 1 year service life) considering the replacement of SMPS & microcontroller after 5 years.

The Shelf life of the product is nil and the resuscitation accessories is 1.5 years (18 months) from the date of manufacture.

4.3 Life time of IR Heater

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

4.4 Transporting position

When transporting the Infant radiant warmer,

- Remove the baby from the mattress.
- Remove the IV bottle from the IV pole.
- Remove the equipments if exists on the mayo tray.
- Release all brakes then move safely.

If the transport position of the infant radiant warmer is more than 10°, over balance may occur.

4.5 Lamp Replacement (Phototherapy)

- To replace a lamp and clean the interior of the lamp housing necessitates opening the Phototherapy Unit and should be carried out by a qualified Service Engineer.
- Take the nice 5000 RP out of service before replacing a lamp (lifetime of the LED is 20000 hours).
- If a single lamp fails during operation the unit may continue to be used safely until the Operah plus can be taken out of service but the therapeutic effect will be reduced.
- If all the lamps in a unit fail, switch off the unit and take the equipment out of service as soon as possible.

Note: which lamp has failed, then switch OFF all the equipment, disconnect the power supply cable and allow the unit to cool down.

Do not touch the lamps or filters with bare hands as contamination will reduce lamp life and optical efficiency.

Do not touch the LED or reflector with bare hands.

Burn in time: After replace the Lamp the equipment should be put it ON minimum three hours for burn in test, to verify the functions of phototherapy unit.

4.6 Operational tests (T-piece resuscitator)

- These test procedures must be applied on all routine service inspections or after repair or replacement has been carried out which could affect the function or specification of the equipment.
- On conclusion of any test procedure the relevant controls and cylinder valves MUST be returned to a fully closed position.

a) Flow meter - Airway Ventilation

- Adjust the Variable Pressure Relief Valve setting to 40 cmH_2O.
- Connect the oxygen supply to either a pipeline or cylinder source.
- Set the Flow meter to 2 liters per minute and occlude the outlet.

i. **Check:** Gauge indicates not less than 27 cmH_2O.

- ❑ Set the Flow meter to 6 liters per minute and occlude the outlet.

ii. **Check:** Gauge indicates not greater than 40 cmH_2O.

- ❑ Set the Flow meter to 6 liters per minute and occlude the outlet.

iii. Adjust the Variable Relief Valve to 20 cmH_2O.

- ❑ Set the Flow meter to 2 liters per minute and occlude the outlet.

iv. **Check:** Gauge indicates not less than 17 cmH_2O.

- ❑ Fully open the Flow meter and occlude the outlet.

v. **Check:** Gauge indicates not greater than 23 cmH_2O

- ❑ Fully close the Flow meter control valve.
- ❑ Test Completed.

b) Flow meter - Auxiliary Oxygen

- Connect the oxygen supply to either a pipeline or cylinder source.
- Fully open the Flow meter control valve and occlude the outlet.

vi. **Check:** Indicated flow is not less than 10 liters per minute and relief valve is functioning.

- ❑ Fully close the Flow meter control valve.
- ❑ Test Completed.

c) Suction System

- Disconnect the Suction Tube from the Control Panel Connector. Press the connector flange towards the panel and pull out the tube adaptor.
- Connect the oxygen supply to either a pipeline or cylinder source.
- Set the Suction Switch to the on position and fully open the control valve.

vii. **Check:** Suction (Vacuum) gauge indicates zero.

- ❑ Reconnect the Suction Tube to the Control panel.

viii. **Check:** Gauge reading does not exceed 150 mmHg. Where this reading is excessive, replace the Tube.

- ❑ Occlude the Patient Tube outlet.

ix. **Check:** Gauge reading is 0 mmHg (Minimum) to 150 mmHg (Maximum).

- ❑ Set the Suction Switch to the off position.
- ❑ Occlude the Patient Tube outlet for approximately 20/30 seconds.

x. **Check:** Gauge indication remains at zero.

- ❑ Fully close the Control Valve.
- ❑ Test completed.

d) Leak Test

- Close the Flow meter controls and set the Suction Switch to OFF.
- Connect a cylinder to one of the yoke assemblies or remove a cylinder where two are fitted to the equipment.
- Open the Cylinder Valve to charge the system. Ensure that the cylinder pressure gauge indicates not less than 35 bar.
- Note the pressure indicated by the gauge.
- Close the Valve on the cylinder.
- Release the yoke clamp screw and remove the cylinder from the unit.

xi. **Check**: Indicated gauge pressure does not fall by more than 7 bar from pressure noted at Item 4 after 15 minutes.

- ❑ Fully open a Flow meter control valve and when the cylinder pressure gauge indicates zero fully close the control valve.
- ❑ Replace the cylinders on the unit and source.

- ❑ Test Completed.

Section 5: Specifications

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

Electrical Characteristics	
Supply Mains	~230V/50Hz
Supply Current	Maximum 3.2Amps
Rated Power	740 VA
Circuit Breaker	10A

Physical Characteristics	
Height	1858 mm + 200 (height adjustment)
Depth	1315 mm
Width	997 mm
Weight (excl. accessories)	120 kg
Mattress Size	78 X 53 X 5 cm
Mattress Platform height Adjustment	91 – 111 cm
Castors	5-inch Castors 4nos with brake.
Heater Rotation	±90° to the side to facilitate X-ray procedures. (Automatically focuses the mattress center)
Mattress platform tilting	±15° Trendelenburg and Reverse Trendelenburg. (Freely Adjustable)
Side panels	Transparent acrylic with aluminum hinge
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.
Infusion pump pole Load	3 kg.
Storage cabinet Load	3 kg.

System Characteristic	
Display	8 inch TFT-LCD with Touch screen
Add-on Modules	Pulse Oximeter (Masimo Rainbow Set), LED Phototherapy, Resuscitation System.
Battery Backup	5 minutes for display only.
Trend Data	Skin temperature (T1), Skin temperature (T2), %SpO_2 , Pulse Rate, Perfusion Index, Baby Weight,Alarm.
Trending	72 hours Trend data with 1 min resolutions.
Infant Radiant Warmer	
Mode	Baby, Manual, Prewarm, Safe & HIE
Temperature Display Range	10.1 – 50.1°C
Temperature Display Accuracy	± 0.2°C (25 – 40°C)
Skin Set Temperature Range in Baby & Safe Mode	32 – 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 Function	No heater power
Temperature Sensor Interchangeability	Accuracy ± 0.2°C
Temperature Sensor Calibration	Not required
Apgar Timer	1 – 59 min, Count up/Count down
Observation Lamp	Dimmable 1W White LED X 6 White LED light, 1100 lux @ center of mattress
	Colour Temperature: 4000 – 4500 K
Thermostat	Autoreset 90^0C ± 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.
Skin temperature >39°C	If baby skin temperature (T1 or T2) is > 39°C.
Skin temperature (T1) Sensor Fault	If baby skin temperature Sensor (T1) is removed or damaged.
Skin temperature (T2) Sensor Fault	If baby skin temperature Sensor (T2) is removed or damaged.
Heater Fault	If Heater is disconnected or fails
Pulse Oximeter (Masimo Rainbow Set)	
Data Display	%SpO_2 , Pulse Rate, Perfusion Index, Plethysmographic waveform & Signal IQ.

Sensitivity Mode	Normal, Max, APOD. (Default APOD)
Averaging time	2-4, 4-6, 8 to 16 in steps of 2
Oxygen Saturation (SpO_2)	
Measurement range	0-100%
Resolution	1%
Accuracy	±3 % for motion & No Motion, ±2% for Low Perfusion
Pulse rate (PR)	
Measurement range	30 – 235 bpm
Resolution	5 bpm
Accuracy	±5 bpm for motion, ± 3 bpm for no motion & Low Perfusion
Perfusion Index (PI)	
Measurement range	0.03 to 19%
Pulse Oximeter Alarms	
SpO_2 High	2 – 99%
SpO_2 Low	1 – 98%
PR High	35 – 235 bpm
PR Low	30 – 230 bpm
PI High	0.04 – 19%
PI Low	0.03 – 18%

Integrated T Piece Resuscitation	
Gas Inlet Supply Pressure	30 – 75 psig. Output flow rate will be diminished if either supply pressure is below 50 psig; output flow will increase if both supply pressures are above 50 psig.
Wall Pipeline terminals	British Oxygen Company (BOC) Compatible (Std)
Medical Air & Oxygen Input Terminal	DISS fitting as per CGA V-5:2008
Cylinder	Pin-Index Type
Airway Ventilation System	
Flow Range	5LPM (min) to 15LPM (max) If the gas Inlet flow rate increases from 5 to15LPM, the peak inspiratory pressure may be increased approximately 8cm H_2O
Flow Accuracy	0 – 10 LPM ± 1 LPM, 11 – 15 ± 2 LPM
Airway Pressure Manometer	-20 to 80 cmH_2O
Manometer Accuracy	+/- 2.0% of Full Scale deflection
Maximum pressure relief	@7LPM 1 to 66 cm H_2O Factory Set @ 40 cm H_2O

Peak inspiratory pressure (PIP)	@5 LPM 1 to 64 cmH_2O @7 LPM 1 to 66 cmH_2O @10 LPM 1 to 68 cmH_2O @15 LPM 1 to 70 cmH_2O
Positive end-expiratory Pressure (PEEP)	@5LPM 1 to 6 cmH_2O @7LPM 1 to 9 cmH_2O @10LPM 2 to 15 cmH_2O @15LPM 4 to 25 cmH_2O
Inspiratory and Expiratory resistance	1cm H_2O @ 3 and 6 LPM
Recommended Baby Weight	up to 10 Kgs
T Piece Patient breathing circuit	ID - 12mm Disposable (standard) ID - 10mm Reusable (Optional)
Patient Mask	Size 0, 00, 01
Gas supply system complying with ISO 10651, duration (400L Cylinder)	@8 LPM, 50 Minutes
Auxiliary Oxygen System	
Flow Range	0 – 15 LPM
Flow Accuracy	0 – 10 LPM ± 1 LPM, 11 – 15 ± 2 LPM
Maximum outlet pressure	38 – 42 cmH_2O at 10 L/min (pre-set
Outlet Connector	6mm Tubing Adaptor Stem
Tube dimensions	ID 6mm X thickness 2.0mm X 1 meter Length
Suction Control System	
Suction control	Pneumatic activated venturi system with adjustable control valve and Pneumatic ON/OFF switch
Vacuum Range	0 – (-150) mmHg
Vacuum gauge range	0 – (-200) mmHg
Dryness and composition for inlet gases	
Air	Medical Air supply should meet the requirements of ANSI Z86.1 – 1973 commodity specification for Air, type 1 grade D or better
Oxygen	Oxygen supply must meet all requirements of Medical Grade Oxygen
Dew Point:(ONLY for CE requirements)	Both inlets should remain 10°F (-12.22°C) or more below the lowest temperature to which the air distribution system equipment is exposed. At a temperature of 25°F (-3.9°C) and a pressure of 90 psi (6.33 kg/cm2) this equates to 2000 mg/m3
LED Phototherapy	
Light Source	3 High Bright Blue LED
Power	27VA
Lamp wattage	9 Watts
Wavelength	Range 450 to 465nm, Peak 460nm

Irradiance	25 - 40μW/cm²/nm at a distance of 73 cm. (Irradiance can be variable)
Effective Surface Area	500mm X 300mm
Stabilization period	0.5 hour
Irradiance Output variable	25 – 100% increment of 25 %
Total Lamp Usage Hours	1 – 20000 hours (non-resettable).
Treatment Timer	1 – 24 hours (resettable).
Burn-in Period	0.5 – 3 hours
Timer Alert	After elapsed the set treatment time
Lamp Replacement Alert	> 20,000 hours

Accessories	
Standard	Skin temperature (T1) Probe, Skin temperature (T2) Probe, Mattress, Pulse oximenter Extension Cable, Pulse Oximeter Multisite Sensor, IV Pole, Monitor Shelf, X-ray cassette tray, Disposable T Piece Patient Breathing Circuit, Silicone Resuscitation Mask Size 00, 0, 01, Suction Jar, Air Inlet Hose, Oxygen Inlet Hose
Optional	Reusable T Piece Patient Breathing Circuit, Pulse Oximeter Disposable Sensor, Pin Index O_2 Cylinder, Pin Index Air Cylinder

Alarm Algorithm	
High Priority	975 Hz tone, 10 Pulse burst, Pulse spacing: 0.1s, 0.1s, 0.3s, 0.1s, 0.5s, 0.1s, 0.1s, 0.3s, 0.1s repeat time: 2.5s
Medium Priority	975 Hz tone, 3 Pulse burst, Pulse spacing: 0.2s, 0.2s repeat time: 7.5s
Low Priority	975 Hz tone, 2 Pulse burst, Pulse spacing: 0.2s, repeat time: 7.5s
Sound Pressure Level	High Priority Alarm - 69 dB, Medium Priority Alarm – 67 dB, Low priority alarm 66 dB

MDD/MDR Product Classification	Class IIb

Compliance	
IEC 60601-1 Specifications	
Type of Protection against electric shock	Class I
Degree of Protection against electric shock	Type BF (Skin temperature (T1) Probe, Skin temperature (T2) Probe), Type B (Mattress)

Mode of Operation	Continuous
Protection against hazardous of explosion	Not protected
Ingress Protection	IP 20
Quality Test Approval	
Quality	ISO 13485:2016
Electrical Safety	IEC 60601-1
Product Safety	IEC 60601-2-21, IEC 60601-2-50, ISO 10651-5, ISO 11195, ISO 10079-3, ISO 80601-2-61.
EMC Safety	IEC 60601-1-2
Alarm	IEC 60601-1-8
Graphical Symbol	ISO 15223-1:2021

Factory Default Setting	
Mode of operation	Baby Control (Servo Skin) Mode
Baby Control Temperature	36.5°C
Heater Percentage in Manual Mode	30%
Apgar Time	20 Minutes Count-up

Section 6: Warranty

6.1 Conditions

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

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.85-86, Krishna Industrial Estate,
Mettukuppam, Vanagaram,
Chennai-600095. Tamil Nadu,INDIA
Ph: 91-44-24762594, 24764608
Email: service@niceneotech.com, info@niceneotech.com
Web: www.niceneotech.com
Toll Free No. 1800-425-2594 (India only)

Section 7: Trouble Shooting

7.1 General System Failure

Sl. No	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	System failure indication displayed	System failure	Contact nice Neötech.
3	Height cannot be adjusted	Motor fault	Contact nice Neötech
4	Can’t move the machine	Brakes may be applied on the castors.	Release the brake.
		Castors damaged	Change the Castors
5	Unable to tilt the heater module	Heater module may be struck	Slightly shake and rotate the heater module
			Contact nice Neötech

T-piece resuscitator

Sl. No	Problems	Possible Causes	Recommendation
1.	Proximal pressure is not shown in pressure gauge	No gas supply, Patient circuit is disconnected.	Check the gas supply
			Check the patient circuit is intact.
			Otherwise contact nice Neötech
2.	Suction pressure is not shown in pressure gauge	No gas supply, Suction bottle lid may be loose.	Check the gas supply
			Check the suction bottle lid
			Otherwise contact nice Neötech.

7.2 System Fault

7.2.1 Infant Radiant Warmer

Sl. No	Problems	Possible Causes and Remedy
1	No display on the control panel	Check A/C supply voltage
		Check if power cord is disconnected
		Check fuse in the rear side of Pillar

		Other wise, contact nice Neötech
2	No heater output	Check internal wiring connected between control module to heater module
		Set temperature may be less than actual temperature
		Check heater connection
		Other wise contact nice Neötech
3	Machine working, but observation lamp & heater output not working	Check internal wiring connected between control module to heater module
		Check fuse in the rear side of heater module
		Replace observation lamp
		Replace IR heater
4	Machine not giving Audio Indication	Check the Temperature it may near to the Set temperature
		Check Timed Acknowledged ON.
		Other wise contact nice Neötech
5	Control panel displays Skin 1 Sensor fault or Skin 2 Sensor fault with high priority audible and visual alarms	Check if skin temperature sensor is disconnected from the machine.
		If skin temperature sensor is defective, replace new sensor
		Other wise contact nice neötech
6	Display shows Heater Failure	Check internal wiring connected between control module to heater module
		Check heater connection
		Other wise contact nice neötech
7	Display shows Temperature > 39°C	Check environment temperature above 39°C
8	Continuous skin 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
9	Continuous skin temperature low indication	Check patient temperature is 1°C below set temperature
		Sensor may be wet.
		Otherwise contact nice Neötech
		Check strong air conditioning draft
10	Temperature display does not display infant's temperature accurately	Sensor thermal sensitive portion attached improperly
		Check thermal sensitive portion of sensor covered improperly
11	Skin 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
12	Heater output is off after some time in manual mode	Check manual timer time. Can be set 2 to 30 minutes

		Check the heater output is off after set time
		If heater output is off before set time contact nice Neötech
13	In baby mode, baby is 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)

7.2.2 Phototherapy

Sl. No	Problems	Possible Causes	Recommendation
1	Lamps are not ON (LED)	Power Failure	Check the Power
		LED may be defective	Contact nice Neötech
		Fuse blown	Replace Fuses
2	Lamps are frequently fluctuating(LED)	Power Fluctuation	Use Stabilizer
3	Lamp usage Hours display is not working	Microprocessor may be defective	Contact nice Neötech
4	Irradiance level not adjustable	Microprocessor may be defective	Contact nice Neötech
5	LED Lamps are turned ON but the fan is OFF.	Defective wiring	Contact nice Neötech
6	Some LED’s are not lit	LED may be defective	Contact nice Neötech

7.2.3 Resuscitator

S.No.	Problem	Remedy
1	Unable to achieve the PIP and PEEP pressures during setup procedure.	Check that the gas flow rate is set to 7-10 L/Min.
		Inspect the test lung for sign of damage.
		Ensure firm connection between the gas supply, resuscitator and T-Piece circuit.
		Ensure the test lung is firmly connected to the T-Piece.
		Confirm that the manometer shows zero with no gas flow
		Check the maximum pressure relief is set correctly.
2	The infant’s chest and upper abdomen are not rising during the inspiratory cycle.	Confirm the good seal between the mask and infant’s face has been achieved.

7.2.4 Masimo Pulse Co-oximeter

Pulse Oximeter System Exceptions

S.No.	Problems / Exception messages	Possible Causes	Recommendation
1.	**No cable connected**	Cable not attached or not fully inserted into the connector.	Disconnect and reconnect cable into connector.
2.	**Replace Cable Next Patient**	The patient cable is non-functional, or the life of the cable has expired.	Replace the patient cable.
	Replace cable	The patient cable is defective or unrecognized	
3.	**Incompatible cable**	Not a proper cable.	Replace with a proper cable.
4.	**Cable near Expiration**	The life of patient cable is near expiration	Replace the patient cable.
5.	**No sensor connected**	Sensor not fully inserted into the connector	Check to see if the sensor LED is flashing. Disconnect and reconnect the sensor into the Patient Cable Connector. If the LED fails to operate, replace the sensor.
		Maybe an incorrect sensor or a defective sensor or cable.	
		Instrument is searching for patient's pulse.	
		Sensor is disconnected from patient cable.	
		Sensor connected upside down into patient cable.	
6.	**Incompatible Sensor**	Not a proper Masimo sensor.	Replace with a proper Masimo sensor.
		SpO_2 sensor is attached to a instrument without SpO_2 installed.	Use a non- SpO_2 sensor. Contact nice Neotech/authorized dealer to learn more about the optional SpO_2 upgrade.
7.	**Replace sensor Next Patient**	SpO_2 reusable sensor has used all its available monitoring time.	Replace sensor.
	Replace Sensor	Sensor is non-functional, defective or unrecognized sensor.	
8.	**Sensor near Expiration**	The life of patient sensor is near expiration.	Replace the patient sensor.

9.	**No Adhesive Sensor connected**	When a single patient use sensor is used, the adhesive portion of the sensor is not connected.	Ensure the adhesive portion is firmly connected to the sensor.
10.	**Replace Adhesive Sensor Next Patient**	When a single patient use sensor is used, the adhesive portion of the sensor is non-functional, or the life of the adhesive portion of the sensor has expired.	Replace the adhesive portion of the sensor.
	Replace Adhesive Sensor		
11.	**Incompatible Adhesive Sensor**	Not a proper Masimo sensor.	Replace with proper Masimo sensor.
		SpO_2 sensor is attached to an instrument without SpO_2 installed.	Use a non- SpO_2 sensor. Contact nice neotech/authorized dealer to learn more about the optional SpO_2 upgrade.
12.	**Sensor initializing**	Instrument is checking the sensor for proper functioning and performance.	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.
13.	**Sensor Off patient**	Sensor off patient	Disconnect and reconnect the sensor. Reattach sensor.
		Sensor not connected to patient properly. Sensor is damaged.	Properly reapply the sensor on the patient and reconnect the sensor to the instrument or patient cable. If the sensor is damaged, replace the sensor.
14.	**Pulse search**	Instrument is searching for patient's pulse	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If pulse search continues, remove sensor and replace on a better perfused site.
15.	**Interference Detected**	High intensity light such as pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight, or other monitor displays.	Place a Masimo Optical Light Shield over the sensor.
		Incorrect monitor line frequency setting (Hz).	Access the Traditional User Interface. Select Config and enter the password. Adjust the Line Frequency to the correct Hz setting.
16.	**Low Perfusion Index**	Improper sensor type.	Verify proper sensor and sensor size for the patient.
		Poorly perfused site/ Signal too small.	Move sensor to better perfused site
		Sensor is too tight.	Check and see if blood flow to the site is restricted. Be sure that the sensor is not on too tight.

		A disorder such as hypothermia, vasoconstriction, hypovolemia, peripheral vascular disease or anemia.	Set instrument to MAX sensitivity. Warm the patient or sensor site.
		Sensor is damaged.	If the sensor is damaged, replace the sensor.
17.	**Adhesive Sensor near Expiration**	The life of adhesive sensor is near expiration.	Replace the adhesive sensor.
18.	**Check Sensor Connection**	Sensor is not connected firmly into patient cable, or the sensor is not connected firmly to the instrument.	Reconnect sensor firmly into patient cable, or to the instrument.
19.	**SpO_2 Only Mode**	"SpO_2 Only Mode" message occurs during an unsuccessful sensor calibration/ pulse search routine, or during monitoring.	Review the sensor's Directions for use instructions. Use a Masimo light shield to cover the sensor and adjust the sensor.

Parameter Exceptions

S.No.	Problems / Exception messages		Possible Causes	Recommendation
1.	**Low SpO_2 SIQ**		SpO_2 measurement is obscured. Indication: Blue dot on the respective parameter display.	Ensure proper sensor application. Check sensor to see if is working properly. If not replace the sensor.
2.	**Low PR Confidence**		Improper sensor type or application. **Indication:** Blue dot on the respective parameter display.	Excessive motion relative to perfusion. Sensor is damaged or not functioning. Check and see if blood flow to the site is restricted. Check the placement of the sensor. Reapply sensor or move to a different site.
	Low PI Confidence			
3.	**Start up state**	**SpO_2**	Sensor initializing. **Indication: Pink dot** on the respective parameter display.	The pink dot disappears after the successful initialization.
		PR		
		PI		
4.	**Invalid parameter**	**SpO_2**	**Indication:** Dashed parameter "--"	Contact nice Neötech Service personnel.
		PR		
		PI		

7.3 Maintenance Intervals

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

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

Don't misalign the EMI Shielding and the beads it may cause the EMI interference to the equipment

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

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

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

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	50-05-239	Skin temperature probe	1	No.
3	50-05-031	Mayo tray fixed	1	No.
4	50-05-046	Access panel assembly FR/RR	2	No.
5	50-05-045	Access panel assembly LH/RH	2	No.
6	50-05-091	T-Piece patient circuit assembly	1	No.
7	50-05-044	IV Assembly	1	No.
8	87-00-126	Mattress	1	No.
9	91-00-034	Lamp IR heater 600W	2	No.
10	91-00-073	Thermostat,90 Dec NC	1	No.
11	96-00-089	X Ray cassette tray	1	No.
12	50-05-047	Test Lung assembly	1	No
13	30-05-068	Suction bottle assembly	1	No.
14	50-05-006	Resuscitation assembly	1	No.
15	50-05-051	Inspiratory pressure regulator assembly	1	No
16	88-00-231	Proximal pressure gauge	1	No
17	88-00-193	Vacuum pressure gauge	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 nice 5000 RP Operah plus 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	

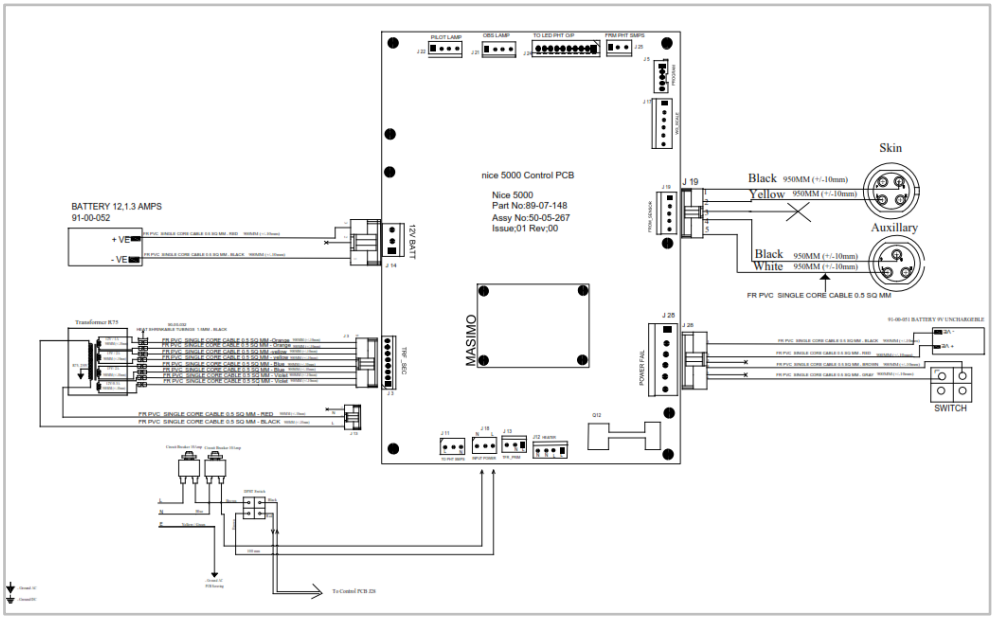
Guidance and manufacturer's declaration – electromagnetic immunity			
The Infant Radiant Warmer is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant Radiant Warmer should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 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 B	Mains power quality should be that of a typical commercial or hospital environment. If the user of the nice 5000 RP Operah plus requires continued operation during power mains interruptions, it is recommended that the nice 5000 RP Operah plus be powered from an uninterruptible power supply or a battery.
	70 % dips for 25 cycles 0% short interruption for 250 cycles	Criteria B	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Criteria A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

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

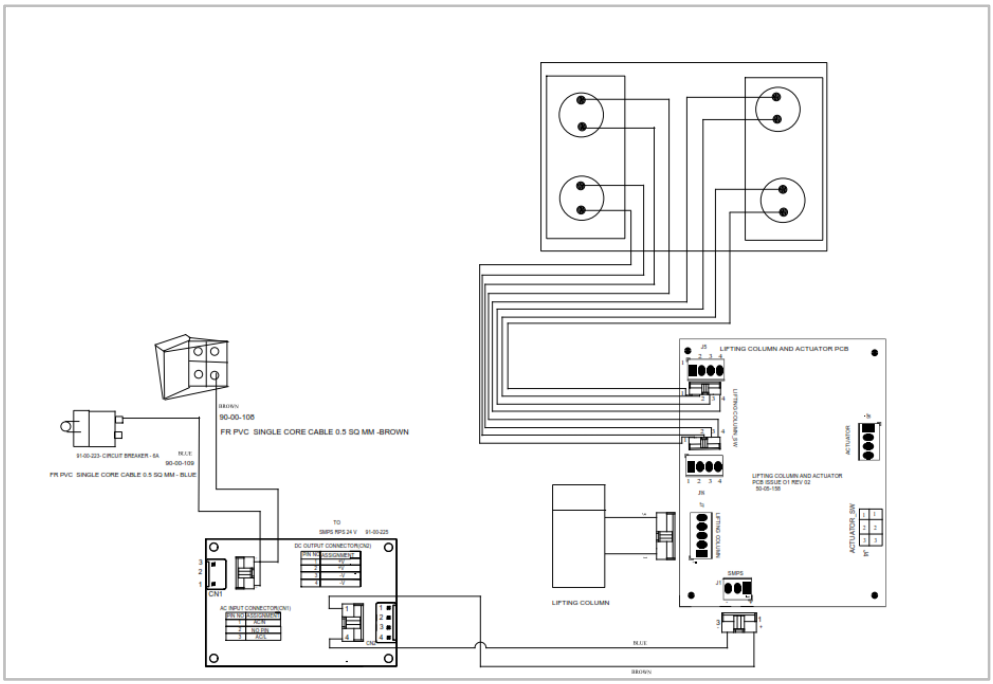
Acceptance criteria

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

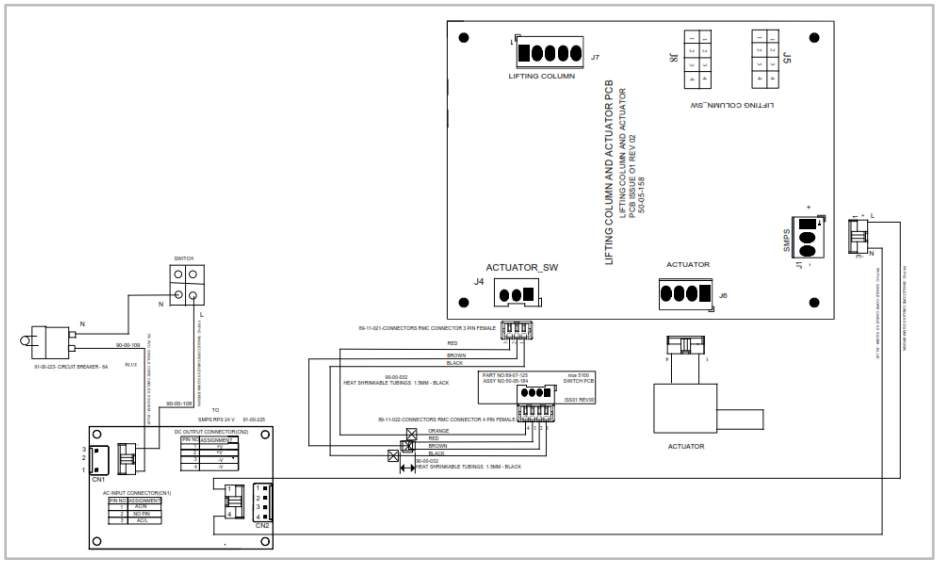
Section 10: Wiring diagram



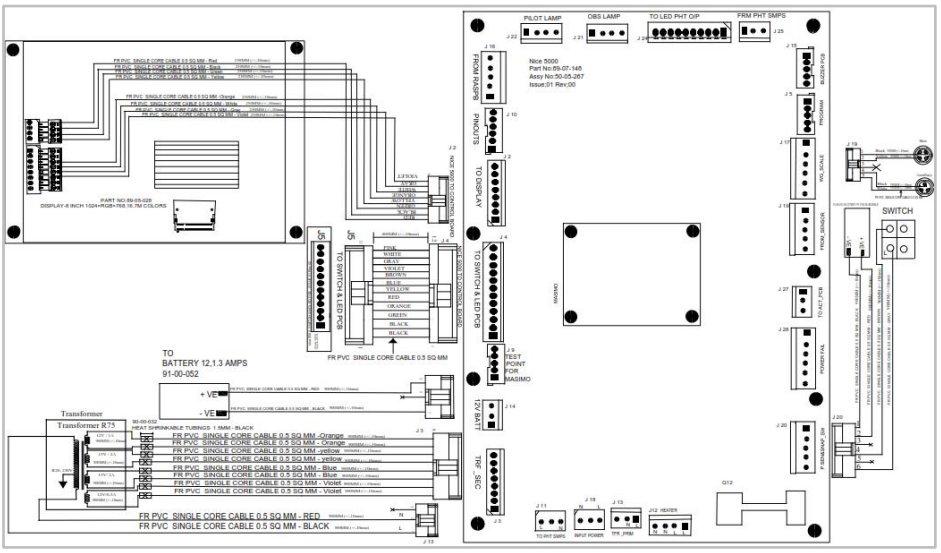
Pillar Assembly



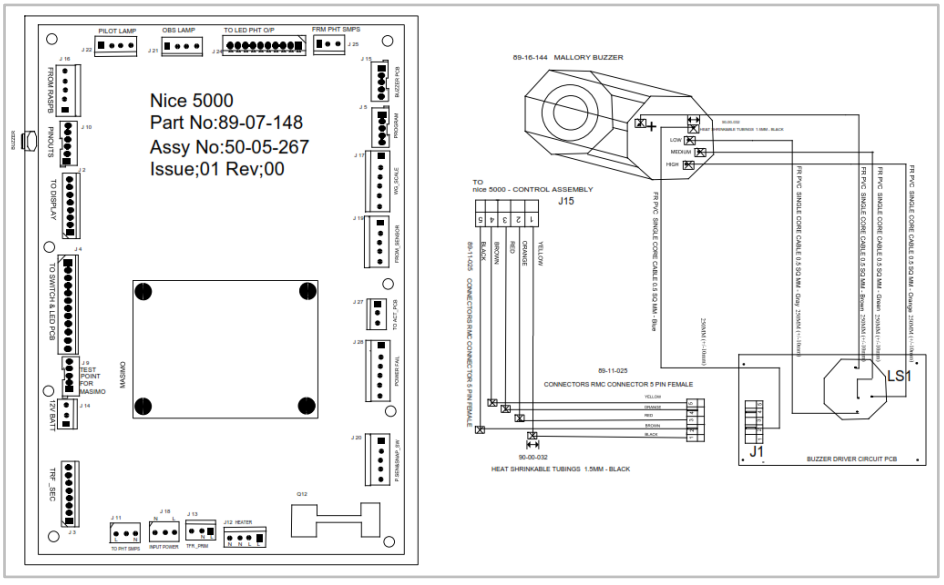
Variable Height Adjustable Assembly



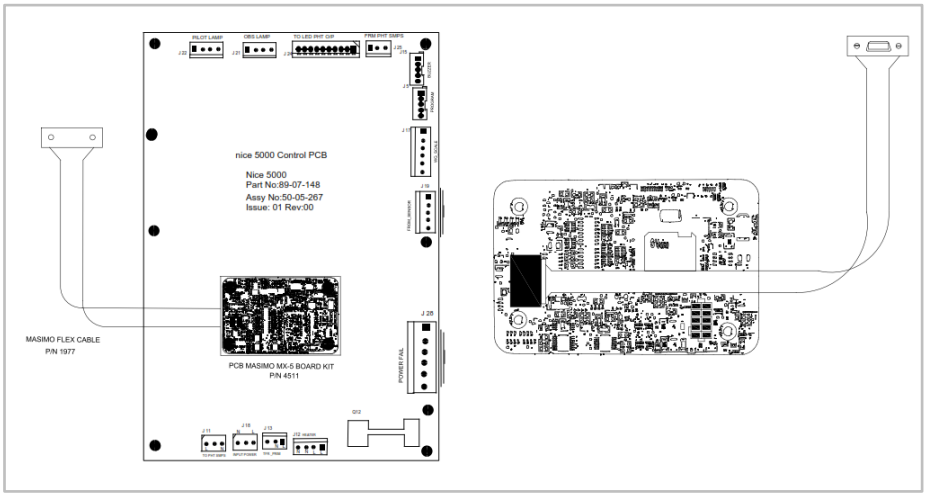
Pedestial Stand Assembly



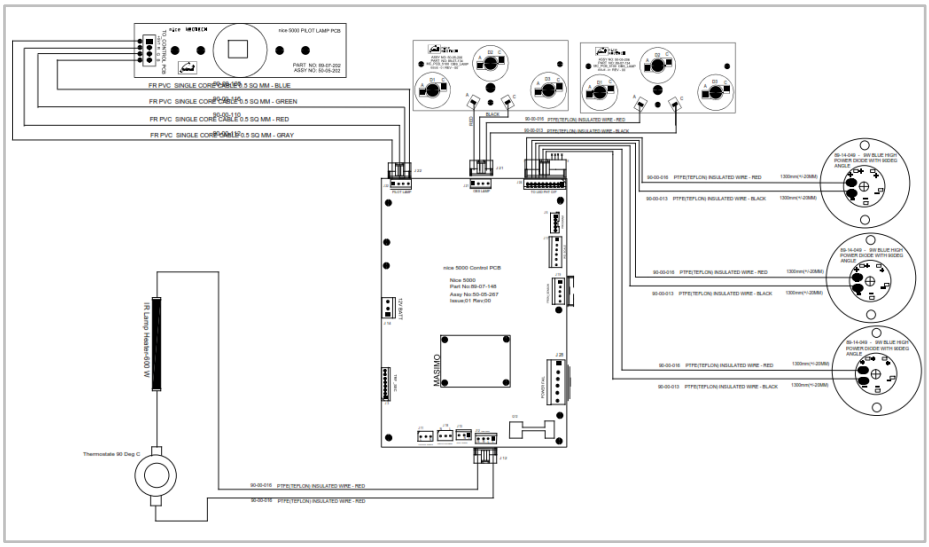
TFT Unit Assembly



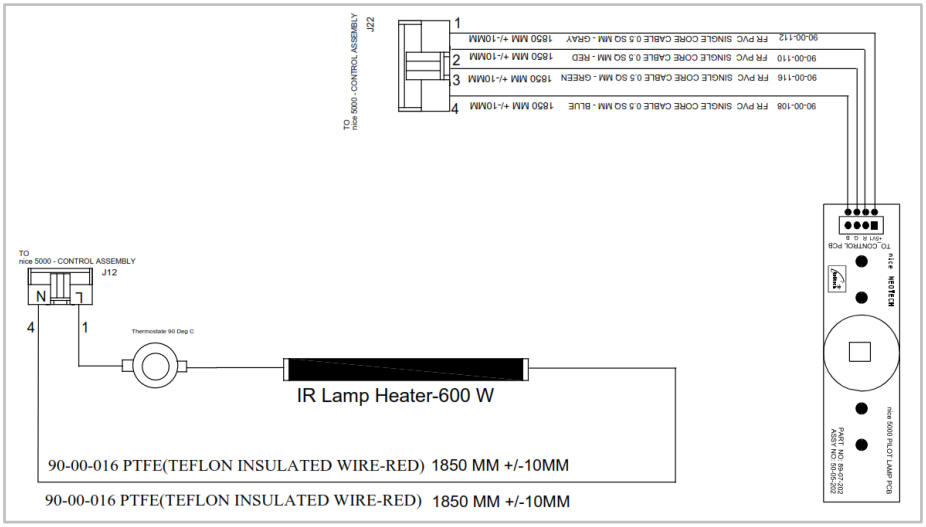
TFT Unit Assembly



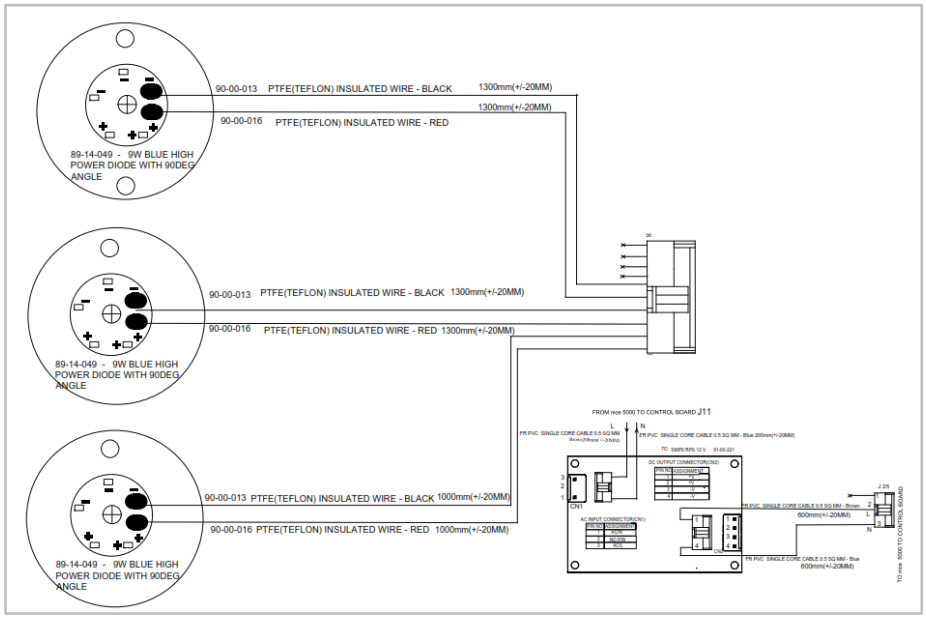
Masimo Pulse Oximeter Assembly



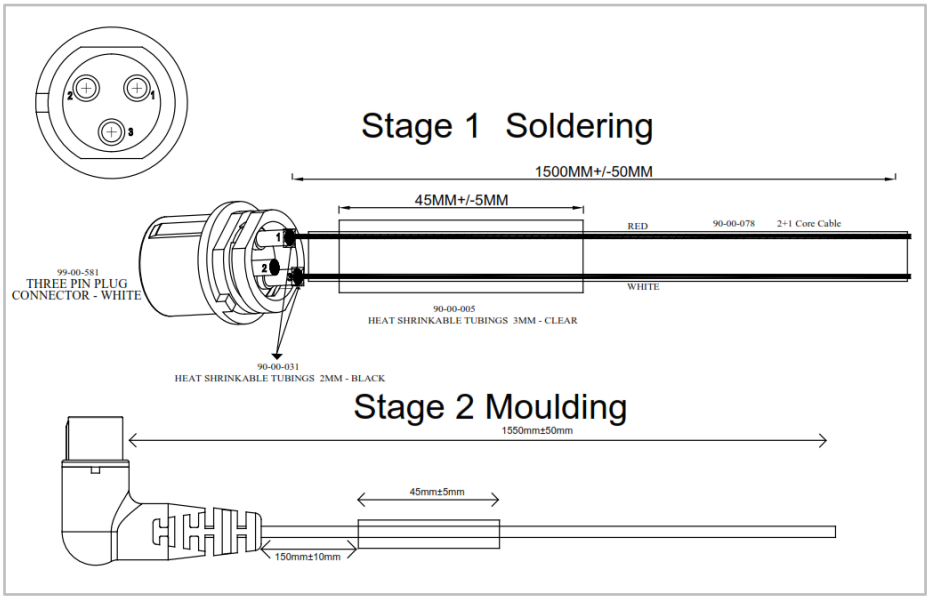
Heater Module Assembly



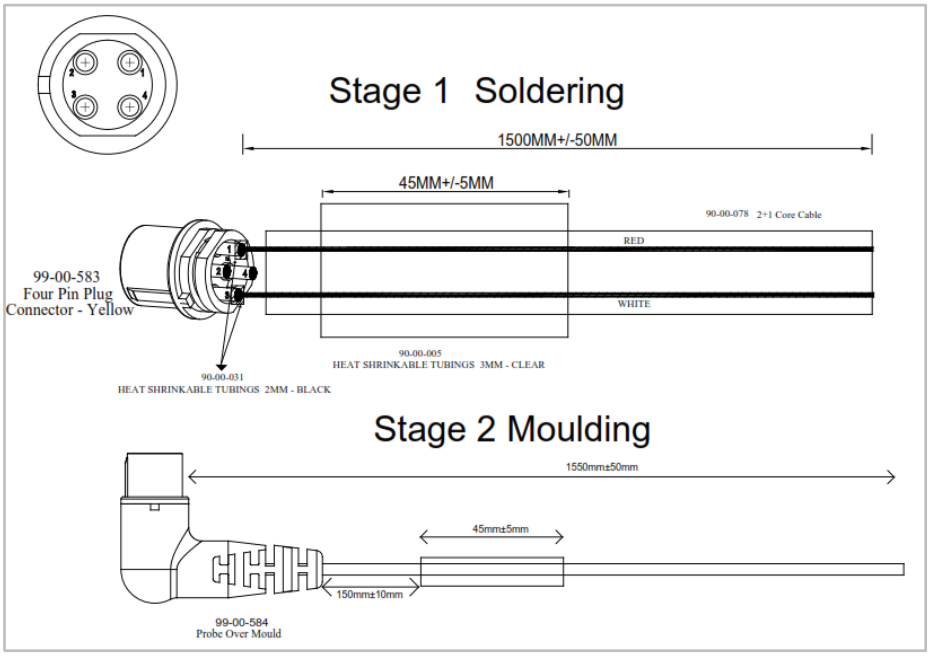
Heater Module Assembly



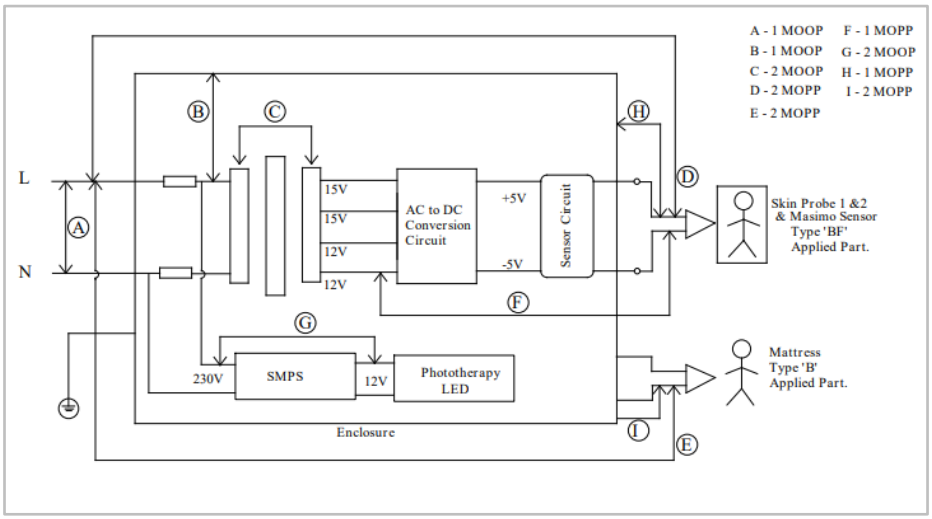
nice 5000RP Phototherapy Rh Mcpcb Assembly



Auxiallary Probe Three Pin Plug Connector assembly



Skin Probe Four Pin Plug connector Assembly



Insulation Diagram

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

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

In case of adverse events, fill the below details:

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

For comments:

For Complaints:

For Feedbacks:

Kindly fill the above and send the same

From:

_____

_____

_____

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

Note: In case of serious/adverse events, report the incident to nice Neötech, 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
nice Neötech Medical Systems Pvt. Ltd. No. 85, Krishna Industrial Estate, Vanagaram, Mettukuppam Chennai-600095. Tamil Nadu, INDIA. Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594 E-mail: service@niceneotech.com /info@niceneotech.com Web: www.niceneotech.com SRN: IN-MF-000010243	**Amstermed BV** 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	**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

Section 12: EC certificate notified body

Name:

PCBC – POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.

Notified body number:

1434

Address:

02-844 Warsaw,
469 Pulawska Street,
Poland.

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