Wallaby

Neötech®
HEALTH CARE EXCELLENCE

Infant Incubator with Servo Humidity Control

nice 3010
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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Table of Contents

User Responsibility / Operator Profile 5
Declaration for Languages 5
Declaration for RoHS 5
Model Descriptions 5
Definitions 6
Definition of Warning indication 7
Hazards of Infant Incubator 7
Section A: Warnings 8
Section B: Cautions 12
Section C: Symbols and Labels 14
Section 1: Description 26
1.1 Intended Use 26
1.2 Medical Indication/Conditions 26
1.3 Contraindication 26
1.4 Side-effects 26
1.5 Intended Patient Population 26
1.6 Device Intended User 26
1.7 Operating Environment 26
1.8 Working Principle 26
1.9 Device Description 28
1.9.1 Mechanical Layout 28
1.9.2 TFT Touch Control Panel 29
1.9.3 Fan 30
1.9.4 Filter 30
1.9.5 Heater 30
1.9.6 Humidity control 30
1.9.7 Humidity Reservoir 30
1.9.8 Oxygen control 30
1.9.9 Canopy (Hood) Assembly Area 30
1.9.10 Air Circulation 30
1.9.11 Masimo rainbow set pulse co-oximetry 31
1.9.12 Bed Platform 31
1.9.13 Electrical height adjustment 32
1.9.14 Weighing scale (optional) 32
1.10 UDI Carrier 32
Section 2: Installation 33
2.1 Unpacking and Inspection 33
2.2 Installation of Canopy 33
2.3 Installation of IV pole 34
2.4 Installation of Mayo/Monitor tray 34
2.5 Installation of TFT control panel pole 34
2.6 Installation of Mattress tray 35

2.7 Installation of Sensors....35
2.8 Pre-use Check Instructions....37
2.8.1 Mechanical Pre-use Check Instructions....37
2.8.2 Controller Pre-use Check Instructions....41
2.8.3 Humidity System Operational Checkout....45
2.8.4 Servo control Oxygen Module Operational Checkout....45
2.8.5 Masimo Rainbow SET Pulse Co-oximetry Pre-use Check....45
Section 3: Operation....47
3.1 TFT Touch Control Panel Display....47
3.2 Switches & Keys....51
3.3 General Control Panel Operation....51
3.3.1 Patient Admission....51
3.3.2 Lock function....51
3.4 Incubator Operation....52
3.4.1 Mode selection....52
3.4.2 Baby Mode (Skin Mode)....52
3.4.3 Air mode....55
3.4.4 Humidifier Control....57
3.4.5 Oxygen Administration (Servo control)....58
3.4.5.1 Oxygen Calibration....59
3.4.6 APGAR Timer....60
3.5 Weighing Scale Operation (Optional)....60
3.6 Masimo Rainbow SET Pulse Co-oximetry....61
3.6.1 SpO_2 Monitoring & Setting....62
3.6.2 Perfusion Index (Pi) Monitoring....64
3.6.3 Pulse Rate (PR) Monitoring (bpm)....64
3.6.4 SpMet Monitoring (optional)....65
3.6.5 SpHb Monitoring (optional)....66
3.6.6 Pleth Variability Index (PVi) Monitoring (optional)....67
3.6.7 Signal Indication and Quality Indicator (SIQ)....68
3.6.8 Masimo sensors....70
3.7 Trend Screen....71
3.8 Settings....72
3.8.1 General settings....73
3.8.2 Incubator settings....73
3.8.3 SpO_2 settings....74
3.9 Audio & Visual Indication....75
3.9.1 Alarm priorities....75
3.9.2 Pilot Lamp....76
3.9.3 Setting the volume level....77
3.10 Mattress Platform Operation....77
3.11 Access Panel and Iris port Operation....78
3.12 Height adjustment....79

3.13 Storage cabinet 79
3.14 X-ray Casette Tray 79
3.15 Shut down Procedure 80
3.16 Transport/Movement details 80
3.17 Accessories 80
#..... 81
Accessory Name 81
Single use / Reuse 81
Part no. 81
Intended use 81
Picture 81
3.17.1 Instructions to use – Masimo Sensor [RD SET YI] 81
Section 4: Cleaning & Maintenance 85
4.1 General 85
4.1.1 Disassembly of parts for cleaning 85
4.2 Cleaning and disinfection of Infant Incubator 87
4.2.1 Cleaning and Disinfection of Temperature probe (Skin and Auxiliary probe) 88
4.2.2 Cleaning and Disinfection of Humidity reservoir 88
4.2.3 Cleaning and Disinfection of Hood and Inner walls 89
4.2.4 Cleaning and Disinfection of Heater radiator (Heat sink) and Fan impeller 89
4.2.5 Cleaning and Disinfection of Mattress tray, Main deck and Heater/Impeller cover 89
4.2.6 Reassembly after cleaning 90
4.3 Air filter replacement 90
4.4 Life time of product 90
4.5 Life time of Cartridge Heater 90
4.6 Transport position 90
Section 5: Specifications 91
Section 6: Warranty 97
Section 7: Trouble Shooting 98
7.1 General System Failure 98
7.2 System Fault 98
7.2.1 Infant Incubator 98
7.2.2 Masimo Pulse Co-oximeter 100
7.3 Maintenance Intervals 103
7.4 Disposing of the Unit 103
Section 8: Spare Parts List 104
Section 9: Manufacturer’s EMC Declaration 105
Section 10: Wiring diagram 107
Section 11: For Complaints/Adverse Events/Comments/Feedback 112
Section 12: EC certificate notified body 114

User Responsibility / Operator Profile

This product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This product must be checked periodically. Operator is positioned near to the front panel of the device. The device should be placed leaving space up to 1m from the wall to access the device backside easily. 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.

While switching off the Infant Incubator, switch off the power at control box and then the Main power and disconnect the power cord.

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

Declaration for Languages

User manual and label will be provided in the appropriate language to ensure that the user understands. Language validation will be done for the language of the user manual, label, corresponding documents, when nice 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 3010 Wallaby provide a servo controlled source of humidified air with oxygen for neonates and infants and monitoring pulse co-oximetry parameter using Masimo rainbow SET pulse co-oximeter. The control system uses a microprocessor and provides servo air mode and servo baby mode of operation. nice 3010 is a superior model, designed with all features. The equipment has TFT touch and masimo features.

Definitions

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

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

c. **Average Incubator Temperature:** The average of the maximum and minimum incubator temperature achieved during **temperature equilibrium**.

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

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

f. **Temperature Variability:** The variability of the incubator temperature that will be observed over a one hour period after incubator temperature equilibrium has been reached.

g. **Temperature rise time:** The time required for the Incubator Temperature to rise 11˚C, when the air control temperature is at least 12˚C above ambient.

h. **Temperature Overshoot:** The amount by which incubator temperature exceeds average incubator temperature at incubator temperature equilibrium shall be restored within 15 minutes as a result of an increase in control temperature value.

i. **Temperature Correlation:** Temperature indicator vs. Incubator temperature, the amount the air temperature indicator at incubator temperature equilibrium differs from the incubator temperature.

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

k. **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.

l. **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%.

m. **Methemoglobin* (SpMet):** Methemoglobin is a hemoglobin in the form of metalloprotein, in which the iron in the heme group is in the Fe^{3+} (ferric) state, not the Fe^{2+} (ferrous) of normal hemoglobin. It cannot bind oxygen, which means it cannot carry oxygen to tissues. The range of SpMet is 0-3%.

n. **Hemoglobin* (SpHb):** Hemoglobin is a protein inside red blood cells that carries oxygen from the lungs to tissues and organs in the body and carries carbon dioxide back to the lungs. The normal range for men is 13.5 to 17.5 grams per deciliter (g/dL) and for women, 12.0 to 15.5 g/dL.

o. **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%.

p. **Pleth variability index* (PVi**): Pleth variablitiy index (PVi) is dynamic index between 0-100 which measures the relative variability of the pleth waveform noninvasively detected from a pulse oximetry sensor. It uses the detected pleth amplitudes to automatically calculate the dynamic changes that occur during the respiratory cycle.

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

SpMet*, SpHb*, PVi* - Optional features

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.

Hazards of Infant Incubator

The Infant Incubator 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.

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

Section A: Warnings

- Incubator is intended for use by a qualified practitioner under the direction of qualified physician. Personnel operating the incubator must become thoroughly familiar with the instruction manual prior to using the Infant Incubator with the patients.
- Ensure patient cabling is routed carefully to minimize the risk of entanglement or strangulation. Always prioritize patient safety during setup and operation.
- To avoid the risk of electric shock, Infant Incubator must only be connected to a supply mains with protective earth.
- Limit the load placed on the x-ray cassette tray to 1.5 Kg to avoid a tipping hazard.
- Only facility-authorized personnel should troubleshoot the model nice 3010 Infant incubator. Troubleshooting by unauthorized personnel could result in personal injury or equipment damage.
- Do not use the incubator if it fails to function as described. Personal injury or equipment damage could occur. Refer the unit for servicing by qualified personnel.
- To prevent personal injury or damage to the variable height adjustable pedestal stand when transporting, employ a person of sufficient strength to adequately control the incubator.
- To prevent personal injury, particular care must be taken to ensure that the additional equipment connected to the baby is electrically safe.
- Never use oil or grease during the administration of oxygen. Oils and grease oxidize readily, and in the presence of oxygen, will burn violently.
- Always ensure your hands are clean and the area is dust-free before installing the equipment to maintain safety and functionality.
- A dirty air intake micro filter may affect oxygen concentrations and/or cause carbon dioxide built-up. Check the filter once in 15 days and change it at least every 3 months or when it is visibly dirty. Failure to do so could result in infant injury.
- Proper installation of the Wallaby, including lifting the hood assembly, requires at least two people. Failure to do so may result in personal injury or equipment damage.
- Allow 45 minutes for the heater assembly to cool. Failure to do so could result in personal injury. Removal of heater assembly only by the service personnel.
- Do not perform the pre-use check instructions (Mechanical and Control Unit) while a patient occupies the Infant Incubator.
- Complete the “pre-use check instructions” section of this manual before putting the unit into operation. If the Infant Incubator fails any portion of the pre-use check instructions it must be removed from use and repaired.
- Inspect all patient connected tubes or wires before and after moving or tilting the bed. Tilting or moving the Incubator bed up or down can pull on tubing or leads connected to the patient. This may disconnect tubes or leads, restrict gas or liquid flow, or move sensors out of position.
- When using an infant incubator, change the patient’s diapers frequently. The elevated temperature accelerates urine evaporation, potentially leading to inaccurate urine diagnostic tests and weight measurements.

- Never place an infant on the X-ray cassette tray.
- Do not place any foreign objects on the Incubator 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 Incubator. Check the patient's temperature regularly to ensure the comfort and the safety of the patient, Patient Temperature may increase or decrease.
- Do not place the device near another warmer,phototherapy unit or other heat generating devices unless specifically intended for such use.
- Follow the product manufacturer's instructions. Failure to do so could result in personal injury or equipment damage.
- Make sure that the oxygen supply to the incubator is turned off and that the incubator is disconnected from the oxygen supply when performing cleaning procedures. A fire and explosion hazard when cleaning in an oxygen administration.
- nice 3010 does not having any additional equipment to maintain the hood temperature.
- Failure to clean the heater radiator and fan impeller could result in sufficient lint built-up to reduce airflow, which will affect temperature control and cause high oxygen concentrations. Infant injury could occur.
- Only facility-authorized personnel should perform preventive maintenance on the model nice 3010. Preventive maintenance performed by unauthorized personnel could result in personal injury or equipment damage.
- The Hood/Shell assembly must attach to the pedestal stand using the screws provided. Failure to do so could result in the hood/shell assembly separating from the pedestal stand when sufficiently tilted, particularly with the hood open. Personal injury or equipment damage could occur.
- Never block or obstruct air vents in the incubator. Doing so may result in overheating and increase the risk of burns.
- To keep the incubator from sliding when parked on an incline, the pedestal stand's front locking casters must be facing down the incline and locked.
- Oxygen Flow rates cannot be used as an accurate indication of oxygen concentration in an incubator. Continuously monitor the oxygen concentrations with a calibrated oxygen analyzer. Failure to do so could result in Personal injury or equipment damage.
- Ensure all sensor leads are properly routed. Use cable management clips to avoid entanglement and possible infant injury.
- The use of oxygen increases the danger of fire and the auxiliary equipment producing spark shall not be placed in the equipment.
- 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.
- Even small quantity of flammable agents such as either and alcohol, left in the incubator it can cause fire in connection with oxygen.
- The direct sun light or other radiant heat sources can cause an increase an incubator temperature to dangerous levels

- The warm up time of the incubator is less than 45 minutes to attain the temperature of 32°C in the baby compartment
- The administration of oxygen may increase the noise level for the baby within the incubator.
- 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.
- The patient sensor is not isolated from earth ground. Any additional equipment used with the nice Neötech Infant Incubator must comply IEC Standard.
- The nice 3010 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 3010 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 3010 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 3010 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.
- Use of nice Neotech cables only. Use of 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.
- Replacement of detachable parts and interchangeable parts such as battery, PCB, power cord, heater, fan, etc., should be replaced only by the trained service personnel.
- Modification or alteration of the equipment is strictly prohibited. Any such changes may compromise the safety and performance of the incubator.
- To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
- nice 3010 compliance with EN/IEC 60601-1-2, the use of accessories, sensors and cables other than specified may result in increased emission/or create invalid output of nice 3010.
- **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.
- Consult the manufacturer for repair and replacement of components.
- 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.
- Keep matches, and all other sources of ignition, out of the room in which the incubator is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen. Personal injury or equipment damage could occur.

- Do not use in the presence of flammable anesthetics. Personal injury or equipment damage could occur.

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

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

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

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.

Danger: Do not use in the presence of flammable anesthetic.

Section B: Cautions

- When using Variable Height adjustable pedestal stand, always lower the incubator to its lowest position prior to transport for optimum stability. Failure to do so could result in Personal injury or equipment damage.
- Connect the sensor cable to the corresponding sensor cable connector only. Do not connect the sensor cable to any other connector.
- Be caution when lowering the shell assembly in place on the shell bottom. Ensure that no cables are pinched and that the extrusion bumper fits properly. Failure to do so could result in equipment damage.
- Use cleaning solution sparingly on a cloth when cleaning the Infant Incubator. Do not saturate the unit - excessive solution causes damage to internal components.
- Do not use harsh cleansers, such as scouring pads or heavy-duty grease removers or solvents, such as acetone. Equipment damage could occur.
- 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.
- 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.
- Do not hide or block the Alarm sound way on the control panel. It may reduce or nullify the alarm sound.
- Some chemical cleaning agents may be conductive and/or leave a residue that may enable a built-up of conductive dust or dirt. Do not permit cleaning agents to contact electrical components. Do not spray cleaning solutions onto any of these surfaces. Equipment damage could occur.
- Do not use alcohol for cleaning. Alcohol can cause crazing of the clear acrylic hood.
- Do not expose the hood assembly to direct radiation from germicidal lamps. Ultraviolet radiation from these sources can cause cracking of gaskets, fading of paint, and crazing of the clear acrylic hood.
- To prevent Component damage, ensure that your hands are clean, and only handle the PCB board by its edges.
- When handling electronic components wear an antistatic strap Failure to do so could result in component damage.
- For shipping and Storage Place the removed PCB 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.
- Before lifting the incubator hood for cleaning, ensure that all mounted accessories have been removed to prevent possible interference with the raised hood.
- To avoid Equipment damage, use only distilled or sterile water. Sterile water alone is not an acceptable substitute for distilled water.
- Isolation from the supply mains is by removing the plug because non detachable Power cord is provided
- The equipment may shows incorrect reading while using the defibrillator
- Periodically clean and disinfect the incubator it fails cause cross infection
- When canopy is open heat loss will occur.
- Open the canopy carefully and fit it slowly.
- To lift canopy pull and lift up.
- Change humidifier chamber water every 24 hours.
- Clean and fumigate the incubator after every patient use.
- Change bacteria filter every 15 days (or) when the color is changed.
- Oxygen concentration of the incubator should be checked periodically at the oxygen port, which is provided on the top of the canopy.
- Both side head up/down tilting can be done infinitely.
- Do not disassemble unit, not user serviceable, refer to qualified service personnel.
- If the transport position of the infant incubator is more than 10°, over balance may occur.
- **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 Load	:	maximum load: 1.5 kg.
Storage cabinet	:	maximum load: 3 kg.

Attention: nice 3010 is not indented to Produce X Radiation for diagnostic and therapeutic purposes.

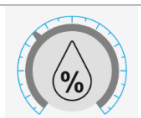
- **Electrical Shock Hazard:** Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. 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.

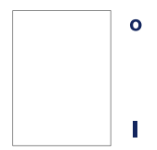
Section C: Symbols and Labels

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 Incubator
	Use no oil
	Warning - Hot Surface area – Protective grill
	General mandatory action
	Alternating current

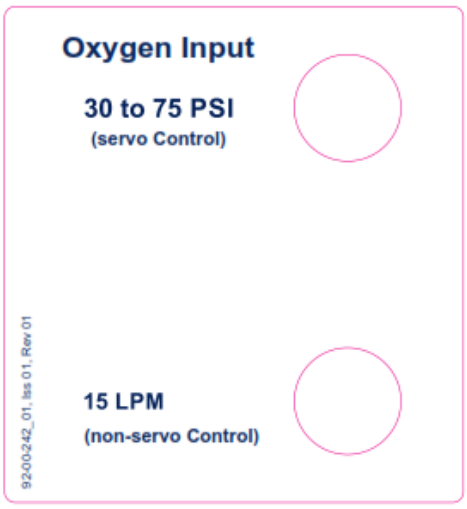
⎓	Direct Current
	Off (Power: disconnection from main)
	On (Power: connection to the main)
	Type BF Equipment
	Type B (Mattress)
	Wi-Fi
	Battery percentage
	Skin temperature
	Set skin temperature
	Auxiliary temperature
	Baby Mode
	Air temperature
	Set Air temperature
	Air mode
	Heater power output

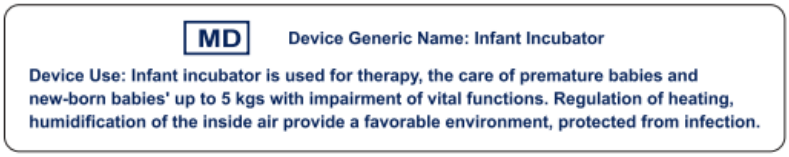
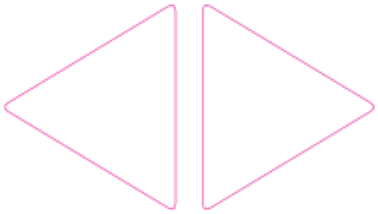
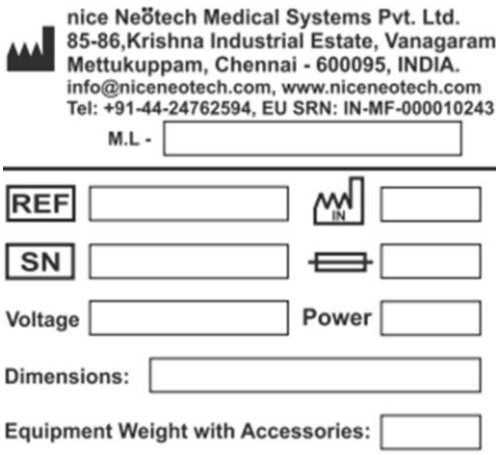
	Humidity percentage
	Oxygen percentage
	Weighing scale display(Optional)
	APGAR timer start
	APGAR timer stop
	APGAR timer Start/Stop
	APGAR Count Up
	APGAR Count Down
	Timer
	Lock
	Unlock
	Menu
	Increase key
	Decrease key
	Calendar
	Time navigation backward (Trend settings)

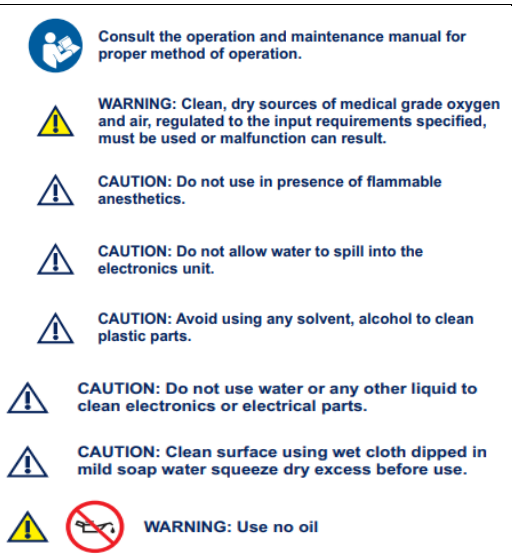
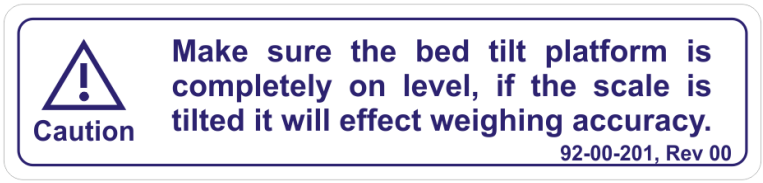
	Time navigation forward (Trend settings)
	Back
	Volume
	Home/ Exit
	Defaults
	OK
	Cancel
	Save
	Screen timer
	Bed tilting
	Bed tilting up/downg
	Main switch
	ON/OFF key

	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

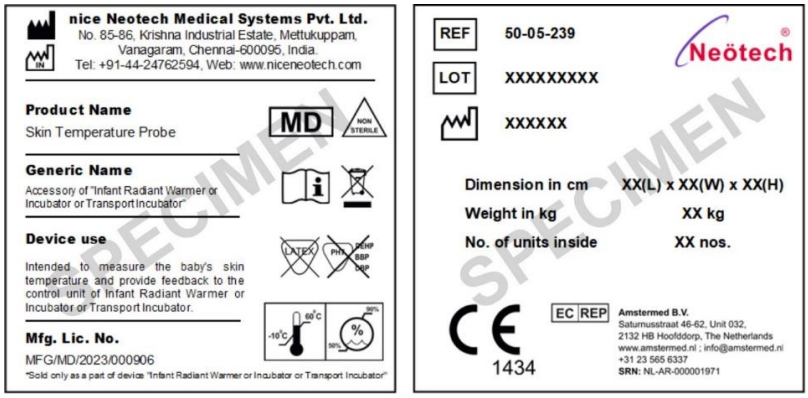
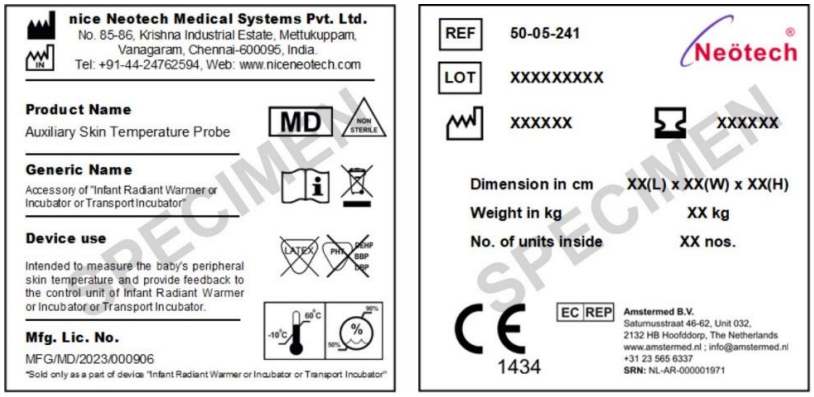
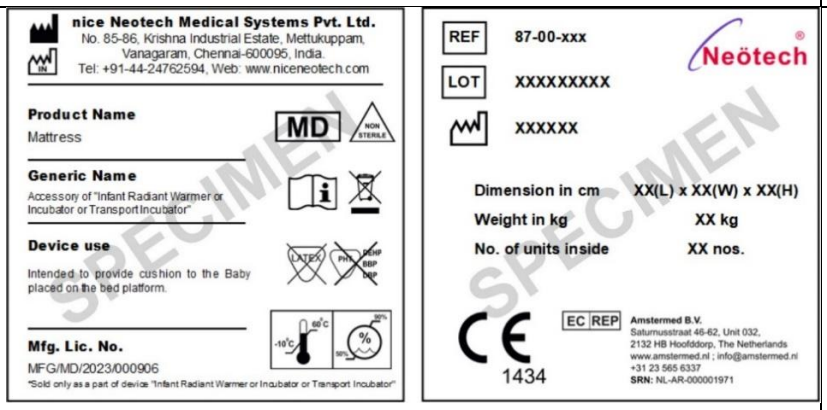
Labels

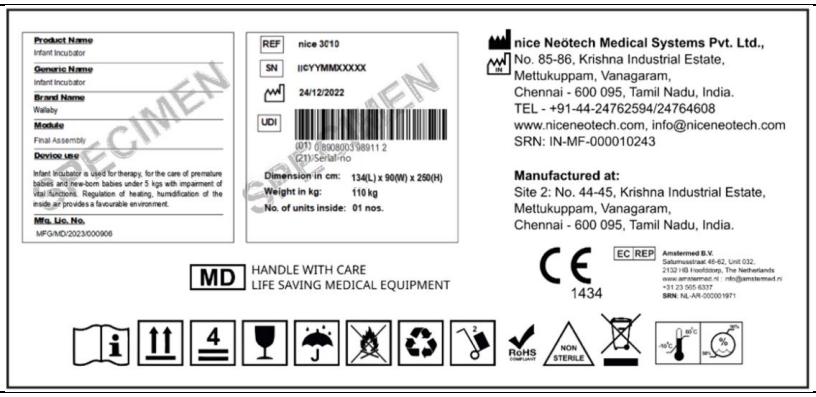
S. No	Label	Part Number	Label Description
1.		92-00-242	Bed tilting keys
2.		92-00-242_01	Oxygen input
3.		92-00-242	Sensor module
4.		92-00-242	Front panel switches (Keypad)
5.		92-00-242_05	Sensor module, SpO_2 cable, display probe, circuit

6.		92-00-242_06	breaker, power cable and power switches
7.		92-00-242_06	Device Use
8.		92-00-242	Label – Pedestal Stand (Foot Press) label
9.		92-00-261_02	Air filter
10.		92-00-242	marking plate& Information

11.		92-00-260	Instructions
12.		92-00-201	Caution - weighing
13.		92-00-239_01	Mattress
14.		92-00-240	Skin and auxiliary temperature probe tag
15.		92-00-239	Safety sign, Hot surface

16.	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.	92-00-242	CE marking
17.		92-00-239	Max weight 1.5kg
18.		92-00-239	Max weight 3kg
19.		92-00-239	Safety sign, do not step on surface
20.		92-00-239	Safety sign, do not lean
21.	Neötech®	92-00-002	Neotech Brand logo (Display panel)
22.	Neötech®	92-00-272	Neotech Logo

23.		92-00-253	Masimo brand label
24.		--	nice 3010 Brand name
25.		--	Packing label – Skin Temperature probe
26.		--	Packing label - Auxiliary Skin Temperature Probe
27.		--	Packing Label - Mattress

28.		--	Label – Packaging, Transportation and storage Instruction
29.		--	UDI Label

Section 1: Description

1.1 Intended Use
1.2 Medical Indication/Conditions
1.3 Contraindication
1.4 Side-effects
1.5 Intended Patient Population
1.6 Device Intended User
1.7 Operating Environment
1.8 Working Principle
1.9 Device Description
1.10 UDI Carrier

1.1 Intended Use

Infant Incubator is used for therapy, for the care of premature babies and new-born babies under 5 kgs with impairment of vital functions. Regulation of heating, humidification of the inside air provides a favourable environment.

1.2 Medical Indication/Conditions

- Therapy for subject with Impairment of vital functions.
- Regulation of heating.

1.3 Contraindication

- Infant Incubator is contraindicated for major congenital abnormalities, severe clinical coagulopathy.

1.4 Side-effects

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

1.5 Intended Patient Population

- Pre-mature, Neonates and Infants upto 5 kg.

1.6 Device Intended User

- Neonatologist and Pediatrician.

1.7 Operating Environment

- The Incubator is used in various hospital locations such as NICU, Gynec Ward.

1.8 Working Principle

Infant Incubator:

The temperature, humidity, and oxygen concentration is controlled by the forced air circulation system. A controlled amount of room air is drawn through the air intake filter by the motor-driven impeller located in the shell.

The impeller internally recirculates air at a much higher flow rate than that of the fresh gas inflow. The total inflow of fresh and recirculated air is directed around the heater. The air enters the infant compartment through the slots at the front and rear of the main deck. It then circulates past the sensor module, which contains the temperature-sensing probe that monitors the air temperature. After circulating within the infant compartment, the air is recirculated through a slot at the right end of the main deck and back to the impeller. When the front access panel

of the hood is open, the air continues to flow upward past the opening, creating a warm air curtain that minimizes the drop in air temperature within the incubator.

Temperature is regulated by using either incubator air or skin temperature. The front panel of TFT display enable the user to select the desired Air or Skin mode. In either mode of operation, the heater output is proportional to the amount of heat required to maintain the desired temperature.

Servo Oxygen control system:

Servo controlled oxygen system allows the user to control the FiO_2 % using the control panel. When installed, the servo oxygen control system maintains oxygen concentration within the hood via a valve and an oxygen sensor module. The sensor module houses 2 independent oxygen fuel cells. Oxygen concentration is displayed on the screen, and oxygen-related alarm conditions are indicated to the user via acoustic and optical alarms.

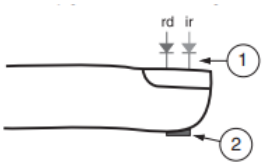
Servo humidity control system:

The actual humidity level is measured by a humidity sensor in the patient compartment. If the set point is higher than the actual measured relative humidity (air too dry), the humidifier receives a signal to allow more water vapour into the patient compartment. Relative humidity inside rises. If the set point is lower than the actual measured relative humidity (air too humid), the humidifier receives a signal to allow less water vapour into the patient compartment. Relative humidity inside falls.

Masimo Pulse Co-oximeter:

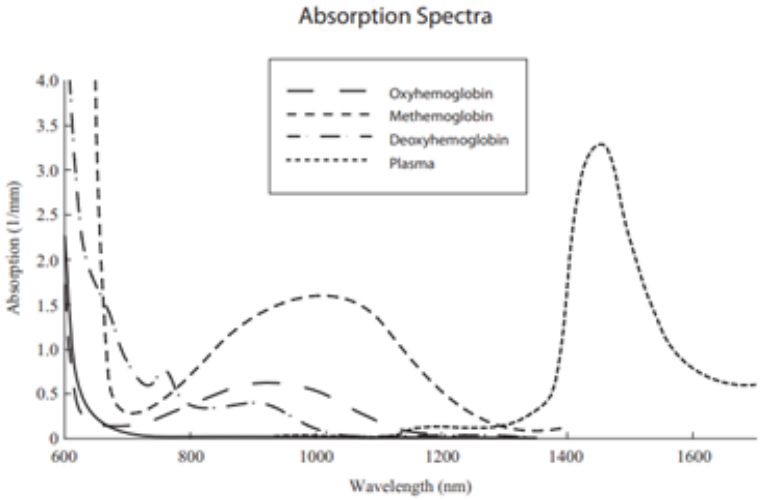
Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).

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.



1. Light Emitting Diodes (LEDs) (7 + wavelengths)
2. Detector

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.



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

1.9 Device Description

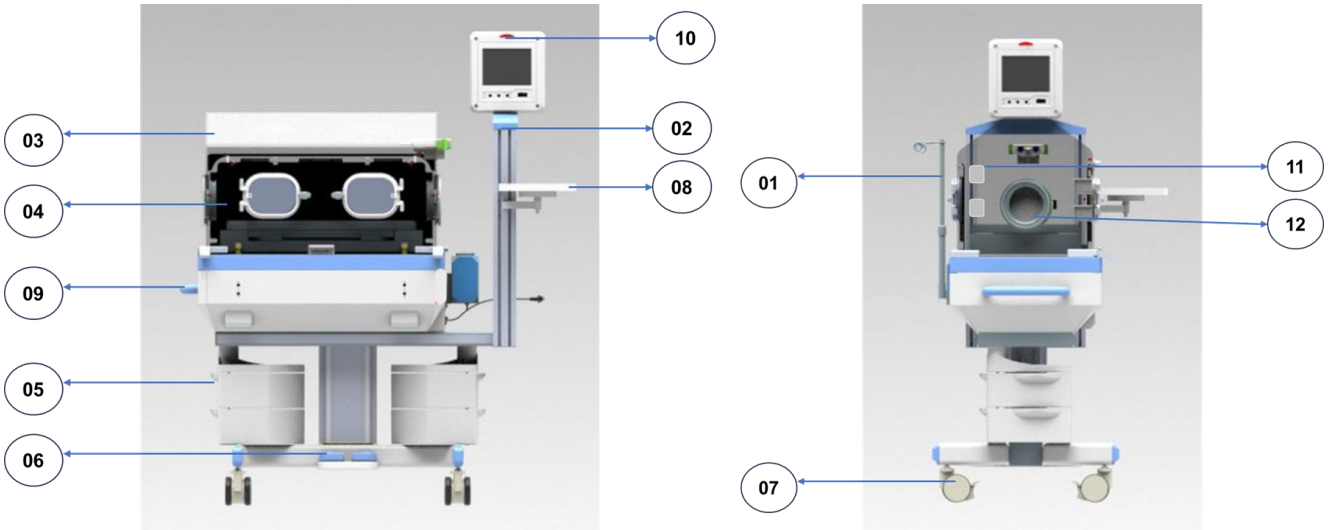
nice 3010 Wallaby is an combination of Infant Incubator with servo controlled Humidity and Oxygen along with Masimo pulse co-oximeter.

Wallaby provides an optimum thermal environment for the infant who's are low weight, high risk and less the gestation period of 36 weeks and monitors SpO_2, SpHb*, PR, Pi, SpMet* and PVi* by Masimo rainbow pulse co-oximeter.

The incubator helps to stabilize the infant's body temperature at the normal level by minimizing the infant's heat loss. The incubator directs the heated air through the air ducts in it and monitors the inside temperature in it with temperature sensors. The air speed in the incubator is limited to less than 25 cm/Sec, thus minimizing the convective heat loss. Fresh heated air is introduced into the incubator along with recirculated air. Fresh heated air is introduced into the incubator along with reticulated air minimizes the evaporative heat loss by humidifying the infant compartment air.

Wallaby comes with a integrated touch display as a control system built using microcontroller. Patient temperature along with set temperature and pulse co-oximeter functions are controlled and displayed in the LCD display. A complete audio and visual indication system is included on the display panel.
SpMet*, SpHb*, PVi* - Optional features

1.9.1 Mechanical Layout



S.NO	PART NAME
1	IV Hook
2	TFT Touch Control Panel
3	Hood Assembly
4	Mattress
5	Storage Cabinet
6	Height Adjustment Pedal
7	Castor Wheel
8	Mayo Tray
9	Handle
10	Label, Neotech Logo
11	Grommet Access
12	Iris Port

1.9.2 TFT Touch Control Panel

Wallaby comes with a integrated TFT touch display control panel to operate infant incubator and Masimo rainbow set pulse co-oximeter operations.
The control panel allows the user to access the incubator operations through two modes of operation: Baby mode, and Air mode. The incubator TFT display Control panel is located on the top-right side of the incubator. The microprocessor-based control system provides a controlled temperature environment for the infant. The TFT display panel visually indicates visual indications on the slots provided in display while an audible indication sounds & visual audio indication to alert the operator to check the condition. The unit also features an over temperature safe system. The patient temperature, the air temperature, Oxygen percentage and humidity percentage are continuously displayed on the TFT displays.

Baby mode:

Baby mode is a servo controlled operation which automatically controls the radiant heater based on the set required temperature and actual temperature of the baby. Actual temperature of the baby will be recorded by the skin temperature sensor and displayed in the control unit, the information from the sensor is supplied to the heater control unit, which proportions the heater output to maintain the baby set temperature. In baby mode, the control unit enables the user to control the baby temperature between 32.0°C to 38.0°C.

Air mode:

Air mode is a servo controlled operation which automatically controls the radiant heater based on the set required temperature and actual ambient temperature. Actual ambient temperature will be recorded by the air temperature sensor and displayed in the control unit, the information from the sensor is supplied to the heater control unit, which proportions the heater output to maintain the set temperature. In air mode, the control unit enables the user to control the baby temperature between 30.0°C to 38.0°C.

Other Features:

Wallaby'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)*.

Wallaby incubator circulates the humidified air with oxygen into the hood by allowing the air through humidity water chamber and oxygen gas path. Humidity inside the hood is servo controlled, the control panel enables the user to control the relative humidity inside the hood by setting the desired humidity %. An integrated oxygen flow meter enables the user to set the flow rate of oxygen to mix with the circulated air inside the hood.

The i-sense technology in the control panel provides extra safety to the patient during skin temperature sensor being displaced or detached from the patient.

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

A memory back up system holds the data of Control temperature and the mode of operation even if the power is OFF and is ON again. A battery operated power failure indication activates when the external power source fails or is disconnected.

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

***Optional features**

1.9.3 Fan

The fan takes the filtered room air and blows it over or through the heating element and the humidifier. Without the fan the heat cannot be conducted away from the heating element and through the heating element and thus the incubator would overheat. To avoid overheat during fan failure, heater will be cut-off through the microcontroller.

1.9.4 Filter

Incubators are equipped with disposable filters. It filters the dust particles in intake air and oxygen.

1.9.5 Heater

A heating element made from coiled resistance wire. The power rating is 350 W. The heater is controlled by a microcontroller via a relay, triac, thermistor sensor (to measure the heater temperature) and 175°C thermostat.

1.9.6 Humidity control

When installed, the built-in humidifier provides humidification of the incubator from 20% to 95% relative humidity (RH) in 1% increments. When the humidity system senses an absence of water an audible and visual Low Humidity Audio and Visual Indication occurs.

The humidifier is a two-part system consisting of a humidity reservoir and evaporator assembly.

Servo control system:

Wallaby incubator circulates the humidified air with oxygen into the hood by allowing the air through humidity water chamber and oxygen gas path. Humidity inside the hood is servo controlled, the control panel enables the user to control the relative humidity inside the hood by setting the desired humidity %. An integrated oxygen flow meter enables the user to set the flow rate of oxygen to mix with the circulated air inside the hood.

1.9.7 Humidity Reservoir

The humidity reservoir has a 1.5 liter capacity. The reservoir permits visual inspection of the water level. It is located at the left side of the incubator shell. The reservoir is connected to an evaporator assembly.The reservoir contains a valve for draining the water, which is located at the bottom.

1.9.8 Oxygen control

Servo control

When installed, the oxygen (servo) control system adjusts the flow of oxygen within the incubator hood with a oxygen sensor module. The sensor module houses oxygen fuel cell.

1.9.9 Canopy (Hood) Assembly Area

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

1.9.10 Air Circulation

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

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

1.9.11 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, methemoglobin concentration (SpMet*) & total hemoglobin (SpHb*) in arterial 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:

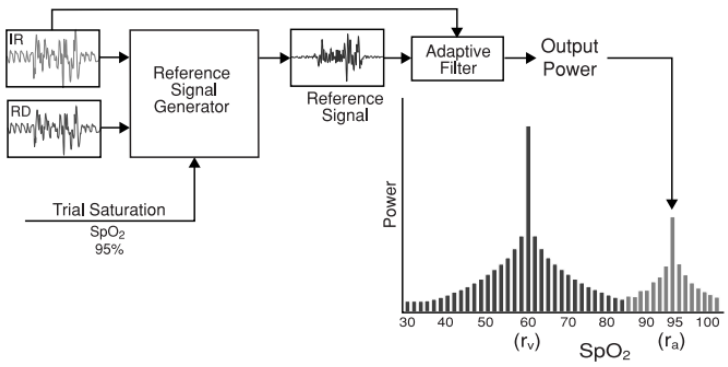
1. As a percent value for arterial oxygen saturation (SpO2)
2. As a pulse rate (PR)
3. As a plethysmographic waveform
4. As a percent value for methemoglobin concentration (SpMet)*
5. As a percent value for total hemoglobin (SpHb)*
6. As a percent value for perfusion index (Pi)
7. Pleth Variability Index (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.



1.9.12 Bed Platform

The incubator Mattress tray includes a mattress. The X-ray cassette can be placed beneath the Mattress.

The external tilt able Mattress tray platform allows Reverse Trendelenburg . The system for the tilt able Mattress tray provides a smooth motion to avoid disturbing the patient.

1.9.13 Electrical height adjustment

The height of Wallaby from the floor can be adjusted by using motorized pedal operation.

1.9.14 Weighing scale (optional)

Weighing scale is used to measure the babies weight to decide fluid requirement, drug dosages & weight gain patterns.Weight record is essential to monitor the adequacy of nutrition as well as fluid balance. Accurate weighing scale is a fundamental need for all special care neonatal units and delivery rooms. Recording weight at birth and daily is essential for the management of Very Low Birth Weight (VLBW) babies. Birth weight helps in identifying the level of care required for the baby and classification into weight for dates categories.

The weighing scale contains load cell present below the bed assembly, measures the weight of the baby even when the baby is showing movement during the measurement of weight, it does not affect the value being measured. The control and settings of the weighing scale is done on the control panel as the baby's weight is measured.

1.10 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 3010	08908003989112	IICYYMMXXXXX IIC- Product Code YY – year MM – Month XXXXX – serial No

UDI label
UDI (01) 0 8908003 98911 2 (21) IIC24090020

Section 2: Installation

2.1 Unpacking and Inspection

2.2 Installation of Canopy

2.3 Installation of IV Pole

2.4 Installation of Mayo/Monitor tray

2.5 Installation of TFT control panel pole

2.6 Installation of Mattress tray

2.7 Installation of Sensors

2.8 Pre-use Check Instructions

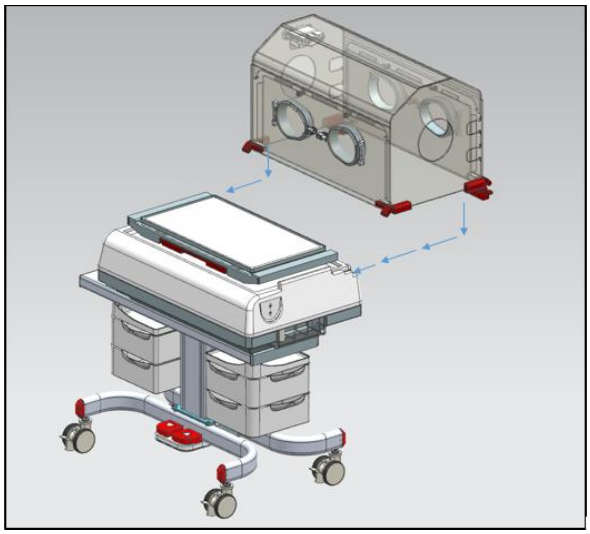
2.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of Wallaby.
- After removal from the shipping containers, inspect the nice Neötech Infant incubator 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 dmage claim with the shipping carrier if damage is found in any of the assemblies or accessories in the container.

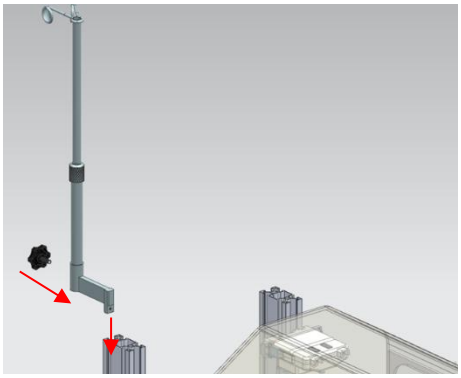
- Do not use the equipment, if it appears or is suspected to be damaged.

2.2 Installation of Canopy

	❖ Place the hood on the shell and Ensure the hood fits evenly on both sides, with the bracket securely positioned in the gaps. ❖ After locating the hood, slide the hood into place, ensuring it sits firmly

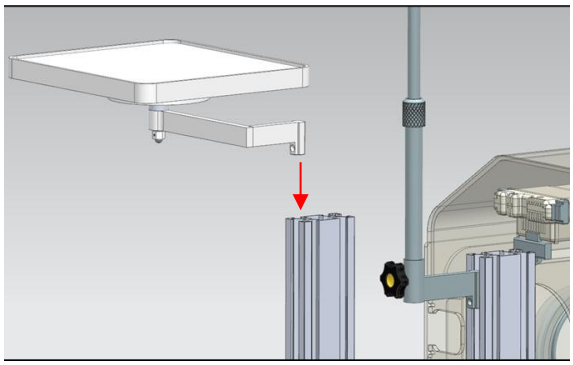
- Make sure the hood attached to the shell. Failure to do so could result in the hood separating from the shell if sufficiently tilted.

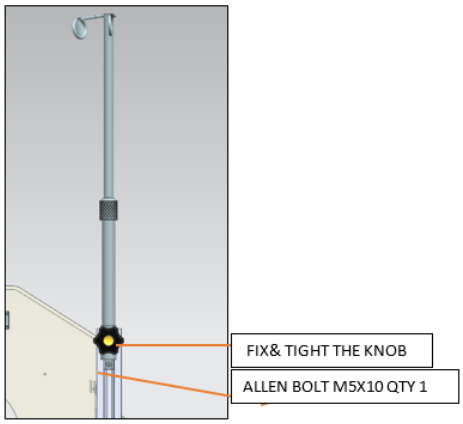
2.3 Installation of IV pole



- Assemble the IV Pole before the Display Assembly.
- Insert the IV Pole and screw it in by tightening the knob securely.
- Loosen the adjustment knob to adjust the height, then set the desired height and tighten the knob to fix it in place.

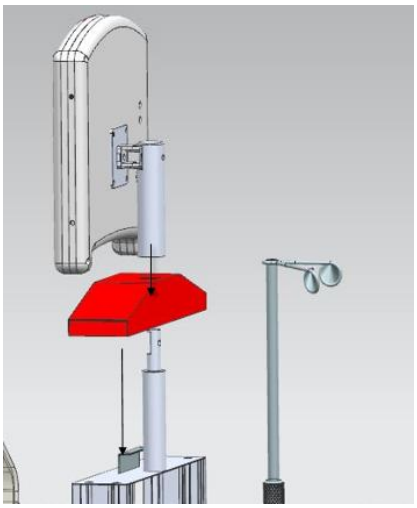
2.4 Installation of Mayo/Monitor tray

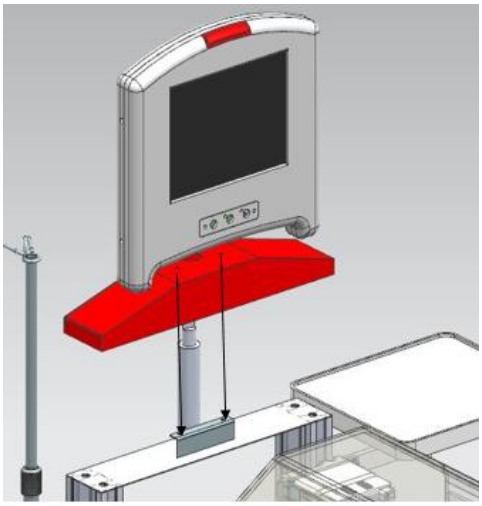




- Attach the Mayo tray arm to the frame and secure it using the screw as shown in pictures.

2.5 Installation of TFT control panel pole





- Locate the control panel pole to their respective grooves as shown in the figure.
- Screw the poles from the bottom.
- Do the wiring to the control panel as per the wiring diagram.

2.6 Installation of Mattress tray

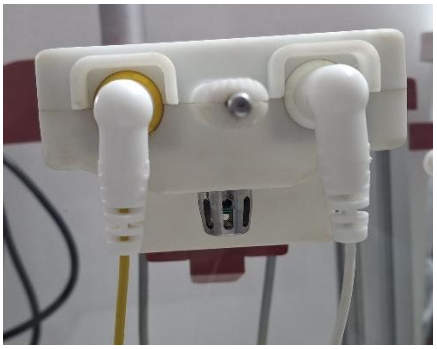
- Open the front doors on both sides of the canopy by rotating (or unlocking) the pawl latches as shown in the figure.
- And then, locate the mattress tray platform to the tilting rod.
- Slide it through the rod until it locks.
- Put the mattress on the tray and close the doors.

Warning

- Make sure that the oxygen supply to the incubator is turned off and that the incubator is disconnected from the oxygen supply when performing cleaning procedures. A fire and explosion hazard when cleaning in an oxygen administration.
- 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 incubator it can cause fire in connection with oxygen
- The administration of oxygen may increase the noise level for the baby within the incubator
- Oxygen Flow rates cannot be used as an accurate indication of oxygen concentration in an incubator. Continuously monitor the oxygen concentrations with a calibrated oxygen analyzer. Failure to do so could result in Personal injury or equipment damage

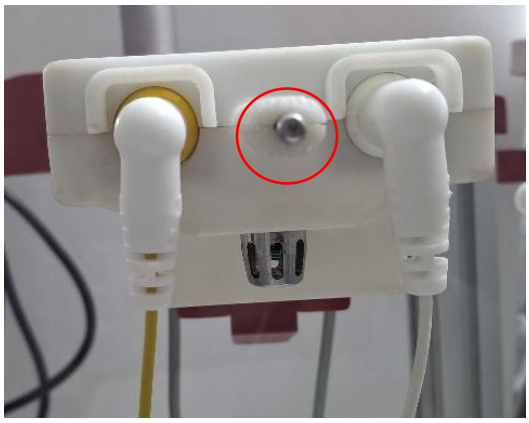
2.7 Installation of Sensors

2.7.1 Installation of sensor Module



- The sensor module is positioned on the right side of the hood for optimal functionality.

2.7.2 Air Temperature Sensor

	❖ The air probe fixed securely inside the sensor module, positioned between the skin socket and the auxiliary socket of the sensor module.

2.7.3 Skin Temperature Probe

	❖ Connect the skin probe with a skin probe socket which is placed on the right side of the control module.

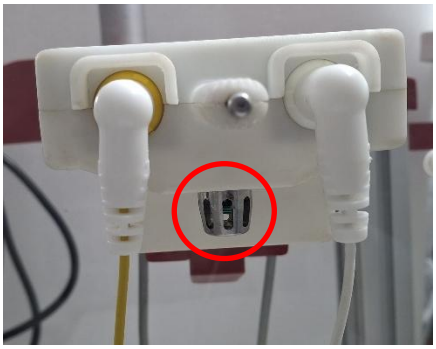
2.7.4 Auxiliary Temperature Probe

	❖ Connect the auxiliary probe with an auxiliary probe socket which is placed on the right side of the control module.

2.7.5 Oxygen Sensor

	❖ The oxygen sensor is positioned at the bottom of the sensor module.

2.7.6 Humidity Sensor Module

	❖ The humidity sensor is positioned at the center of the sensor module for optimal performance.

2.7.7 Masimo Sensor

	❖ Connect the Masimo sensor as shown in the image.

2.8 Pre-use Check Instructions

2.8.1 Mechanical Pre-use Check Instructions

- Before using nice 3010 Wallaby, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury.

- Do not perform the Pre-use Check Instructions (Mechanical and Control Unit) while a patient occupies the incubator.
- Complete the “Pre-use Check Instructions” section of this manual before putting the unit into operation. If the incubator fails any portion of the Pre-use Check Instructions it must be removed from use and repaired.

2.8.1.1 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 incubator. There should be no obvious damage.

Setup and Pre-use Check Instructions

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

- Do not place any accessories or other objects directly over the bed surface. This may block heat energy and lead to cooling of the infant.
- Do not place items on top of the Hood assembly. Items placed on top of the Hood assembly can fall and injure the patient and may pose a fire hazard.

2.8.1.2 Mechanical Checks

1. Mattress Tilting

❖ Check the Mattress tilting mechanism by press down or up arrow which is provided at the sides of the shell to set the different angle.

❖ Check the operation of the tilt mechanism. Verify that the bed platform operates smoothly and locks in normal, ReverseTrendelenburg

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

2. Mattress Tray Operation

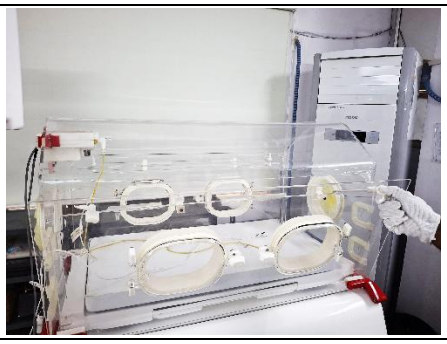
- Rotate the locks and open the access panel.
- Pivot the access panel to the full open position.
- And then, slide out the mattress tray platform from the tilting rod.

Note: before the operation deattach the weighing scale connection.

3. Hood operation

- Lift the hood assembly from the front side of the incubator and hold it to the rear side.

4. Access panel Operation



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

5. Access Door, Latches and Gaskets

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

6. Iris Entry Ports

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

7. Electrical Height Adjustment

- Press the increase and decrease pedal on the base to adjust the height as needed.

➔ **Upward pedal stand**

➔ **Downward pedal stand**

8. Air intake Micro filter

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

- A dirty air intake micro filter may affect oxygen concentrations and/or cause carbon dioxide built-up. Check the filter once in 15 days and change it at least every 3 months or when it is visibly dirty. Failure to do so could result in infant injury.

2.8.1.3 Accessories Checks

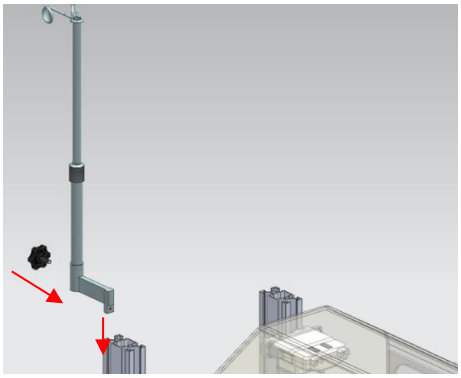
- ❖ Perform these checks if they are applicable.
- ❖ Check that all accessories are mounted securely and that the load limits mentioned in the labels are not exceeded.
- ❖ Where applicable, perform the Pre-use Check Instructions detailed in the Operation and Maintenance Manuals for the accessories.

- Limit the load of accessories to 5 Kgs per side on the Incubator 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
Mattress	: maximum load: 10 kg
Infusion pump pole	: maximum load: 1.5 kg
Storage cabinet	: maximum load: 3 kg

- Check that all accessories are mounted securely and that the load limits are not exceeded. Check that all gas accessories are installed and operating properly. Where applicable, perform the Pre-use Check Instructions detailed in the Operation and Maintenance Manuals for the accessories.

I. IV Stand

	❖ Using the knob, height can be adjusted to desired level ensuring smooth operation. ❖ The maximum Load of the IV pole is 1.5 Kg.

2.8.2 Controller Pre-use Check Instructions

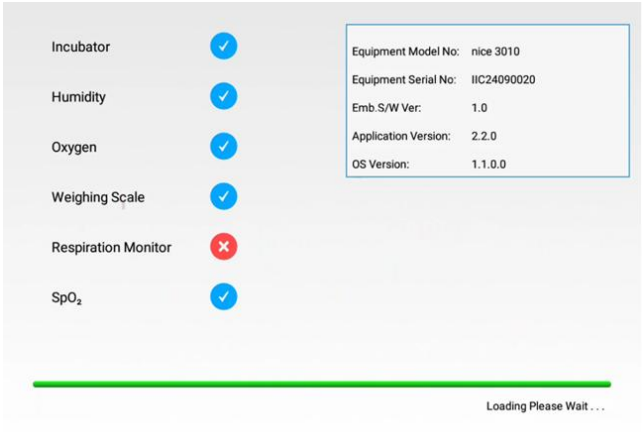
- Do not perform the Pre-use Check Instructions (Mechanical and Control Unit) while a patient occupies the Infant Incubator.

- Complete the “Pre-use Check Instructions” section of this manual before putting the unit into operation. If the nice 3010 Wallaby fails any portion of the Pre-use Check Instructions it must be removed from use and repaired.

System Startup Operation

When the Infant Incubator is switched on, the device initiates a system startup process. The status of all critical component is checked before proceeding to normal operation.

The status of each critical component is displayed with an indicator, such as "✓" to signify normal operation. Once all status is verified, the system will transition to the Control Panel Display. If any issue is detected, the status will show a “✕” message to alert the user.



- After the system startup is complete, it will automatically transition to the Control Panel Display, where operations are monitored.

Note: If the oxygen sensor or humidity sensor is disabled or skin sensor fails, the system will still transition to the control panel.

Control Unit Check

Connect the nice 3010 Wallaby power cord to an appropriate power source. Refer to the rating label on the nice 3010 Wallaby for the proper voltage needed.

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

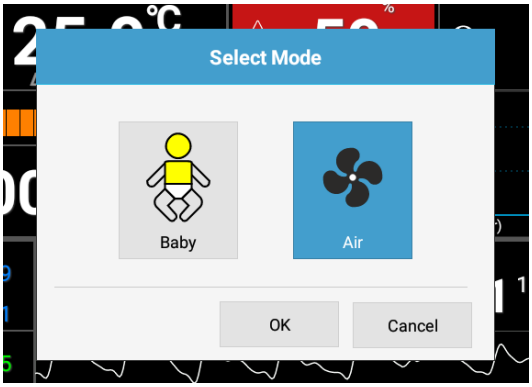
- Check that the control panel switches ON with Neotech logo followed by Wallaby displayed on the screen.
- Check that the system initializes on self-check mode, verify pink light on the pilot lamp in the heater module.

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

- Check that incubator 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 both the modes can be selected and the selected mode is displayed in the control panel.
- Select the Baby mode and unplug the skin temperature sensor to check that the Baby sensor fail indication lits up with both audio & visual indication.
- Press the Audio paused key to check that the audio indications are paused.
  (*Refer to Section 3.4 for full information on operation*)
- Select the APGAR timer and select the desired time and check that the timer is displayed on the control panel.

Air Flow Fail

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

Warning

- The Incubator should not be used, if it fails to function as described. Service should be referred to qualified personnel.
- The Heater can be sufficiently hot to cause burns. Permit the heater to cool for at least 20 minutes before attempting this procedure.

Air Control Mode Operation

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

Note: Check the Air Temperature Display window Shows 25ºC when connect the calibrated test probe.

High/Low Air Temperature indication

- Open the Access panel. In approximately 5 minutes the Audio indicators should activate, the low air temperature visual and audio indication should activate. Close the Access panel.

- Rub the Air temperature sensor with hand to raise the temperature 0.5˚C greater than the set temperature, the high air temperature visual and audio indication should Sound.

Skin Control Mode Operation

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

Note: Check the Skin Temperature Display window Shows 25ºC when connect the calibrated test probe.

High/Low Skin Temperature indication

- Set the skin set temperature to 35˚C. When the temperature stabilizes, open the access panel. in approximately 5 minutes, the low skin temperature visual and audio indication should sound.

- Rub the skin temperature sensor with hand to raise the temperature 0.5˚C greater than the set temperature, the high skin temperature visual and audio indication should sound.

Maximum Air Temperature

- Select the skin mode and set temperature is greater 37˚C. Place the skin temperature sensor outside the incubator. Allow the incubator to heat. If the skin temperature low indication sounds, press the audio paused key.

- The incubator should not heat above 39.9˚C as indicated by the air temperature display. When reaching the air temperature at 39˚C, over temperature indication should sound and the heater power will be cutoff should be OFF.

Skin and Auxiliary temperature sensor Defect

- Disconnect the skin temperature sensor from the socket. The audio indication sound activates and the display shows “Skin Sensor defect” & “Auxiliary sensor defect” and the heater power will be cutoff, reconnect the skin temperature sensor, the incubator should return to normal operation. 50.1

Air temperature probe Fail

- Disconnect the air temperature probe from the socket. The audio indication sound activates and the display shows “Air temperature sensor fault” and the heater power will be cutoff. Reconnect the air temperature probe, the incubator should return to normal operation.

Skin probe sensor Disconnect indication

- In the skin mode fault condition, when disconnecting the skin probe from the socket. The audio indication Sound activates and the display shows “Skin sensor disconnected” (Sensor Open) and the heater supply will be cutoff. Reconnect the skin probe, the Infant Incubator should return to normal operation generating the heater output as per the set temperature.

- The audio indication Sound activates and the display shown as high priority red indication in the pilot lamp with alarm.

Air sensor fault Disconnect indication

- In the Air mode fault condition, when disconnecting the air probe from the sensor module. The audio indication sound activates and the display shows “Air sensor fault” and the heater supply will be cut off. Reconnect the air probe, the Infant Incubator should return to normal operation generating the heater output as per the set temperature

- The visual indication activates and the display shown as high priority red indication in the pilot lamp.

Audio paused time

Press the Timed Acknowledged key to mute the alarm. Audio paused time is 15 minutes.

Memory Back up, power Fail

- **Memory Back** Switch to the Skin Mode. Set the skin set temperature at 36.5°C. Switch OFF the equipment. Switch On the equipment again. The mode and the set value should remain the same.

- **Power Fail:** Remove the power cord and then switch on the equipment. Power Fail LED glows.

2.8.3 Humidity System Operational Checkout

To install the humidity reservoir:

1. Make sure the reservoir is full.
2. Place the probe of a calibrated hygrometer inside the hood at the center of the mattress.
3. Pre-warm the incubator to 35.0°C.
4. Activate the Humidity system
5. Set the humidity set point to 50%.
6. Verify within 20 min that the hygrometer and the humidity display reads 50%± 6% relative humidity (RH).

2.8.4 Servo control Oxygen Module Operational Checkout

Perform the oxygen system operational checkout before the system is first placed into service, and after any disassembly for cleaning or maintenance.

- Place a calibrated oxygen analyzer inside the hood at the center of the mattress.
- Activate the Oxygen system
- Set the oxygen set point to 40%
- Verify the oxygen analyzer reads 40% ± 5% within 5 to 9 minutes.

Note: If the oxygen analyzer and the oxygen display do not read 40% ± 5% within 5 to 9 minutes, contact a local service representative.

2.8.5 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 Wallaby. 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 3.17.1, 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 3.17.1.
4. Switch ON the device and control panel of Wallaby.
5. Make sure the display window is free of alarm and system failure messages (see Section 3.9, Audio and Visual indication)
6. On the display, verify:
    - The high and low alarm limits for SpO2, SpMet*, SpHb*, PI, PVI*, and pulse rate.
    - The readings for SpO2, SpMet*, SpHb*, PI, PVI*, and pulse rate.

NOTE:

- "- - -" initially show';,m s 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 SpO2, PI and pulse rate; up to 25 seconds for SpMet*. In the case of SpHb*, the numeric value will be displayed upon initial stabilization of the number (up to 90 seconds), and the parameter label will continue to flash for an additional processing period to reach optimal confidence (60 seconds). In the case of PVI*, the numeric value will be displayed upon initial stabilization of the number (up to 120 seconds), and the parameter label will continue to flash for an additional processing period to reach optimal confidence (60 seconds).

7. Verify that the patient alarms are functional by setting the high and low SpO2, SpMet*, SpHb*, PI, PVI*, 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 silence operation.
    - Create an alarm condition by lowering the SpO2 or SpMet* or pulse rate high alarm limits beyond the patient readings.
    - Press the Alarm Silence button.
    - The alarm tone ceases for the displayed amount of time.

SpMet*, SpHb*, PVi* - Optional features

Section 3: Operation

3.1 TFT Touch Control Panel Display
3.2 Switches & Keys
3.3 General Control Panel Operation
3.4 Incubator Operation
3.5 Weighing Scale Operation (Optional)
3.6 Masimo Rainbow SET Pulse Co-oximetry
3.7 Trend Screen
3.8 Settings
3.9 Audio & Visual Indication
3.10 Mattress Platform Operation
3.11 Access Panel and Iris port Operation
3.12 Height adjustment
3.13 Storage cabinet
3.14 X-ray Casette Tray
3.15 Shut down Procedure
3.16 Transport/Movement details
3.17 Accessories

3.1 TFT Touch Control Panel Display

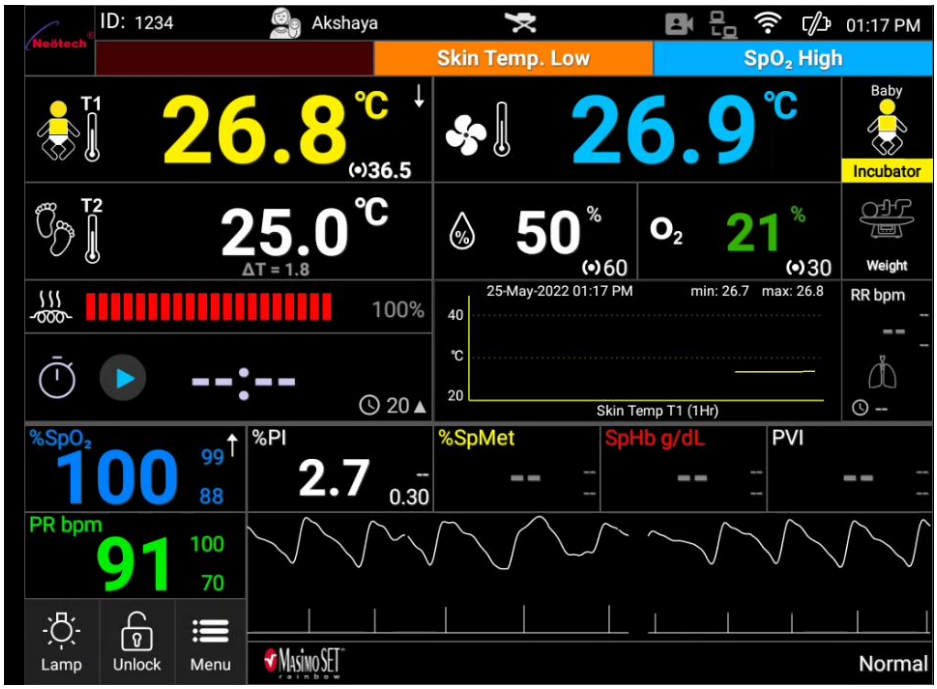
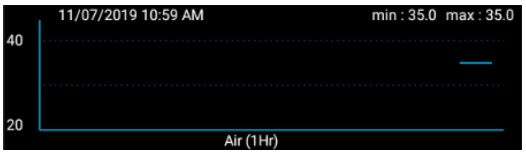
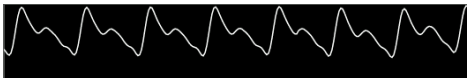


Figure 1

1	ID: 1234	PATIENT ID	Patient ID is displayed on top of the screen
2	Akshaya	MOTHER'S NAME	Mother's name is displayed
3	2	BED NUMBER	Bed no is displayed

4		Wi-Fi	Wi-Fi icon is displayed when Wi-Fi is enabled
5		BATTERY PERCENTAGE	The device's battery percentage is indicated
6		TIME	Curent time is displayed
7		ALARM INDICATION	Indicates the alarm. 3 indications in a row.
8		BABY TEMPERATURE (T1) & BABY SET TEMPERATURE	Baby's temperatue and the baby set temperature is displayed
9		AIR TEMPERATURE & AIR SET TEMPERATURE	Air temperature and the air set temperature is displayed
10		AUXILIARY TEMPERATURE (T2)	The auxiliary temperature of the baby is displayed
11		MODES SELECTION	Used to select modes such as baby mode and air mode
12		SERVO HUMIDITY	Relative humidity control is displayed
13		SERVO CONTROL OXYGEN	Servo control oxygen value is displayed (optional)
14		HEATER OUTPUT	The heater output is displayed as heater output percentage
15		APGAR TIMER	APGAR timer displays time in minutes (1 - 59 mins)

16		WEIGHING SCALE VALUE	The weight of the baby is displayed either in grams or pounds (optional)
17		TREND SCREEN	The trend screen displays the trend data of the Air temperature
18		SpO_2 MEASUREMENT DISPLAY	The value of oxygen saturation is displayed in percentage
19		SpO_2 ALARM LIMITS DISPLAY	High and Low alarm limit of SpO2 are displayed
20		SpMet MEASUREMENT DISPLAY	The measurement of Methemoglobin concentration levels is displayed in percentage (optional)
21		SpMet ALARM LIMITS DISPLAY	High and Low alarm limit of SpMet are displayed (optional)
22		SpHb MEASUREMENT DISPLAY	The measurement of hemoglobin concentration levels is displayed in grams per deciliter (g/dL) (optional)
23		SpHb ALARM LIMITS DISPLAY	High and Low alarm limit of SpHb are displayed (optional)
24		Pi MEASUREMENT DISPLAY	Perfusion index indicates the pulse strength numerically in percentage
25		Pi ALARM LIMITS DISPLAY	High and Low alarm limit of Pi are displayed

26		PVi MEASUREMENT DISPLAY	Pleth variablility index measures the relative variability of the pleth waveform displayed as percentage (optional)
27		PVi ALARM LIMITS DISPLAY	High and Low alarm limit of PVi are displayed (optional)
28		PULSE RATE MEASUREMENT DISPLAY	Pulse rate measured is displayed in beats per minute (bpm)
29		PR ALARM LIMITS DISPLAY	High and Low alarm limit of PR are displayed
30		PLETHYSMOGRAPHIC WAVEFORM	Plethysmographic waveform is displayed as a graph
31		SIGNAL STRENGTH	Signal strength of the plethysmographic waveform is displayed
32		SENSITIVITY MODE	The sensitivity mode of Masimo rainbow SET pulse co-oximeter: normal, maximum (MAX) and Adaptive Sensor Off Detection (APOD) are displayed When in normal mode, this area will appear blank
33		MASIMO SET EXCEPTION MESSAGES	Exception messages of the Masimo rainbow SET pulse co-oximeter are displayed
34		LOCK/UNLOCK	Lock/unlock function is displayed
35		MENU	Menu contains mode, volume, settings, admit which can be selected

3.2 Switches & Keys

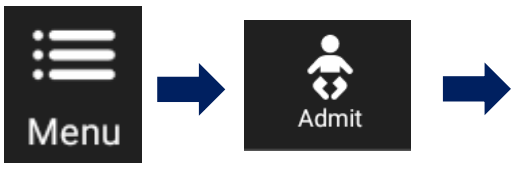
	Main switch	This switch is used to switch ON/OFF the device placed on the side of the machine.
	ON/OFF key	This key is used to switch ON/OFF the control panel.
	Timed Acknowledged key	This key is used to silence the audible indication for 15 minutes. It silences all indications except the power failure indication. The audio pause indication glows when in use.
	Camera ON/OFF key	This key is used to switch ON/OFF the live camera. The camera indication glows when in use.

3.3 General Control Panel Operation

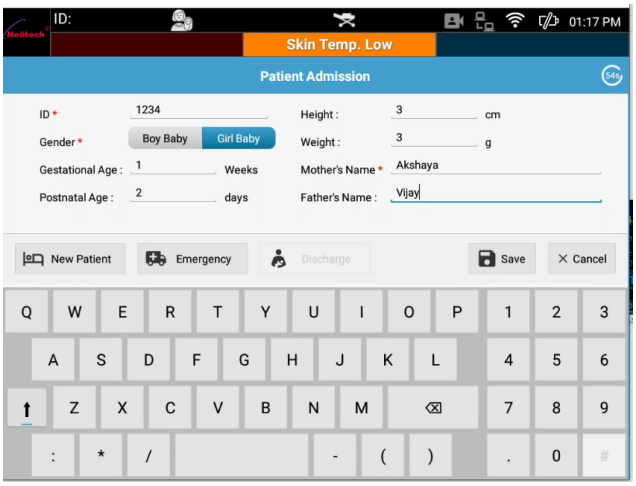
3.3.1 Patient Admission

During patient admission, the patient's ID, patient's mother name and father name, gender, age, height, weight are entered in the control panel through below process:

Select MENU **Then select ADMIT**



Enter the patient details



3.3.2 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 lock 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 unlock** 

Note: All other icons are inaccessible when lock function is in use.

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

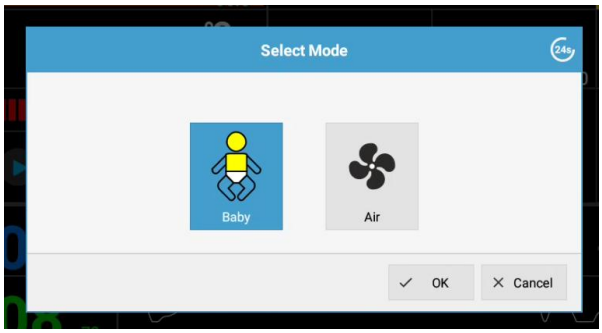
3.4 Incubator Operation

3.4.1 Mode selection

Infant incubator mode 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 incubator 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 keys. The control temperature can be adjusted from 32 to 38°C. In the Baby mode, the temperature sensed by the skin temperature sensor is used by the control system to modulate the radiant heat and maintain the patient’s temperature at the selected control temperature.

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

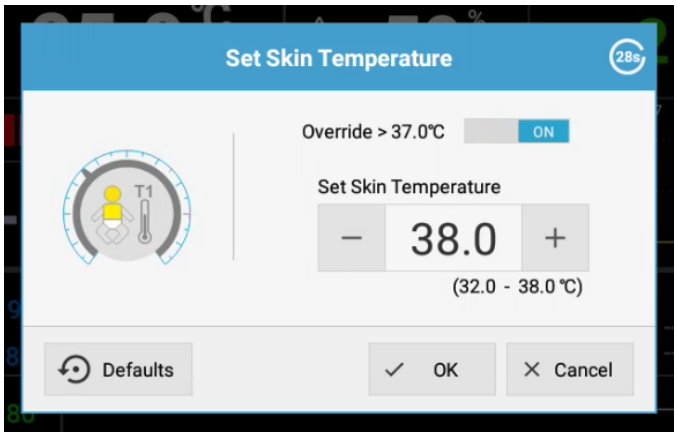
To set the required temperature, follow the steps given below:

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

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

Defaults: Set Skin temperature of the baby mode can be changed to default Skin temperature with 36.5°C.

Override Function: If override function is enabled, in ON condition the control temperature can be adjusted from 37.1° to 38°C. And when disabled, in OFF condition the control temperature can be adjusted only from 32° to 37°C and cannot be exceeded from 37.1° to 38°C.



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 incubator can over or under heat the infant.

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

Warning

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

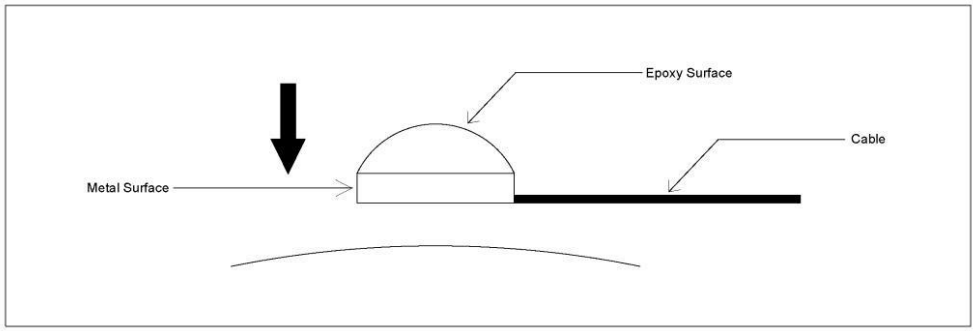
3.4.2.1 Skin Temperature Sensor Attachment

Warning

- 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 incubator 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.



❖ 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 incubator by plugging the sensor connector into the left side of the Connector as viewed from the front.

Warning

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

- Periodically monitor the 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.

Caution

- Always remove the sensor from the patient by grasping and removing the heat reflective patch first, and then remove the sensor from the patient or the patch. Always remove the sensor from the Infant incubator 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.

***i*-sense technology: (baby mode)**
The i-sense technology in the control panel provides extra safety for the patient in cases where the skin temperature sensor is displaced, detached, or detects abnormally high temperatures.

- If the baby's skin temperature ranges between 39°C and 42°C, and the air temperature is less than 3°C below the skin set temperature in th condition for 6 minutes, the heater output is reduced to 30%. In this condition, the skin temperature window is displayed in red colour, and a white colour" *i* " icon appears below baby skin temperature

- If the heater output is greater than 80% and the air temperature is more than 1°C above the skin set temperature in this condition for 20 minutes, the heater output is reduced from over 80% to 30%. A yellow colour "*i*" icon then appears below the baby skin temperature display.

- If The baby Skin Temperature value is higher than the Skin Set Temperature, and the air temperature is less than 3°C below the skin set temperature in this condition for 6 minutes, the heater output is reduced to 30%. A green colour "*i*" icon then appears below the baby skin temperature display.

3.4.3 Air mode

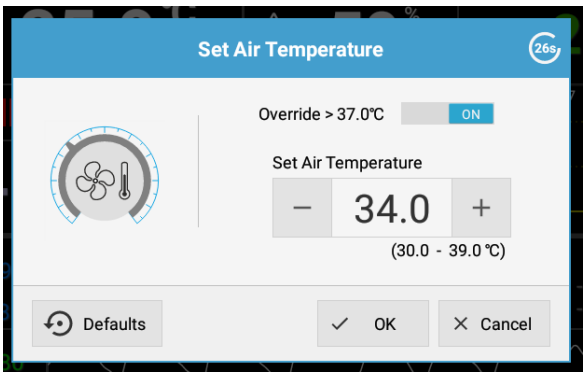
Note: The Air temperature sensor must be properly placed in the sensor module of the Infant Incubator hood.

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

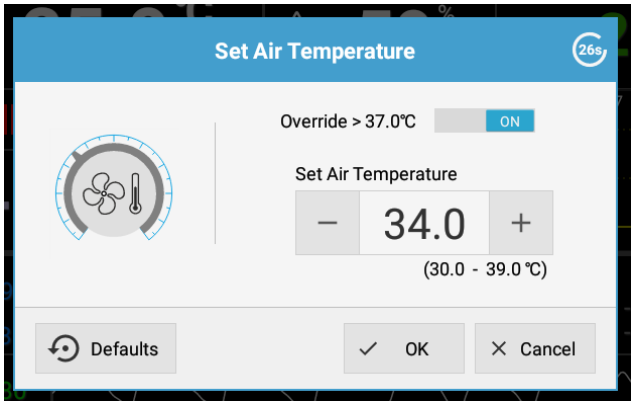
To set the required air temperature, follow the steps given below:

Select Air temperature in the control panel (red circled)

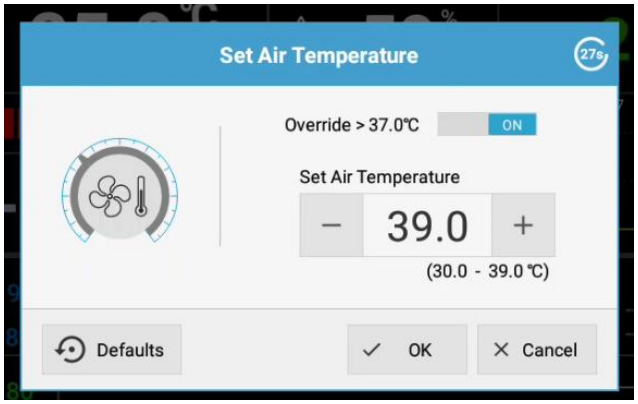
Select the desired air temperature by increasing or decreasing key and then press OK



Defaults: Set Air temperature of the Air mode can be changed to default Air temperature with 34.0°C.



Override Function: If override function is enabled, in ON condition the control temperature can be adjusted from 37.1° to 38°C. And when disabled, in OFF condition the control temperature can be adjusted only from 30° to 37°C and cannot be exceeded from 37.1° to 39°C.



Setting of Air Control Temperature

- The air control temperature is adjusted by pressing the increase (+) and Decrease (-) switches. The control temperature can be adjusted from 30.0°C to 38.0°C. In the air mode, the temperature sensed by the air temperature sensor is used by the control system to modulate the radiant heat and maintain the environment temperature at the selected control temperature.

Note: The Infant Incubator 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.

- In the air mode, verify that the air temperature probe is securely placed in the sensor module of the hood. A dislodged sensor does not always trigger an indication. If the sensor becomes dislodged, the Infant Incubator can over or under heat the infant.

Heater Output power bar colour	Colours	Range
	Green	5 – 30%

	Amber	35 – 60%
	Red	65 – 100%

- In the Baby mode the skin temperature will not automatically control.
- Use the baby mode unless the Air mode. While all modes require patient monitoring, the Baby mode requires constant attention. In the Baby mode, the user should ensure changes in the environment (drafts, direct sunlight, etc.) or the patient condition requiring heater adjustments in response to these changes. In the baby mode and Air mode, the Infant Incubator 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 any mode of operation.

***i*-sense technology: (Air mode)**
The i-sense technology in the control panel provides extra safety for the patient in cases where the skin temperature sensor is displaced, detached, or detects abnormally high temperatures.

- If the baby's skin temperature ranges between 39°C and 42°C, and the air temperature is less than 2°C below the Air set temperature in th condition for 6 minutes, the heater output is reduced to 30%. In this condition, the Air temperature window is displayed in Amber colour, and a blue colour" *i* " icon appears below Air temperature

3.4.4 Humidifier Control

- ❖ Prewarm the incubator in Air mode to the temperature prescribed by the attending physician or according to Nursery Standing Orders.
- ❖ Set the desire humidity percentage from 20.0 – 95.0% by using + and – keys.
- ❖ Once percentage has been set, the humidity heater starts to heat and humidity heater will cuts off before 5% to reach the set value.

- Higher relative humidity will, at any given time, decrease an infant's evaporative water loss, and may cause an increase in infant temperature. This effect is greatest in very low birth-weight, premature infants. The attending physician should prescribe Temperature Control mode, temperature setting, and humidity output level setting. Routinely monitor the infant's rectal and/or axillary temperature according to the attending physician's orders or Nursery Standing Orders. Failure to do so could result in personal injury.

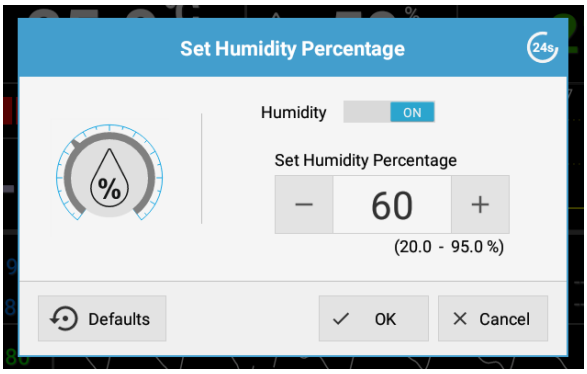
Note: At humidity levels greater than 70 RH%, condensation may form on the inside walls of the hood. This can be minimized or eliminated if desired, by changing the set RH% to a lower humidity setting. If the humidity system is not in use, remove water from the humidity reservoir.

- To prolong the useful life of the humidity module, use only distilled water. Sterile water is not an acceptable substitute for distilled water. Equipment damage could occur.

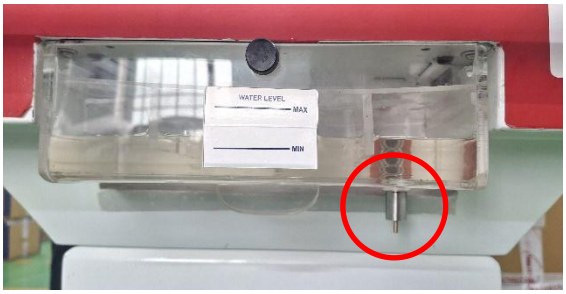
To set the required relative humidity, follow the steps given below:

Select relative humidity in the control panel (red circled)

Select the required humidity percentage by increasing or decreasing key and then press OK



3.4.4.1 Humidity water chamber

	❖ Fill the humidity reservoir with distilled water and close the water tray. ❖ Fix the humidity water tray as shown in the figure.
	❖ Press the valve from the bottom of the reservoir to drain the water from the reservoir.

Note: Humidifier capacity is 1L.

3.4.5 Oxygen Administration (Servo control)

Warning

- ❖ If the patient's arterial oxygen levels cannot be maintained when the oxygen control settings is set to maximum, the attending physician should prescribe alternate means of oxygenation. Failure to do so could result in personal injury or equipment damage.

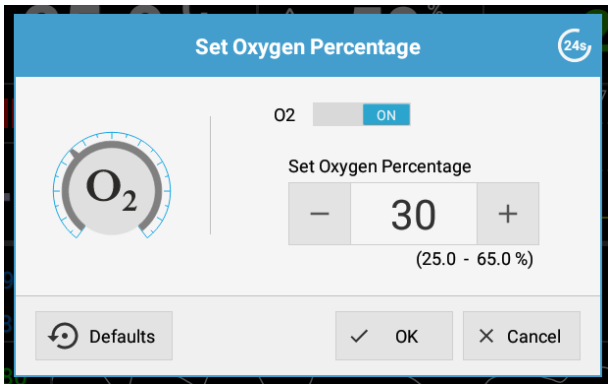
In oxygen control mode, the oxygen sensors and control valve module control the concentration level of oxygen (from 25% to 65%). The Audio and Visual Indication limit default is ± 3% from the current set point. If the oxygen concentration rises above or falls below the ± 3% limit, an audible and visual Audio and Visual Indication occurs.

Note: When using the servo-controlled oxygen system during oxygen administration, the oxygen concentration guide is not valid.

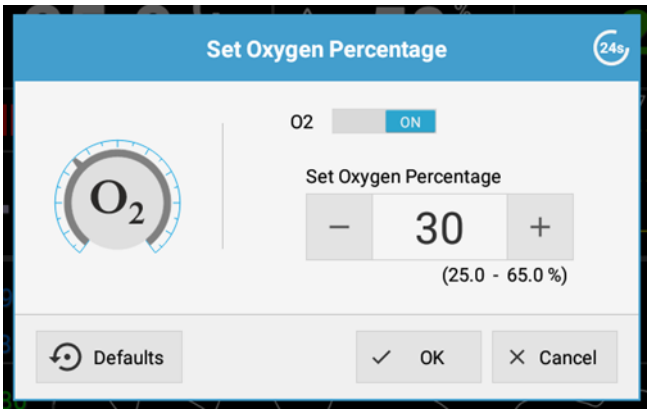
To set the oxygen percentage, follow the steps given below:

Select the oxygen percentage in the control panel (red circled)

Select the required level of oxygen percentage by increasing or decreasing key and then press OK



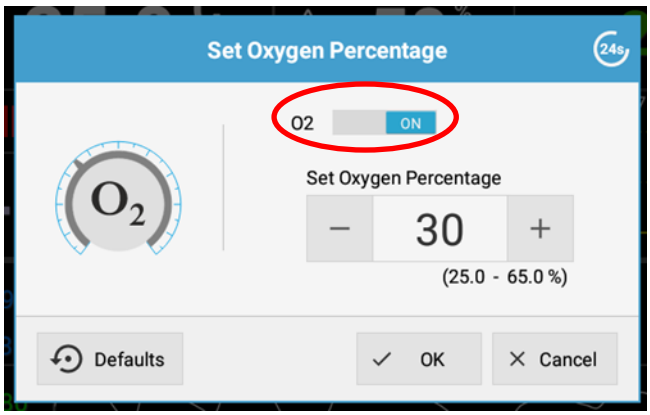
Defaults: Set Oxygen Alarm Limit can be changed to default limit.



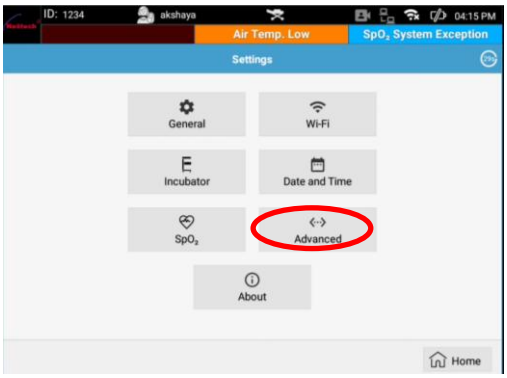
3.4.5.1 Oxygen Calibration

Oxygen sensor module should be calibrated before each and every use to maintain accuracy for continuous use.

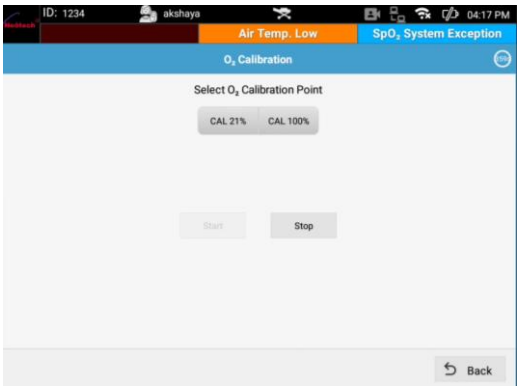
Note: Oxygen can be calibrated only when enabling the Set Oxygen percentage from OFF to ON.



Select Advanced settings and Go to the Oxygen Calibration settings.



Choose CAL 21% to perform calibration then press the start key.



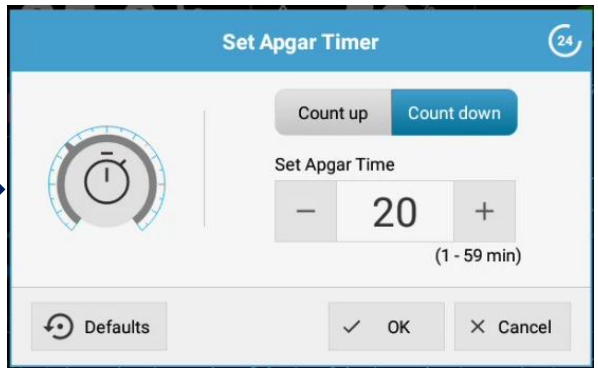
After Pressing the Start option, Please wait is displayed on the screen for few second , then Calibration Success is displayed.

3.4.6 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 incubator 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 incubator activates audio indication at 1st, 5th, 10th and the 13th Minutes.

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

Select the APGAR timer count up/ count down



Defaults: Set APGAR Timer can be changed to default limit.

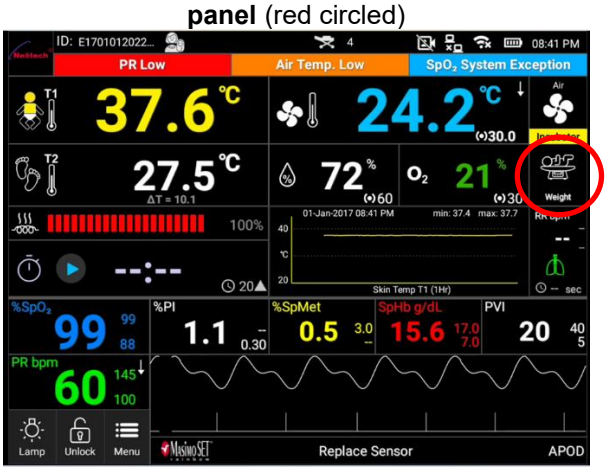
3.5 Weighing Scale Operation (Optional)

- The weighing scale displays the weight of the patient in parameters such as grams and pounds.
- When the displayed is touched, the recent measured weight and previous measured weight can be seen and the control panel displays the words, “Lift the baby” and the baby is lifted from the mattress.
- Then the screen displays “Place the baby” to measure weight.
- As the weight is measured, the control panel displays the measured weight.

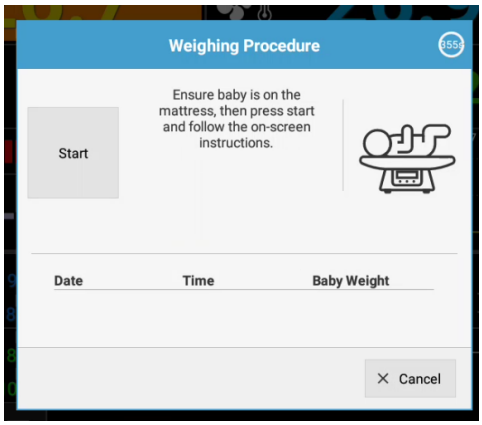
❖ The value can be saved and it is displayed on the Home control panel.

The weighing scale operations can be done as follows:

Select the weighing scale value in the control panel (red circled)



Select the unit of weight either grams (g) or pounds (lb)



Note:

1. Always weigh the infant in the center of the mattress, with the mattress in its flat position.
2. Do not allow stuffed toys or other objects on the mattress to lean against the bed walls or access panels.
3. Inaccurate readings can occur.
4. Do not allow the mattress cover to touch the hood.
5. The mattress should be level, i.e., not in the Reverse Trendelenburg position.

Note:

1. Support the ventilator tubing and IV tubes to ensure they do not touch the mattress.
2. Place the following items so that they return to the same relative position when the infant has been lifted off and returned to the mattress: ventilator tubing, IV tubes, sensor leads.

Warning

- For infant safety, do not leave the infant unattended when the front door access panel is open. Personal injury could occur.

3.6 Masimo Rainbow SET Pulse Co-oximetry

Warning

- 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.

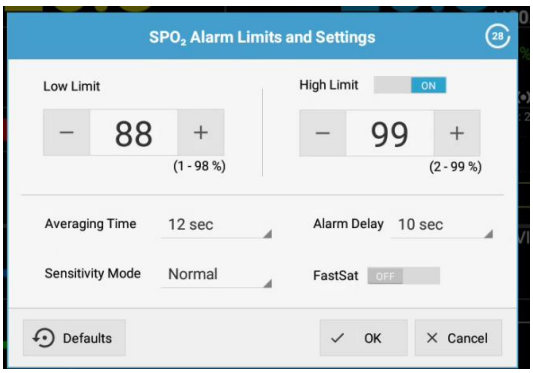
3.6.1 SpO_2 Monitoring & Setting

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.

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.

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 Sensor 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

Defaults: Set SPO2 Alarm Limit can be changed to default limit.

Note: When using the maximum sensitivity setting, performance of the sensor off detection may be compromised. If the instrument 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

- If SpO2 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.

3.6.2 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.

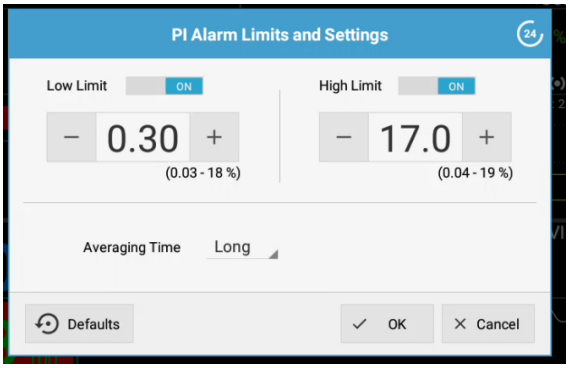
The PI measurement is displayed as follows:

≤ 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.

Defaults: Set PI Alarm Limit can be changed to default limit.

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.

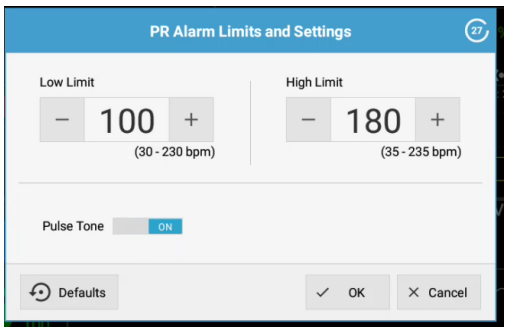
3.6.3 Pulse Rate (PR) Monitoring (bpm)

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.

Defaults: Set PR Alarm Limit can be changed to default limit.

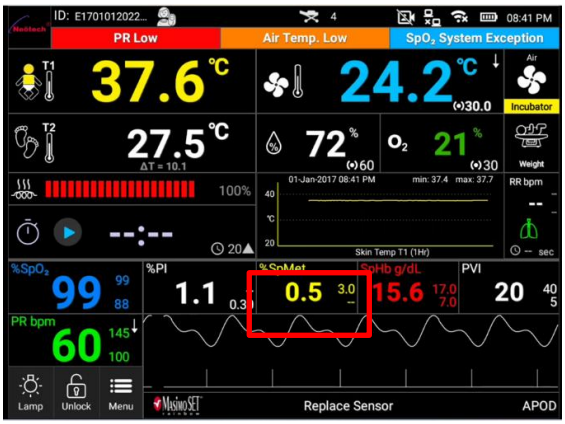
NOTE: The low alarm limit must be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.

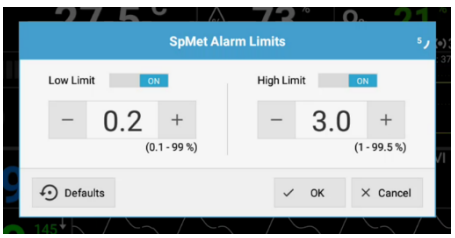
3.6.4 SpMet Monitoring (optional)

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% to 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% to 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.

Defaults: Set SpMet Alarm Limit can be changed to default limit.

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

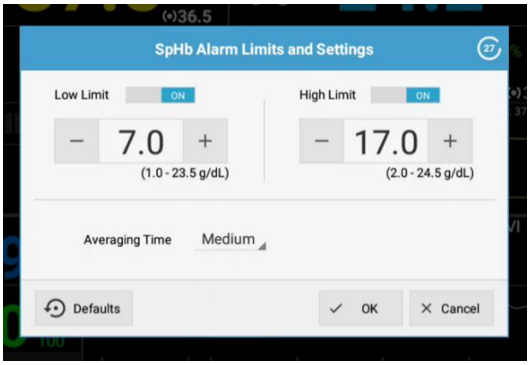
3.6.5 SpHb Monitoring (optional)

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 23.5 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.

Defaults: Set SpHb Alarm Limit can be changed to default limit.

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.

- 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 PaO2 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

- 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.

3.6.6 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

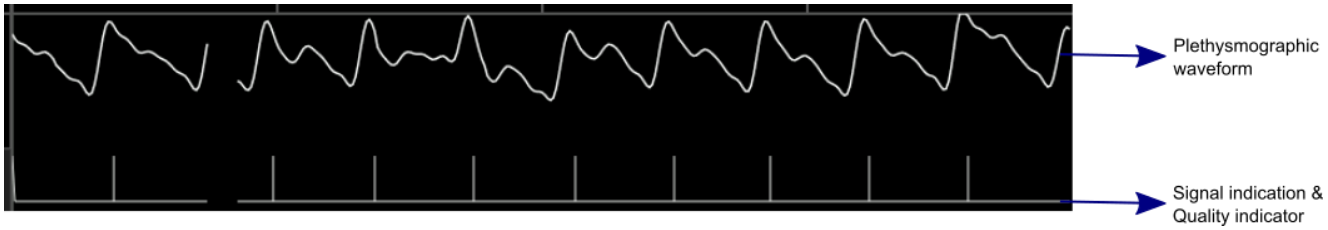
PVI High Limit: The PVI high alarm limit can be set anywhere between 2 and 99, then "---" with a 1 step size between 2 and 99. In the "---" (off) setting, the PVI High Alarm Limit Alarm is disabled.

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.

Defaults: Set PVI Alarm Limit can be changed to default limit.

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.

3.6.7 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 SpO2 values are not based on adequate signal quality. The signal quality indicator displayed on the Pulse CO-Oximeter is called the SpO2 SIQ. The SpO2 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 SpO2 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 SpO2 SIQ.

The height of the vertical line of the SpO2 SIQ indicates the quality of the measured signal. A high vertical bar indicates that the SpO2 measurement is based on a good quality signal. A small vertical bar indicates that the SpO2 measurement is based on data with low signal quality. When the signal quality is very low the accuracy of the SpO2 measurement may be compromised, and a "Low SpO2 SIQ" message is displayed in the message area on the Pulse CO-Oximeter display. When the Low SPO2 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 SpO2 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 section 3.5, 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 SpO2, SpMet,* or SpHb*, PVI*, 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 Wallaby 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.

SpMet*, SpHb*, PVi* - Optional features

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

3.6.8 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 SpO2, 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 "SpO2 Only Mode" to provide SpO2, PR, Pi and PVi* parameters/measurements for the user.

- If a Masimo Rainbow Direct Connect Reusable Sensor is being used and "SpO2 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 "SpO2 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.

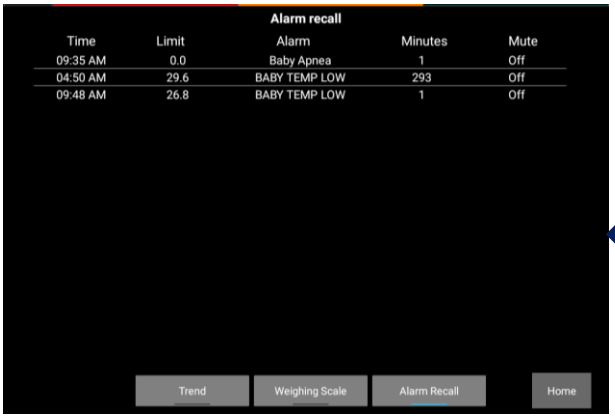
3.7 Trend Screen

- The trend screen displays the trend of each parameter or measurement in the form of graph displayed versus time and scale range.
- T1, T2, SpO_2, PR, Pi, PVi*, SpMet*, SpHb* are displayed graphically with respect to time.
- The weighing scale readings of the baby is stored along with date to ensure the growth of the child.
- Next to it, alarm recall is present which records the time, limit, minutes and alarm pause conditions of each alarm during the treatment time.

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



Weighing scale readings helps determine the baby's growth on the screen

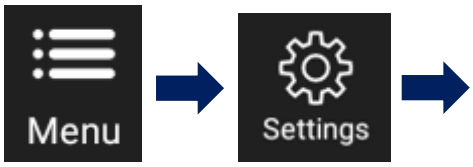
SpMet*, SpHb*, PVi* - Optional features

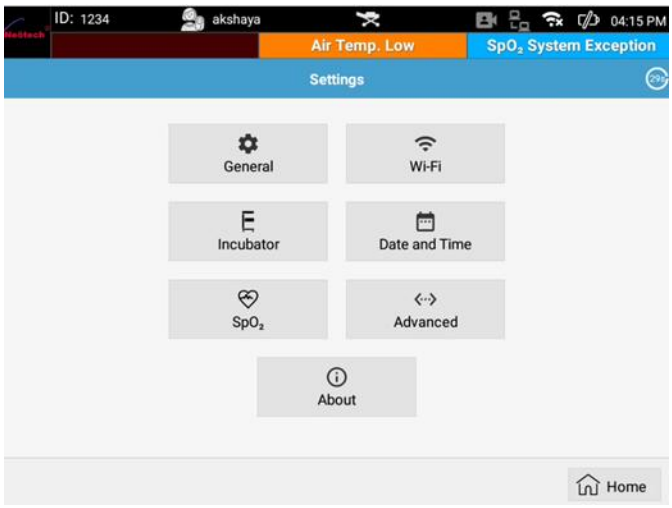
3.8 Settings

The settings instructions of nice 3010 are given here:

Select MENU

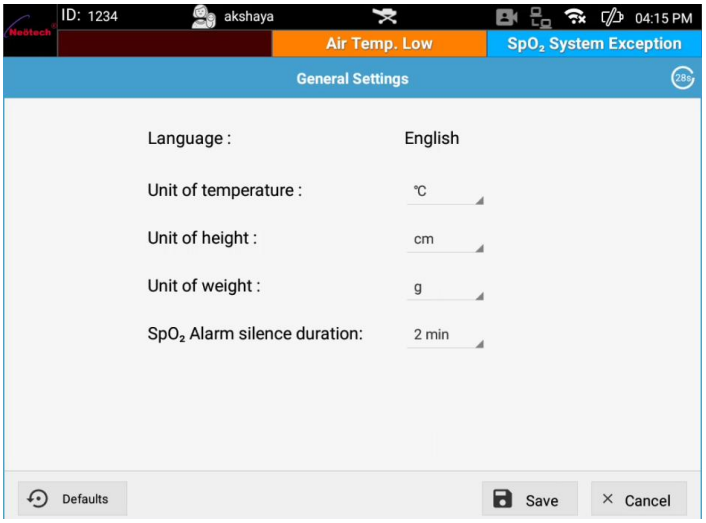
Then select SETTINGS





3.8.1 General settings

The general settings contains the following:



Language: English is the default language setting.

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

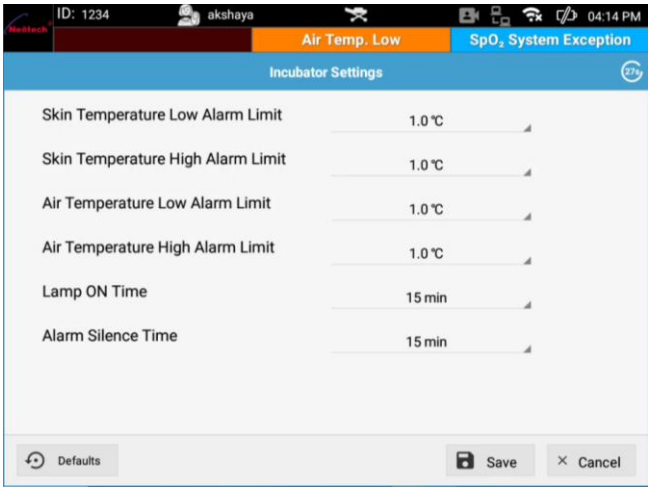
Unit of height: centimeters (cm) or inch

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

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

Defaults: The all set values of time and temperature unit can be changed to default values.

3.8.2 Incubator settings



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

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

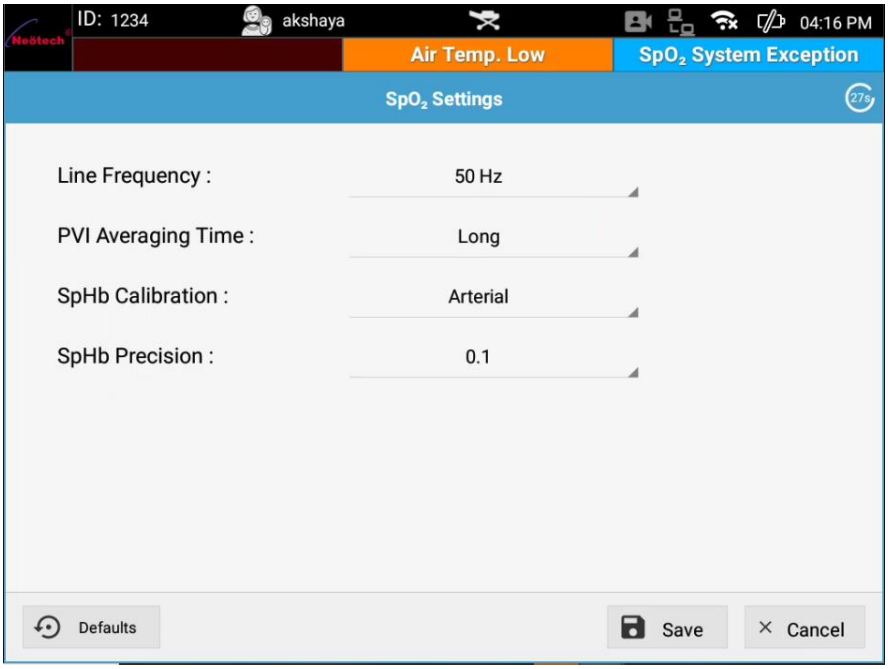
Air Temperature Low Alarm Limit: The user can select the alarm limit for low air temperature at either 1.0°C or 2.0°C or 3.0°C.

Air Temperature High Alarm Limit: The user can select the alarm limit for high baby temperature at either 0.5°C or 1.0°C.

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

Defaults: The all set Alarm Limit can be changed to default limit.

3.8.3 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 Long or Short.

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 or 1.0 increments. This feature allows the user to set the decimal for SpHb.

Defaults: The all set SPO2 Limit can be changed to default values.

3.9 Audio & Visual Indication

3.9.1 Alarm priorities

An audio and visual indication occurs when there is an alarm or an emergency to attend to the patient.

According to the level of priority, color codes are indicated along with pilot lamp indication which is explained in the sub-section 3.9.2

Wallaby 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 temperature exceeds 39°C
	Air sensor over temperature	Activates when Air temperature exceeds 39°C
	Skin sensor disconnected	Activates when Primary skin temperature sensor is detached from the baby's skin in Baby mode
	Air sensor disconnected	Display when the Air probe sensor gets disconnected or fails to sense the temperature inside the hood.
	Skin sensor defect	Activates when primary skin temperature sensor fails or is short in Baby mode
	Air sensor defect	Activates when primary air temperature sensor fails or is short in Air mode
	Heater Fault	Activates when the heater is defected or disconnected from the equipment in any mode of operation.
	Air flow sensor defect	Display when the heater disconnected or fails to sense or control the heat reach greater.
	Fan Fault	Display when the fan fails to rotate.
	POWER FAIL	Activates when power supply to the equipment is cut-off.
	SpO_2 LOW	Activates when the saturated oxygen percentage of baby decreases then the set alarm limit for % of SpO_2 .
	PR HIGH PR LOW	Activates when the pulse rate of baby raises or decreases then the set alarm limit for pulse rate in bpm.
	SpO_2.comm.error	Activates when board failure and diagnostic failure codes exception messages are displayed in the control panel
Medium Priority	Skin temperature high	Activates when baby's skin temperature raises more than 1°C from the set required temperature in skin mode
	Skin temperature low	Activates when baby's skin temperature decreases more than 1°C from the set required temperature in skin mode
	Air Temperature high	Activates when air temperature raises more than 0.5°C from the set required temperature in Air mode
	Air Temperature low	Activates when air temperature decreases more than 3°C from the set required temperature in Air mode
	O2 sensor disconnect	Display when the Oxygen probe sensor gets disconnected or fails to sense the Oxygen present inside the hood.
	Oxygen High	Display when the oxygen present inside hood exceeds by 3% from the set oxygen alarm limit.

	Oxygen Low	Display when the oxygen present inside hood less than by 3% from the set oxygen alarm limit.
	Humidity sensor disconnect	Display when the humidity sensor gets disconnected/ fail to sense
	Overload Error	Activates when the load on the mattress is too high during weighing scale operation.
	Load cell Error	Activates when the load cell in the weighing scale is defected or damaged.
Low Priority	Auxiliary sensor disconnected	Activates when Auxiliary skin temperature sensor is detached from the baby's skin
	Skin sensor disconnected	Activates when Primary skin temperature sensor is detached from the baby's skin in Air mode
	Auxiliary sensor defect	Activates when Auxiliary skin temperature sensor fails or is short.
	SpO_2 HIGH	Activates when the saturated oxygen percentage of baby raises than the set alarm limit for % of SpO_2 .
	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
	No sensor	Activates when the masimo sensor is searching for the pulse or when the masimo sensor is not connected

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

NOTE: All the above audio alarms can be paused using the Audio pause key on the pillar.

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

- 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 incubator 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.

3.9.2 Pilot Lamp

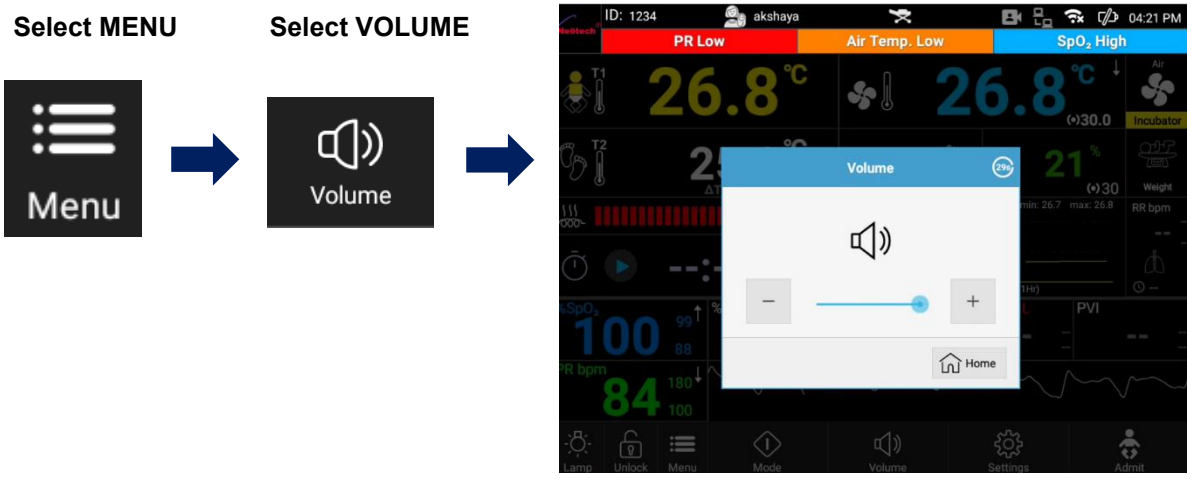
A pilot lamp is fixed in the pillar above the control panel to produce different audio and visual indications for low, medium and high priority alarms other than the control panel. It produces visual indications based on colors such as pink for self-test, green for normal condition, blue for low priority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

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

3.9.3 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**



3.10 Mattress Platform Operation

Mattress Tilting

- The mattress platform tilts for Reverse Trendelenburg and positioning capabilities. Press the down ↓ or up ↑ arrow located on the left side of the shell to adjust the bed's position (up or down).

Warning

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

Caution

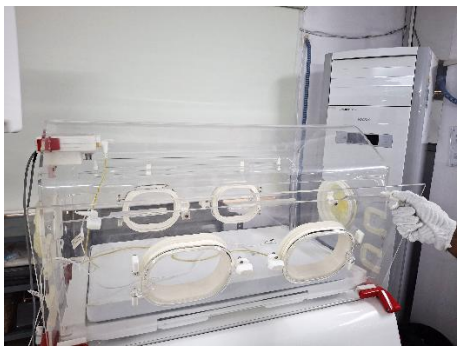
- When the mattress in the tilting position, ensure any additional support is provided to minimize the baby falling.

Mattress Tray Operation

	❖ Open the front door on both sides of the canopy by rotating lock as shown in the figure. ❖ And then, slide out the mattress tray platform from the tilting rod.

3.11 Access Panel and Iris port Operation

I. Access panel Operation

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

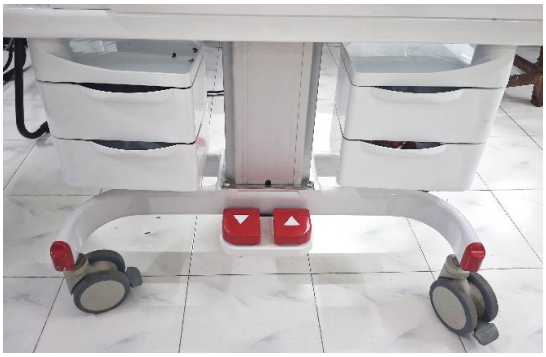
II. Access Door, Latches and Gaskets

	❖ Press the door release of each access door. ❖ The access door should swing open. ❖ Close the door and check for proper latching and quietness. ❖ Check the access door gaskets are placed properly on the inner and outer walls.

III. Iris Entry Ports

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

3.12 Height adjustment

	❖ Press the increase and decrease pedal on the base to check the height between the bed platform and heater module is changing accordingly ➔ **Upward pedal stand** ➔ **Downward pedal stand**

3.13 Storage cabinet

	❖ 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.

3.14 X-ray Casette Tray (optional)

	❖ Open the front doors on both sides of the canopy by rotating (or unlocking) the pawl latches as shown in the figure. ❖ The X-ray cassette may be placed in the slot under the bed platform or in the X-ray cassette tray, if installed. ❖ The X-ray cassette tray facilitates X-ray procedures while patients occupy the Incubator mattress. An X-ray cassette can be placed on the tray and slid into the cavity beneath the bed without disturbing the patient.

3.15 Shut down Procedure

- Remove the baby from the mattress of nice 3010 Wallaby..
- Ensure oxygen supply is stopped.
- Switch OFF the Infant Incubator by ON/OFF key.
- Switch OFF the main switch of the nice 3010 Wallaby.

3.16 Transport/Movement details

- Check that all castors are in fine contact with the floor and that the Incubator unit is stable & moves freely.
- Lock the brakes in antistatic castors to hold the unit in static position.
- Unlock the brakes in antistatic castors to move the unit again.

3.17 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 patient body (baby) temperature.	
2.	Auxiliary temperature Probe	Multiple-use, Non-sterile	50-05-241	Intended to measure the baby's peripheral temperature.	
3.	Mattress	Multiple-use, Non-sterile	87-00-009	Intended for the placement of patient (baby) under Infant incubator during treatment	

4.	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	
5.	Masimo Sensor [RD SET YI]	Multiple-use, Non-sterile	89-16-110	Intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor)	

Optional Accessories:

#	Accessory Name	Single use / Reuse	Part no.	Intended use	Picture
1.	Masimo Sensor [RD SET INF]	Single-use, non-sterile	--	Intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor)	
2.	Masimo Sensor [RD SET NEO]	Single-use, non-sterile	--		
3.	X-ray Cassette Tray	Multiple-use, Non-sterile	96-00-089	Intended to facilitate X-ray procedures while patients occupy the Infant Incubator bed.	

3.17.1 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

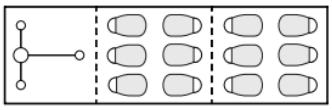
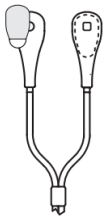
- The preferred sites are the outer aspect of the foot, under the fourth toe or the outer aspect of the palm of the hand.

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)

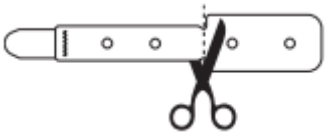
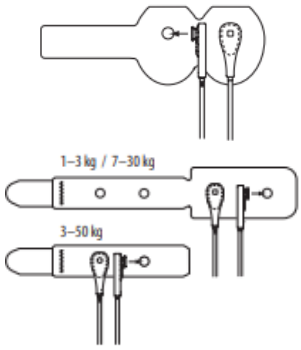
- For improved adherence of the adhesive squares to the sensor wipe the sensor pads with 70% isopropyl alcohol and allow to dry prior to attaching the adhesive squares.

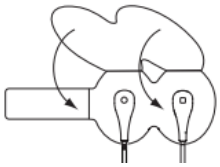
S.No.	Image/Figure	Instructions
1.		• Remove the adhesive squares from the backing.
2.		• Attach one square to each window of the sensor pads (emitter and detector). Avoid touching the sticky side prior to applying to the sensor pads. • Do not remove the release liner until ready to apply the sensor to the site.

Caution

- 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.

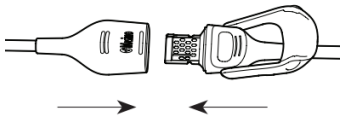
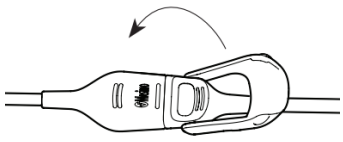
3.		• For the CleanShield Wrap only, fold the upper portion of the attachment tape down over the sensor pads and remove the release liner from the folded over section of the adhesive wrap prior to applying the sensor to the site.

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.

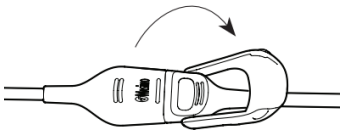
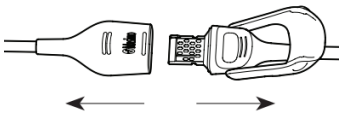
NOTE: When placing the YI on the hand, it is recommended that the EMITTER (cable is marked with a red indicator) pad be placed on the palm of the hand, under the 4th or 5th finger.

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, and 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.

Section 4: Cleaning & Maintenance

4.1 General
4.2 Cleaning and disinfection of Infant Incubator and its parts
4.3 Air filter replacement
4.4 Life time of product
4.5 Life time of Cartridge Heater
4.6 Transport position

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 Incubator into service.
- ❑ After Cleaning, ensure the canopy seals are fully dry before placing the incubator back into use.

- Make sure that the Oxygen supply to the Incubator is turned OFF and that the Incubator is disconnected from the oxygen supply when performing cleaning and Maintenance procedures; a fire and explosion hazard exists when performing cleaning and/or Maintenance procedures in an oxygen administration.
- Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging
- Switch off the equipment and disconnect the Power cord from the mains before take in to cleaning
- Don't pour the water for cleaning it may enter into the electronics circuits it cause short circuit and get shock.
- Don't use flammable agents for cleaning even Small quantity of flammable agents such as ether and alcohol, left in the incubator it can cause fire in connection with oxygen.
- Disconnect power to the Infant Incubator 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 Incubator. Do not saturate the unit - excessive solution causes damage to internal components.
- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance.
- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.

4.1.1 Disassembly of parts for cleaning

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

- Refer to section 2 and disconnect the Sensor cables from the Shell and slowly raise the hood.

Caution

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

4.1.1.1 Removal of Mattress Tray

	• Open the canopy from the rear side and take the Mattress tray from the shell assembly.

4.1.1.2 Removal of Main Deck (Main Cover)

	• After the removal of mattress tray, take the main deck from the shell assembly as shown in the figure.

4.1.1.3 Removal of Heater/impeller covers

Warning

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

		• Pull the heater. • Pull the impeller of the motor shaft

4.1.1.4 Removal of Access Door Gasket

	• Remove Access door Gaskets from each side of the hood by pulling them free

4.1.1.5 Removal of Access Tube Grommet

	❖ Remove Tubing Access Grommets from each side of the hood by pulling them free.

4.1.1.6 Removal of Micro Filters

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

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

4.2 Cleaning and disinfection of Infant Incubator

During cleaning the Infant Incubator and its accessories, the processing shall comply with ISO 17664:2021 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 Incubator that has been chemically disinfected for reuse, because tap or distilled water may harbour microorganisms. However, when rinsing with sterile water is not feasible, instead, rinse with tap water or filtered water (i.e. water passed through a 0.2 µ filter).
5. Dry Infant Incubator using dry towel or cloth.

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

4.2.1 Cleaning and Disinfection of Temperature probe (Skin and Auxiliary probe)

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

1. Physically clean the 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 leave for 3 minutes.
3. Then rinse the temperature probe by wiping using water damped cloth.
4. Dry temperature probe using dry towel or cloth.

- 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.

4.2.2 Cleaning and Disinfection of Humidity reservoir

1. Fill with water at 80°C and leave for 10 minutes and wash the chamber (Rinse phase).
2. Disinfect with a cloth dampened with 2% Glutaraldehyde and leave for 3 minutes.
3. Then rinse the humidity reservoir by wiping using water damped cloth.
4. Dry humidity reservoir using dry towel or cloth.

4.2.3 Cleaning and Disinfection of Hood and Inner walls

The Inner walls are hinged on the access Panel(s) or rear Wall of the incubator. Refer to figure and release the inner Wall by pressing on the catches located at the top of the inner wall

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

4.2.4 Cleaning and Disinfection of Heater radiator (Heat sink) and Fan impeller

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

4.2.5 Cleaning and Disinfection of Mattress tray, Main deck and Heater/Impeller cover

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

- Alcohol can cause crazing of the Clear Acrylic hood. Do not Use alcohol for Cleaning.
- Do not expose the Hood assembly to direct radiation from germicidal lamps. Ultra violet radiation from these sources can cause cracking of gaskets, fading of paint, and crazing of the Clear Acrylic hood.
- Failure to clean could result in sufficient lint built-up to reduce air flow, which will affect temperature control and cause high oxygen concentrations.

4.2.6 Reassembly after cleaning

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

- Install the Heater Radiator and Fan Impeller.
- Install the Heater/Impeller Cover.
- Install the Main Deck.
- Install the Mattress Tray and X-ray Tray.
- Install the Disposable Mattress cover. Place a new disposable mattress cover over the mattress, and then place the mattress onto the tray.
- Install a new Air Intake Micro filter if necessary (Discolored or dirty). Replace the Air Intake Micro filter Cover and tightens the two thumbscrews

Important: Perform a complete functional checkout (Refer section 2.8) before returning the unit to service.

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

4.3 Air filter replacement

A dirty Inlet filter may affect oxygen Concentration and/or cause carbon dioxide built-up. Be sure the filter is checked on every 15 days commensurate with local conditions. Particularly, if the incubator is used in an unusually dusty environment, more frequent replacements may be necessary.

4.4 Life time of product

Since the product is classified under programmable medical electrical system and incase of unavailability of microcontroller the life time of the product can be considered as five years and Service life of the device is extendable up to 1 years considering the replacement of spares and faulty components. So, the service life of the device is six years (5 years of lifetime + 1 year service life).

4.5 Life time of Cartridge Heater

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

4.6 Transport position

When transporting the Infant incubator,

- Remove the baby from the mattress.
- Remove the IV bottle from the IV pole.
- Remove the equipment if exists in the monitor tray.
- Drain the water from the chamber as per drain procedure.
- Release all brakes then move safely.

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

Section 5: Specifications

Environmental Specification	
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 2.6 Amps
Rated Power	700 VA
Circuit Breaker	10 A

Physical Characteristic	
Height	1700 mm without lifting column (1700+200=1900mm) with lifting column
Width	700 mm
Length	1415 mm
Weight (with. accessories)	110 kg
Mattress Size	L – 69 cm W - 39 cm H - 4 cm
Mattress Platform height Adjustment	1100mm – 1300 mm
Castors	5-inch Castors 4nos with brake.
Mattress platform tilting	± 8 - 12° Trendelenburg and Reverse Trendelenburg. (Freely Adjustable)
IV Pole max. Load	1.5 kg.
Mayo Tray max. Load	3.0 kg.
Mattress max. Load	10.0 kg.
Storage cabinet Load	3 kg.

System Characteristic	
Display	8 inch TFT-LCD with Touch screen
Add-on Modules	Pulse Oximeter (Masimo Rainbow Set), Integrated Weighing Scale, Respiration rate, Servo Oxygen, Apnea Monitor, neonet App. CNS (Central Nursing Station) & Camera, Electrical Height Adjustment.
Battery Backup	12V, 1.3AH Sealed Rechargeable battery - 5 minutes for display only.
Trend Data	SkinTemperature (T1), Skin Temperature (T2), Air Temperature, Heater %, Humidity %, Oxygen %, %SpO2, Pulse Rate, Perfusion Index, % SpMet, SpHB, PVI, Baby Weight, Alarm recall
Trending	24 hours Trend data with 1 min resolutions.
Infant Incubator	
Mode	Baby, Air
Temperature Display Range	10 – 50°C
Temperature Display Accuracy	± 0.2°C (25 – 40°C)
Temperature Unit Conversion	°C & °F
Skin Set Temperature Range in Baby Mode	32 – 38.0°C, Override 37 - 38°C
Air Set Temperature Range in Air Mode	30 – 38.0°C, Override 37 - 38°C
Temperature sensor	Thermistor based
Accuracy of sensor	± 2°C
Temperature Sensor Interchangeability	Accuracy ± 0.2°C
Temperature Sensor Calibration	Not required
Resolution in Air mode	0.1°C
Resolution in Baby mode	0.1°C
Initial Temp Overshoot	< 1.0ºC
Temperature uniformity @ Level Mattress	<0.8ºC
Temperature Variability	<0.5ºC
Temperature Rise Time	<50 minutes (Typical @ 23ºC ambient Temperature)
Noise level within Hood environment	<60dB
Air Velocity in the enclosure	<0.35 m/s
Air Filter capacity	99% (0.5 microns)
Air Intake volume without filter	250 liter/min
Air Intake volume with filter	25 liter/min
Co2 Level within the Hood	Less than 0.8% when a mixture of CO2 in air is delivered at 750ml/min at a point 10cm above the centre of mattress
Observation Lamp	Dimmable 10 W White LED Light, 1000 lux on the mattress, Colour Temperature: 4000 – 4500K

Thermostat	Manual reset 175^0C ± 5% in normally closed
Infant Incubator 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.
Sensor Fault	If baby skin temperature sensor (T1 or T2) is removed or damaged
Air Temperature High	If Air temperature is > 0.5 °C from set temp.
Air Temperature Low	If Air temperature is < 3°C from set temp.
Air Temperature >39°C	If Air temperature is > 39°C.
Air Temperature sensor fault	If Air Temperature sensor is removed or damaged
Heater Fault	If Heater is disconnected or fails
Fan Fault	If fan is disconnected or fails.
Air Flow Fail	If there is no Air Flow in the heater
Other Audio visual	
Indication alarms	System failure alarm, Low battery, Main power failure, Humidity (±10%), Oxygen (±5%), Water reservoir empty, Door open & SpO2 alarms
Servo Humidity	
Humidity Control Range	20% to 95% in 1% increments (at high ambient humidity levels, low level humidity settings may not be attainable)
Humidity control accuracy between 10% and 90% @ 20°C to 40°C	±10% RH
Humidity control operating time without refilling	36 hours maximum @ 85% RH and 36°C, in Air mode
Humidity control reservoir capacity	1500 ml
Maximum humidity levels	>85% (incubator set temp at 39°C, with at least 30%RH at ambient)
RH High or low alarm	If RH above or below 10% from the set value
Display range	0% - 100%
Resolution	1%
Servo Oxygen	
Oxygen Inlet Pressure	30 psi to 50 psi
Oxygen inlet flow rate	30 liters/min
Oxygen control range	25% to 65%
Oxygen display resolution	1%
Oxygen control accuracy at 21% calibration	±5%
Oxygen High or Low Alarm	If oxygen above or below 3% from the set value
Display range	21% to 100%

Pulse Oximeter (Masimo Rainbow Set)	
Data Display	%SpO2, Pulse Rate, Perfusion Index, Plethysmographic waveform & Signal IQ
Sensitivity Mode	Normal, Max, APOD. (Default APOD)
Averaging time	2-4, 4-6, 8 to 16 step 2
Oxygen Saturation (SpO2)	
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%
Methemoglobin Saturation (SpMet) (Optional)	
Measurement range	0 – 99.9%
Resolution	0.1%
Accuracy	1 – 15 % ±1%
Total Hemoglobin (SpHb) (Optional)	
Measurement range	0 – 25 g/dl
Resolution	0.1 g/dl
Pleth Variability Index (PVI) (Optional)	
Measurement range	0 – 100%
Pulse Oximeter Alarms	
SpO2 High	2 – 99%
SpO2 Low	1 – 98%
PR High	35 – 235 bpm
PR Low	30 – 230 bpm
PI High	0.04 – 19%
PI Low	0.03 – 18%
SpMet High	1 – 99.5%
SpMet Low	0.1 – 99 %
SpHb High	2 – 24.5 g/dl
SpHb Low	1 – 23.5 g/dl

PVI High	2 – 99%
PVI Low	1 – 98%
Integrated Weighing Scale	
Weighing Range	0 to 10000 grams
Weight Resolution	5g
Weighing Accuracy	±5g upto 5kg
Unit of Weight	g/lb
Weighing Procedure	Manual

Accessories	
Standard	Skin Temperature (T1) Sensor, Skin Temperature (T2) Sensor, (optional), Pulse oximenter Extension Cable, Pulse Oximeter Multisite Sensor, IV Pole, Monitor Shelf, Mattress, X-ray cassette tray (optional)
Optional	Pulse Oximeter Disposable Sensor

Alarm Algorithm	
High Priority	Pulse Frequency – 293.9 Hz, More than 4 Harmonics, 10 Pulse burst, Pulse spacing: 103.1ms, 99.5ms, 369.3ms, 100.5ms, 514.9ms, 102.7ms, 98.6ms, 369.8ms, 99.3ms, Visual - Red
Medium Priority	Pulse Frequency – 247.1 Hz, More than 4 Harmonics, 3 Pulse burst, Pulse spacing: 232.6ms, 232.9ms, Visual - Amber
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.

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) Sensor, Skin Temperature (T2) Sensor), Type B (Mattress)
Mode of Operation	Continuous

Protection against hazardous of explosion	Not protected
Protection against increase of liquid	IP20

Certification	
Quality	ISO 13485:2016
Electrical Safety	IEC 60601-1
Product Safety	IEC 60601-2-19, ISO 80601-2-61.
Biocompatibility	ISO 10993, ISO 18562
EMC Safety	IEC 60601-1-2
Alarm	IEC 60601-1-8
Graphical Symbol	ISO 15223 - 1

Factory Default Setting	
Mode of operation	Baby Control (Servo Skin) Mode
Baby Control Temperature	36.5^{o}C
Air Control Temperature	34.0^{o}C
Skin Temperature Low Alarm Limit	1.0°C
Skin Temperature High Alarm Limit	1.0°C
Air Temperature Low Alarm Limit	3.0°C
Air Temperature High Alarm Limit	0.5°C
Alarm Silence Time	15 minutes.
Set Oxygen percentage	30%
Set Humidity percentage	60%

SpMET*, SpHB*, PVi* - Optional features

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

Section 7: Trouble Shooting

7.1 General System Failure
7.2 System Fault
7.3 Maintenance Intervals
7.4 Disposing of the Unit

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	Height cannot be adjusted	Motor fault	Contact nice Neötech
3	Can't move the machine	Brakes may be applied on the castors.	Release the brake.
		Castors damaged	Change the Castors

7.2 System Fault

7.2.1 Infant Incubator

Sl. No	Problems	Possible Causes and Remedy
1	No display on the control panel	Check A/C supply voltage
		Check if power cord is disconnected
		Check fuse in the rear side of pillar
		Other wise, contact nice Neötech
2	No heater output	Check the relay and fuse.
		Set temperature may be less than actual temperature
		Check heater connection
		Otherwise contact nice Neötech
3	Equipment working but fan & heater output not working	Check the fan connection
		Check fuse in the PCB.
		Check transformer voltage
		Replace Fan.
		Otherwise contact nice Neötech
4	Equipment not giving the audio indication	Check the temperature it may be near to the set temperature
		Check audio paused ON.

		Other wise contact nice Neötech
5	Control panel displays Skin 1 Sensor fault, Skin 2 Sensor fault or air temperature sensor fault with high priority audible and visual alarms	Check if temperature sensor fault is disconnected from the machine.
		If temperature sensor fault is defective, replace new sensor
		Other wise contact nice Neötech
6	Display shows Heater Fail	Check the relay and fuse.
		Check heater connection
		Other wise contact nice Neötech
7	Display shows Temperature > 39°C	Check environment temperature above 39° C
8	Continuous baby temperature high indication	Check patient temperature is 1°C above set temperature
		Check environment temperature is 1°C above set temperature
		Otherwise contact nice Neötech
9	Continuous baby temperature low indication	Check patient temperature is 1°C below set temperature
		Sensor may be wet.
		Otherwise contact nice Neötech
10	Continuous air temperature high indication	Check environment temperature is 1°C above set temperature
		Otherwise contact nice Neötech
11	Continuous air temperature low indication	Check environment temperature is 1°C below set temperature
		Sensor may be wet.
		Other wise contact nice Neötech
12	Temperature over mattress does not rise	Check low ambient temperature it should be approximately (22-30°C)
		Check draft around air conditioning outlet
		Check percentage heater output is set at low in manual mode
		Low supply voltage
13	Temperature over Mattress rises excessively	Check direct sun light, heating device or other heat source
		Percentage heater output is set at high in manual mode
14	Temperature over Mattress dose not stabilize	Check unstable ambient temperature (should be 22-30°C)
		Check strong air conditioning draft
15	Temperature display does not display Infant's Temperature accurately	Sensor thermal sensitive portion attached improperly
		Check thermal sensitive portion of sensor covered improperly
16	Baby temperature not correlate 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
17	In baby mode baby getting over heat but machine gives low temperature indication	Check the sensor is intact with lower abdomen of baby
		Check the sensor is removed and keep away
		Check the set temperature is high
		Check the set heater output is high (Manual Mode)

7.2.2 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.	**Startup 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

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

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

Section 8: Spare Parts List

Sl. no	Part No	Part Name	Qty	Unit
1.	50-05-239	Skin temperature sensor assembly	1	No.
2.	50-05-241	Auxiliary temperature sensor assembly	1	No.
3.	30-05-109	Air Sensor assembly	1	No.
4.	30-05-011	Hood Assembly	1	No.
5.	30-05-012	Access panel assembly	1	No.
6.	87-00-126	Mattress	1	No.
7.	76-00-037	Air filter	1	No.
8.	93-00-038	Castor 5" with Brake	4	No.
9.	91-00-051	Battery 9V Unchangeable	1	No.
10.	50-05-044	IV Pole Assembly	1	No.
11.	90-00-100	Power Cord Open Type 16A	1	No.
12.	91-00-201	Motor 57MM Brushless DC Fan	1	No
13.	99-00-761	Humidity reservoir	1	No
14.	89-05-033	Dwin Display-DMG10768T104-34WTC (10.4-inch Capacitive Touchscreen without enclosure)	1	No.
15.	91-00-240	Circuit Breaker - 10A	2	No.
16.	97-00-041	X Ray cassette tray	1	No.
17.	91-00-225	SMPS 24 V	1	No.
18.	91-00-052	Battery 12V 1.3 AH	1	No.

Section 9: Manufacturer's EMC Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The Infant incubator is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant incubator should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Class A	The nice 3010 Wallaby is suitable for use in Professional hospital environment
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

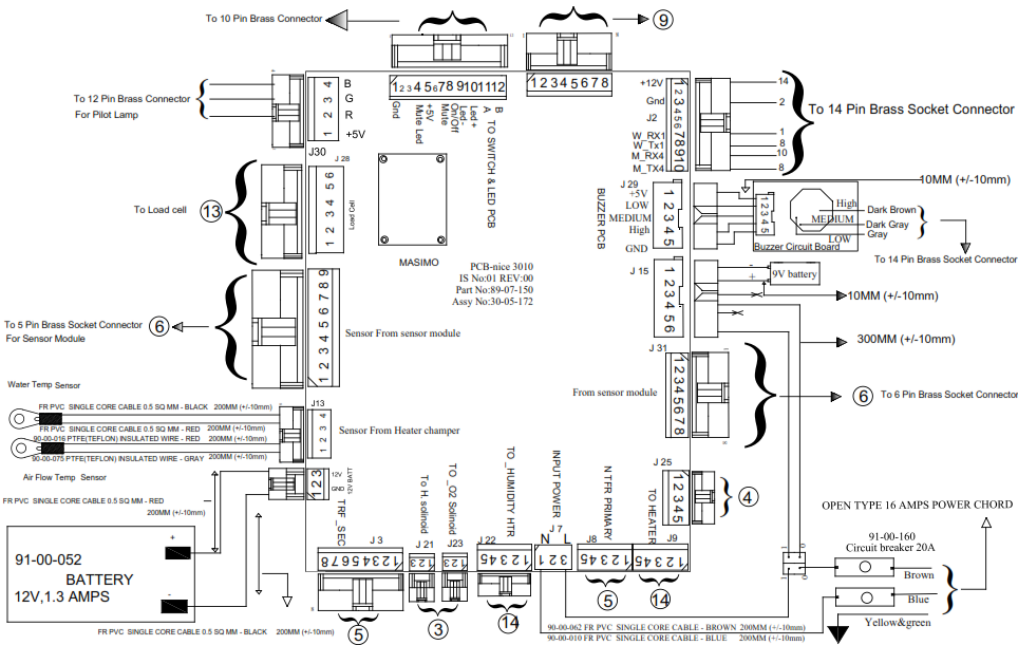
Guidance and manufacturer's declaration – electromagnetic immunity			
The Infant incubator is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant incubator should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 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 B	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% of dips for 0.5 & 1.0 cycle	Criteria A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the nice 3010 Wallaby requires continued operation during power mains interruptions, it is recommended that the nice 3010 Wallaby be powered from an uninterruptible power supply or a battery.
	70 % dips for 25 cycles 0% short interruption for 250 cycles	Criteria A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Criteria A	Power frequency magnetic fields should be at levels characteristic of a typical location in a

			typical commercial or hospital environment
NOTE: UT is the a.c. mains voltage prior to application of the test level.			
Guidance and manufacturer's declaration – electromagnetic immunity			
The Infant incubator is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant incubator should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM 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.			

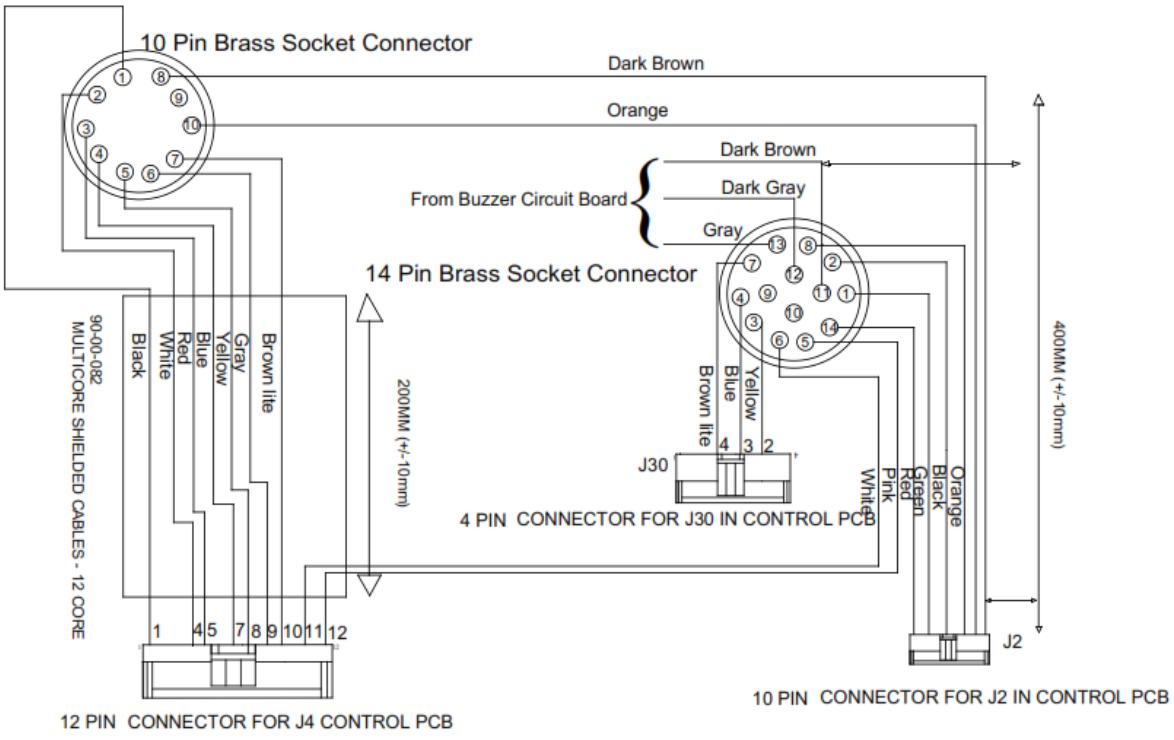
Acceptance criteria

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



Shell Assembly



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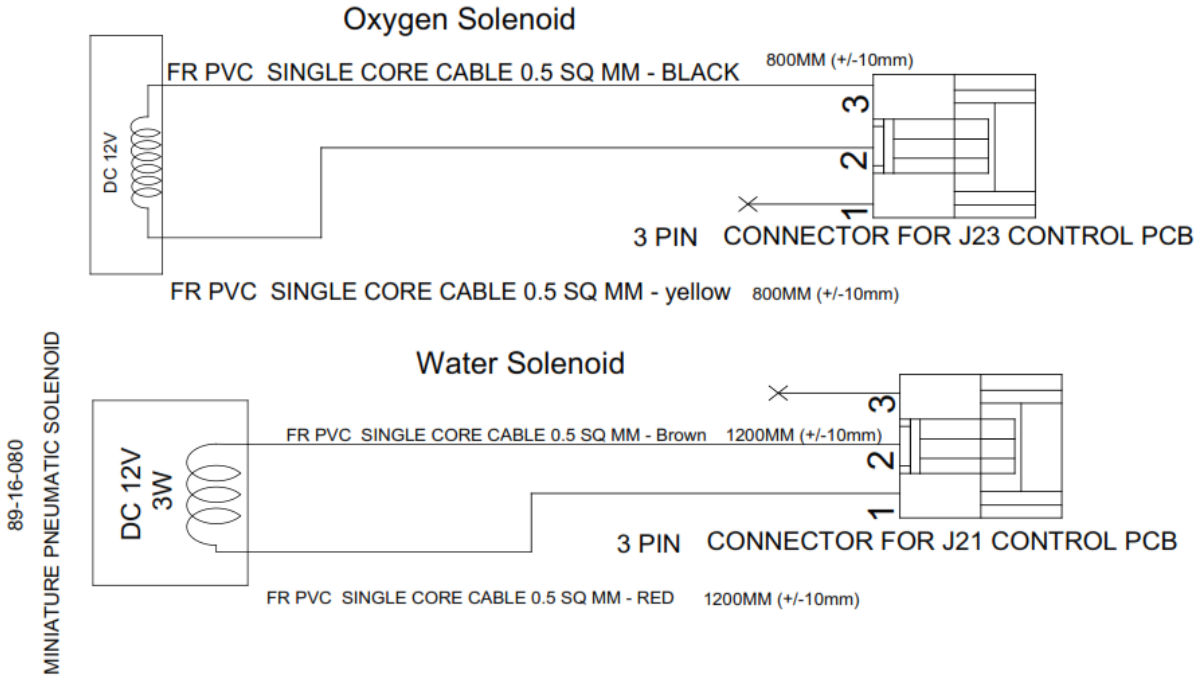

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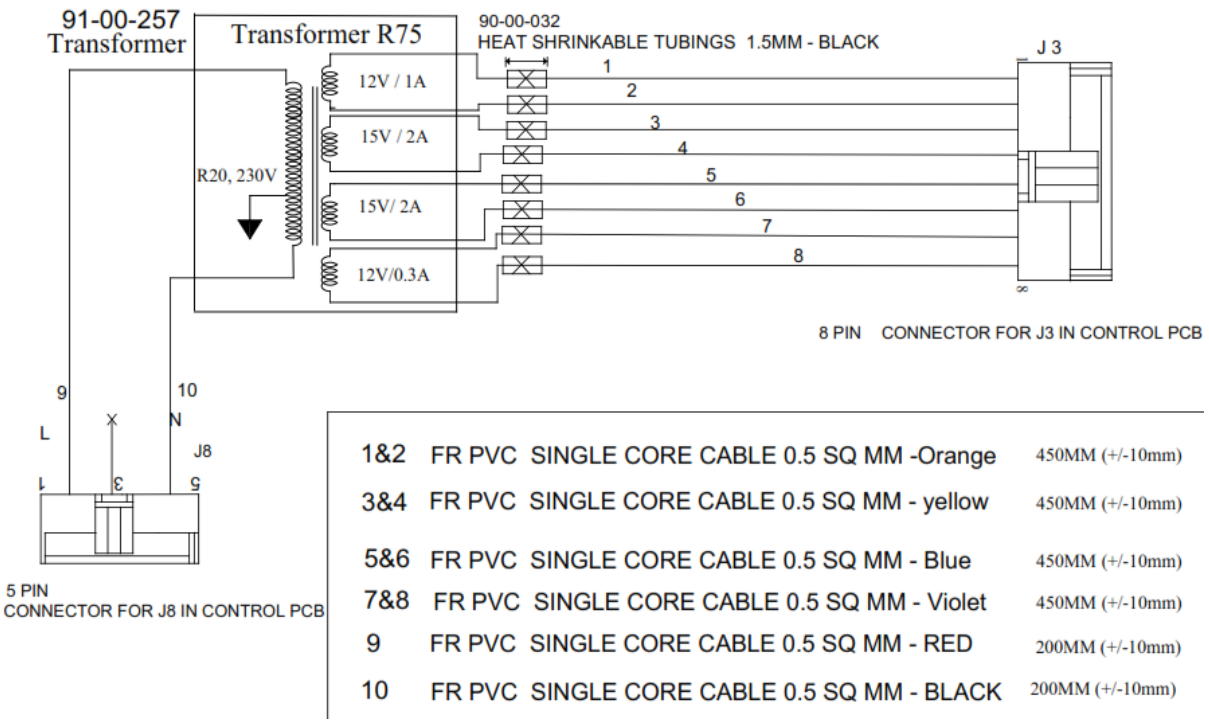

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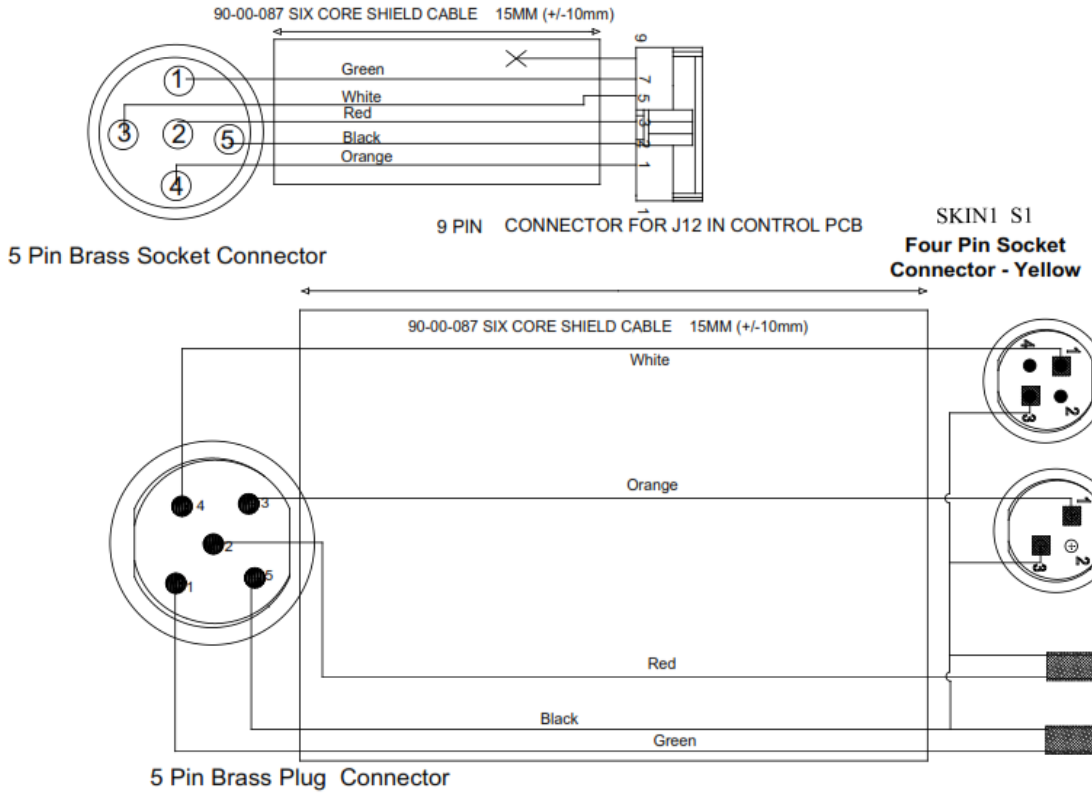
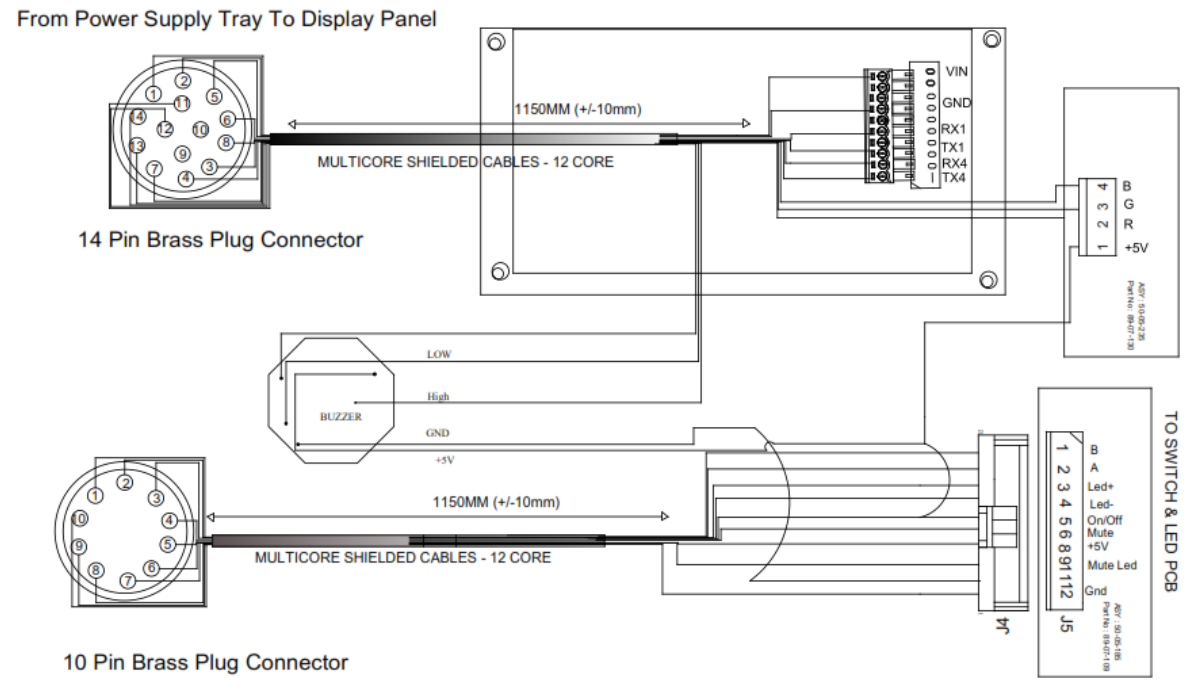
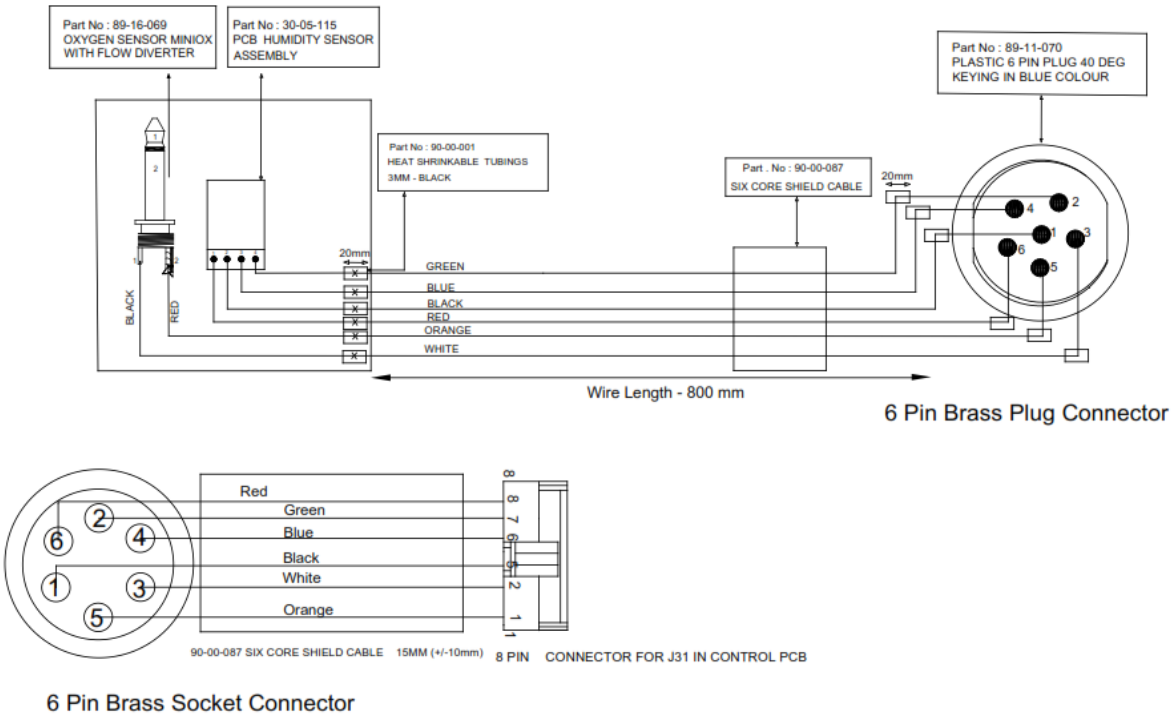


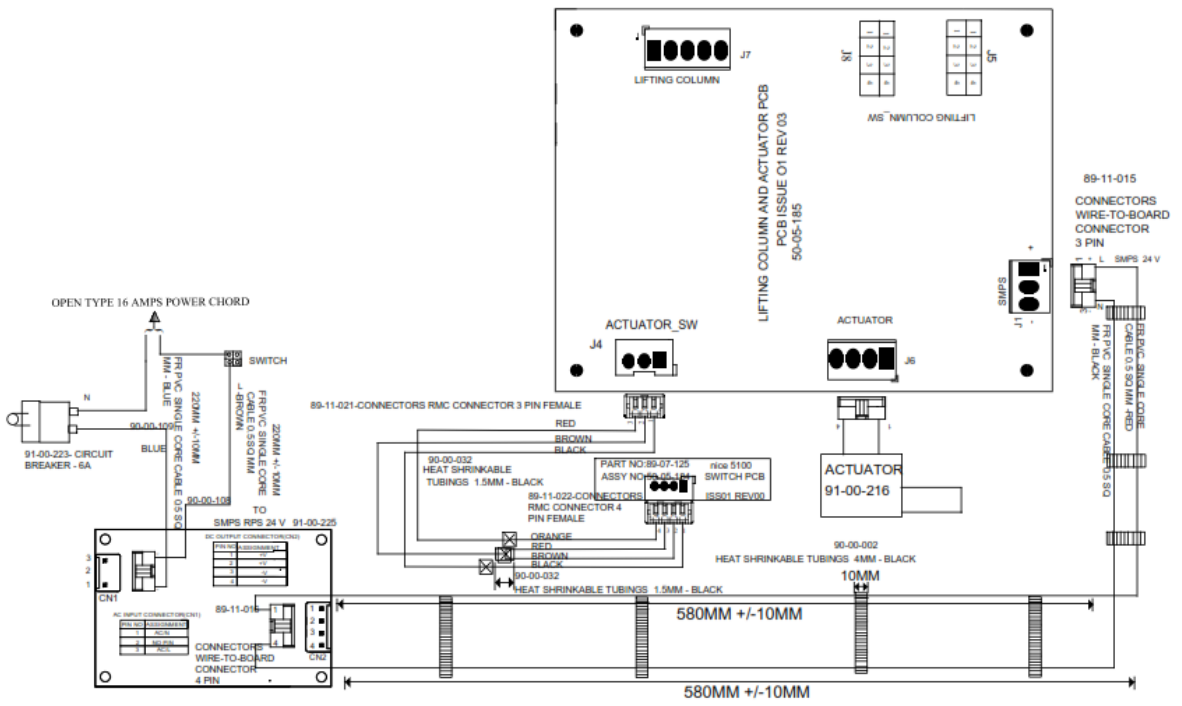
Sensor Module Assembly



Display Unit Assembly



Sensor Module Assembly



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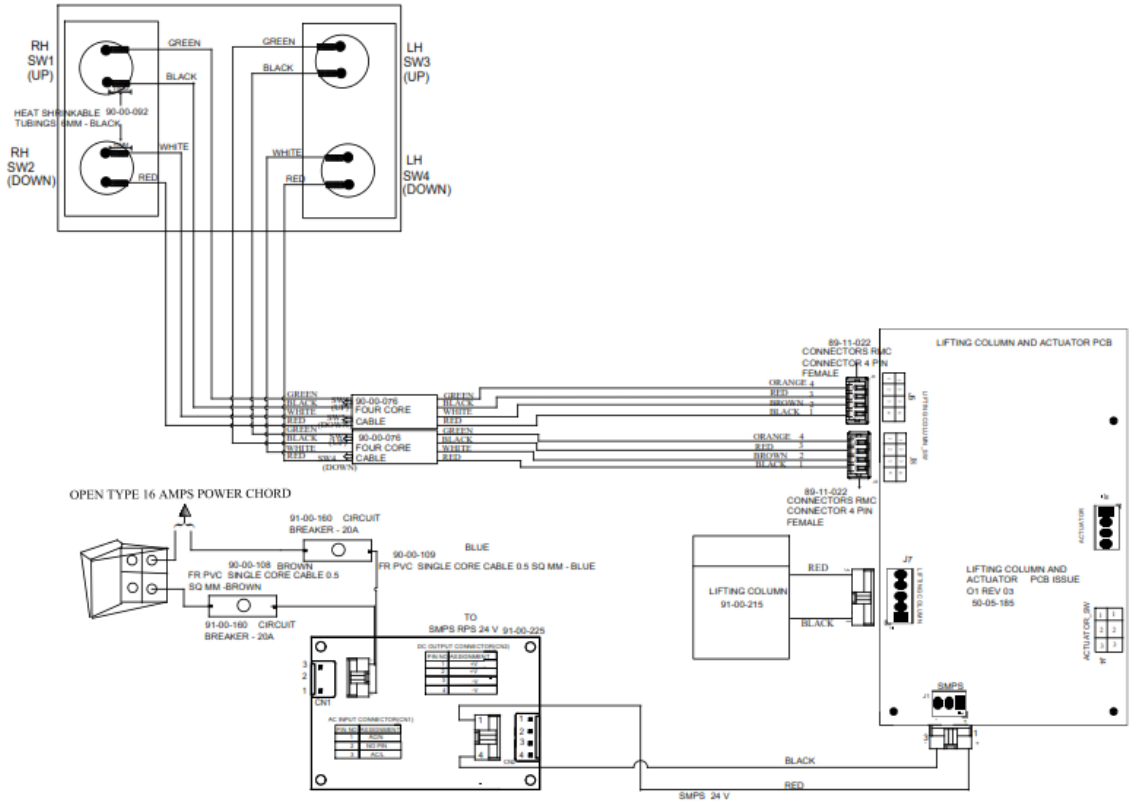

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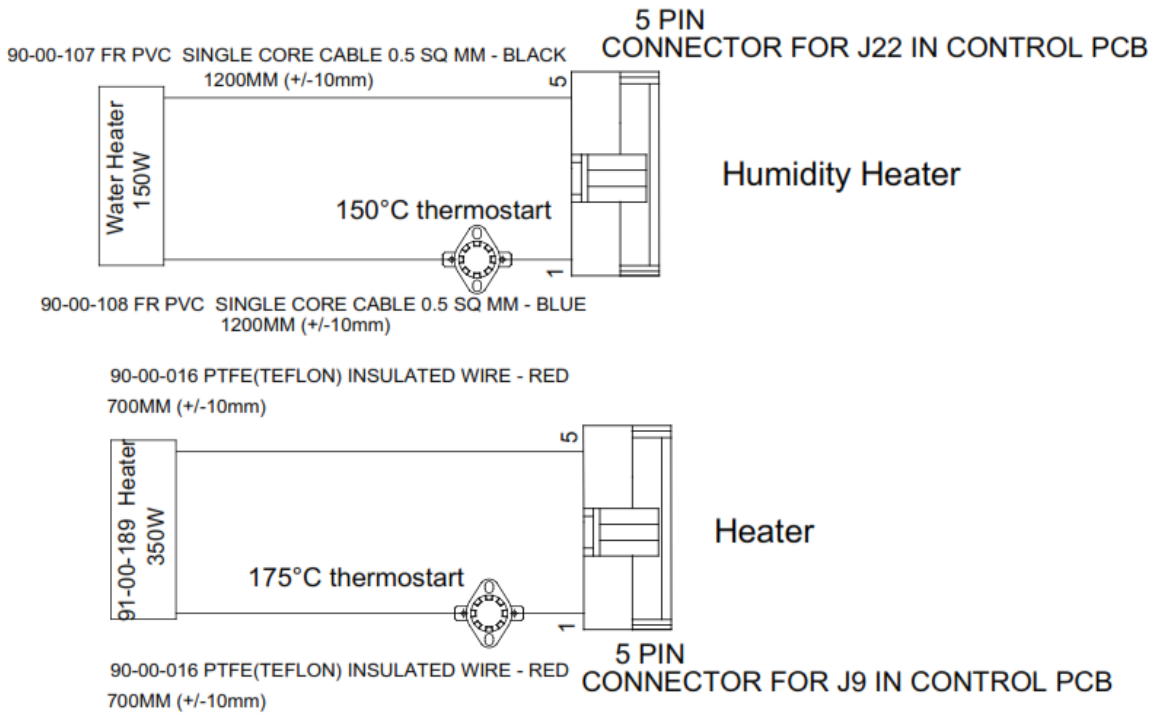

Shell Assembly

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. 85-86, Krishna Industrial Estate, Vanagaram, Mettukuppam Chennai-600095. Tamil Nadu, INDIA. Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594 E-mail: service@niceneotech.com /info@niceneotech.com Web: www.niceneotech.com 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 BADANI CERTYFIKACJI

Notified body number:

1434

Address:

02-844 Warsaw,
469 Pulawska Street,
Poland.

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