NuBORNe®

500 Infant Warmer

Infant Radiant Warmer

Operator's Manual

international BIOMEDICAL®

NuBORNe®

500 Infant Warmer

Infant Radiant Warmer

Operator's Manual

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  Austin, TX 78754
  USA

- ***Authorized representative in Europe for Regulatory Affairs:***

  Emergo Europe
  Prinsessegracht 20
  2514 AP
  The Hague, The Netherlands

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Notice

European Regulatory Affiars Representative
The authorization regulatory affairs representative in Europe for the warmer is:

Emergo Europe
Prinsessegracht 20
2514 AP
The Hague, The Netherlands

For general assistance or for parts and accessories, contact:

International Biomedical
8206 Cross Park Drive
Austin, Texas 78754

(512) 873-0033

Warranty

Unless otherwise specified, International Biomedical warrants all products of its manufacture at the time of shipment to be free from defects of material and workmanship for a period of twelve months from the date of shipment when owned by the original purchaser. Any product which is believed to be defective, if returned within twelve months after date of shipment by the Company with freight prepaid and found by the Company's inspection to be defective within the terms of this warranty, will be repaired or replaced free of charge and shipped, freight prepaid, to any point in the United States. If inspection by the Company of any such product does not disclose any defect within the terms of this warranty, the Company's regular charges for repairs or replacement and freight shall apply. All consumable and disposable products are guaranteed to be free from defects upon shipment only. The warranty period for batteries is limited to 90 days from date of shipment.
This warranty specifically excludes and replaces all other express and implied warranties. The Company shall have no liability under any warranty in any amount greater than the Company receives for the sale of the product involved. The use and manner of use of the Company's products shall be the responsibility of the purchaser and the purchaser covenants and agrees to indemnify and save harmless the Company in respect to any loss and damage that may arise through the use by the purchaser, or others, of any of the Company's products.

This warranty is rendered void and International Biomedical cannot be held liable for conditions resultant therefrom if:
1. Damage to the unit is incurred as a result of mishandling.
2. The customer fails to maintain the unit in a proper manner.
3. The customer uses any parts, accessories, or fittings not specified or sold by International Biomedical.
4. Sale or Service is performed by a non-certified service / dealer agency or any other unauthorized agency.

All shipping claims must be made within 30 days from date of shipment from International Biomedical, otherwise factory will not be liable for claims of missing items. Any item ordered in error and returned to the factory for credit, will be subject to a minimum restocking charge of 15%. Requests for returning items must be made within 30 days of factory shipment date.

International Biomedical will accept no returned goods without a Returned Material Authorization number (RMA) obtained from Customer Service Department.

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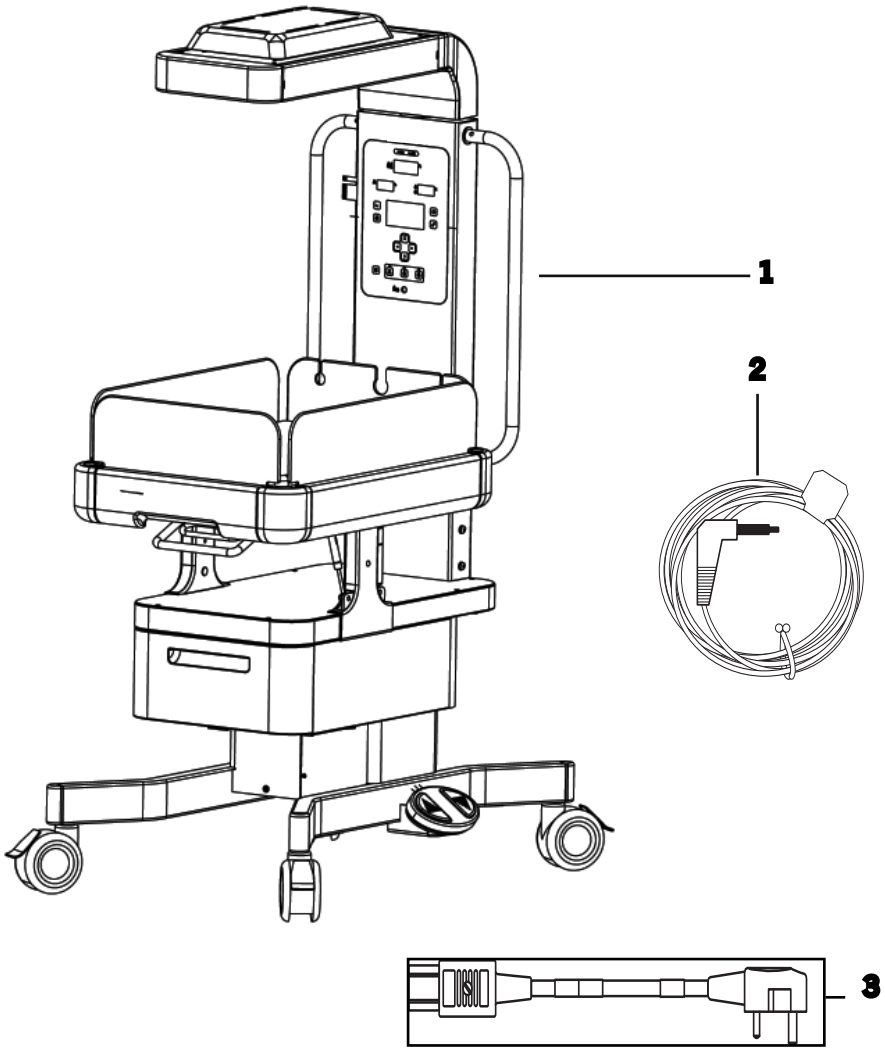
Table of Contents

Chapter 1. Introduction

This chapter provides an overview of the NuBorne 500.

Package Contents

The NuBorne 500 package includes the following items:



Sr. #	Description	Quantity	Remarks
(1)	NuBorne 500 Device	1	Assembly to be done as per Installation instructions by International Biomedical authorized personnel.
(2)	Reusable Skin Probe	1	
(3)	AC Power Cord	1	
(4)	User Manual	1	Not shown.

Introduction

This user manual describes the system, setup, operation, cleaning, maintenance, troubleshooting, and technical specifications for the NuBorne 500. Read the NuBorne 500 manual thoroughly to understand all instructions, warnings, cautions, and notes before operating the device. International Biomedical is not responsible for any malfunction due to improper use or service by unauthorized International Biomedical personnel. For any technical problem contact your International Biomedical representative.

Intended Use

The NuBorne 500 is an open care environment used for providing controlled infrared heat to neonates who are physiologically unable to maintain their body temperature or may require external heat to ease the transition from the mother's womb to the external environment.

The device is intended to be used in a Labor & Delivery environment for warming the infants immediately after birth, or in a Neonatal Intensive Care Unit for providing premature infants long duration thermoregulation therapy, or in newborn care areas, for providing external heat to low-birth weight infants, and for cases where clinical indications require short/long duration warming therapy.

The device allows access to the infant for various procedures, tilting of the mattress, weighing the infant and x-ray diagnostics. The device provides three modes of warming: Manual, Skin, and Standby mode for varying care requirements. Also, allows attaching optional accessories on the rail for therapy and monitoring of the infant.

Training

Contact International Biomedical at 1-800-433-5615 or sales@int-bio.com to obtain operational training on the NuBorne 500 Infant Warmer.

Chapter 2. System Description

Main Parts

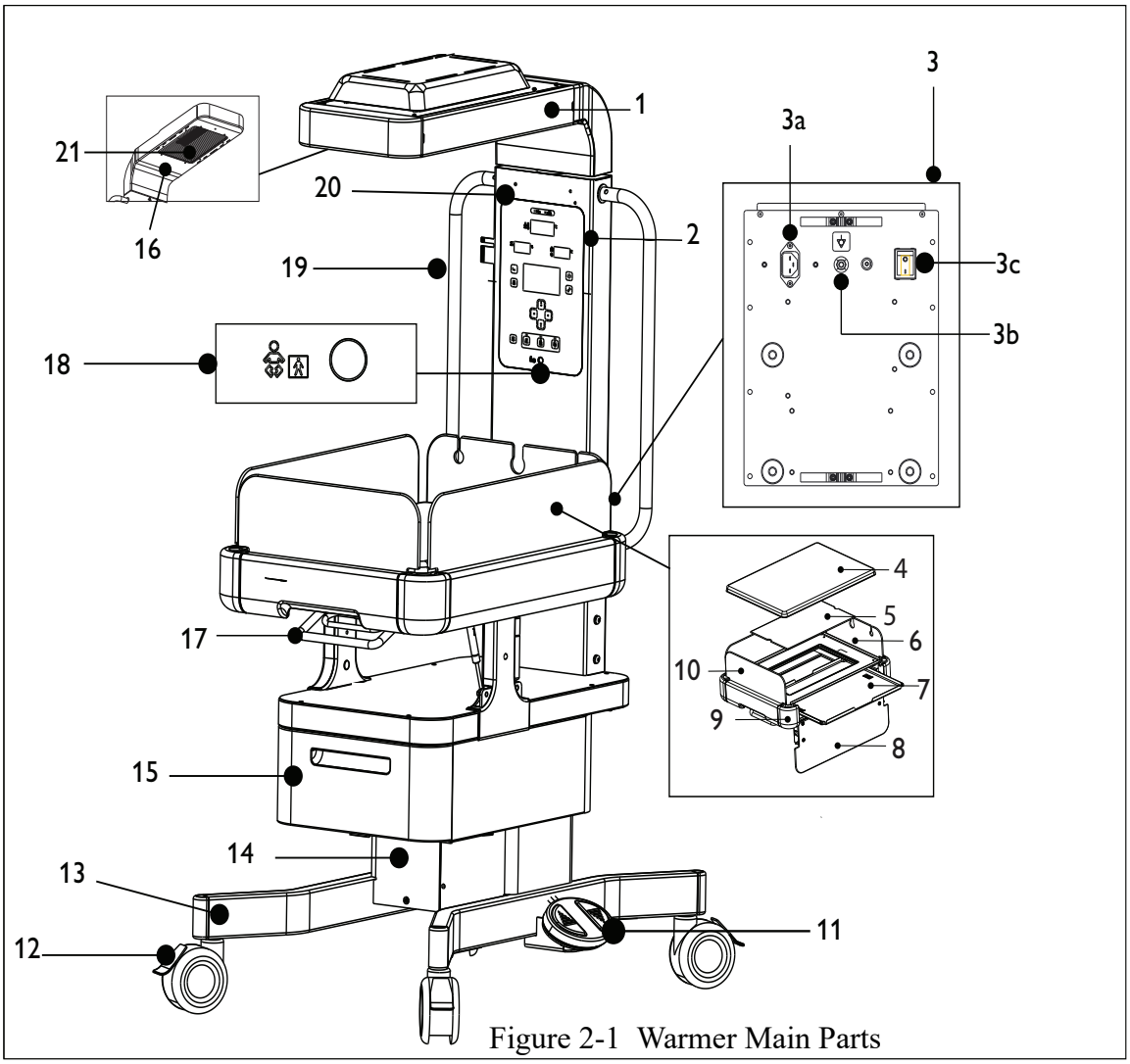


Figure 2-1 Warmer Main Parts

#	Name	#	Name
(1)	Heater hood	(10)	Short sidewall
(2)	Display panel	(11)	Footswitch
(3)	Power panel	(12)	Caster wheel
(3a)	Power socket for power cord connection	(13)	Pedestal
		(14)	VHA cover
(3b)	Potential equalization terminal	(15)	Storage drawer
(3c)	Power switch	(16)	Observation Light
(4)	Mattress	(17)	Bed tilt handle
(5)	Bed acrylic tray	(18)	Skin temperature probe socket
(6)	Short sidewall with tubing slots	(19)	Accessory rail
(7)	X-ray cassette tray (optional)	(20)	Vertical pillar
(8)	Long sidewall	(21)	Heater grill
(9)	Corner block		

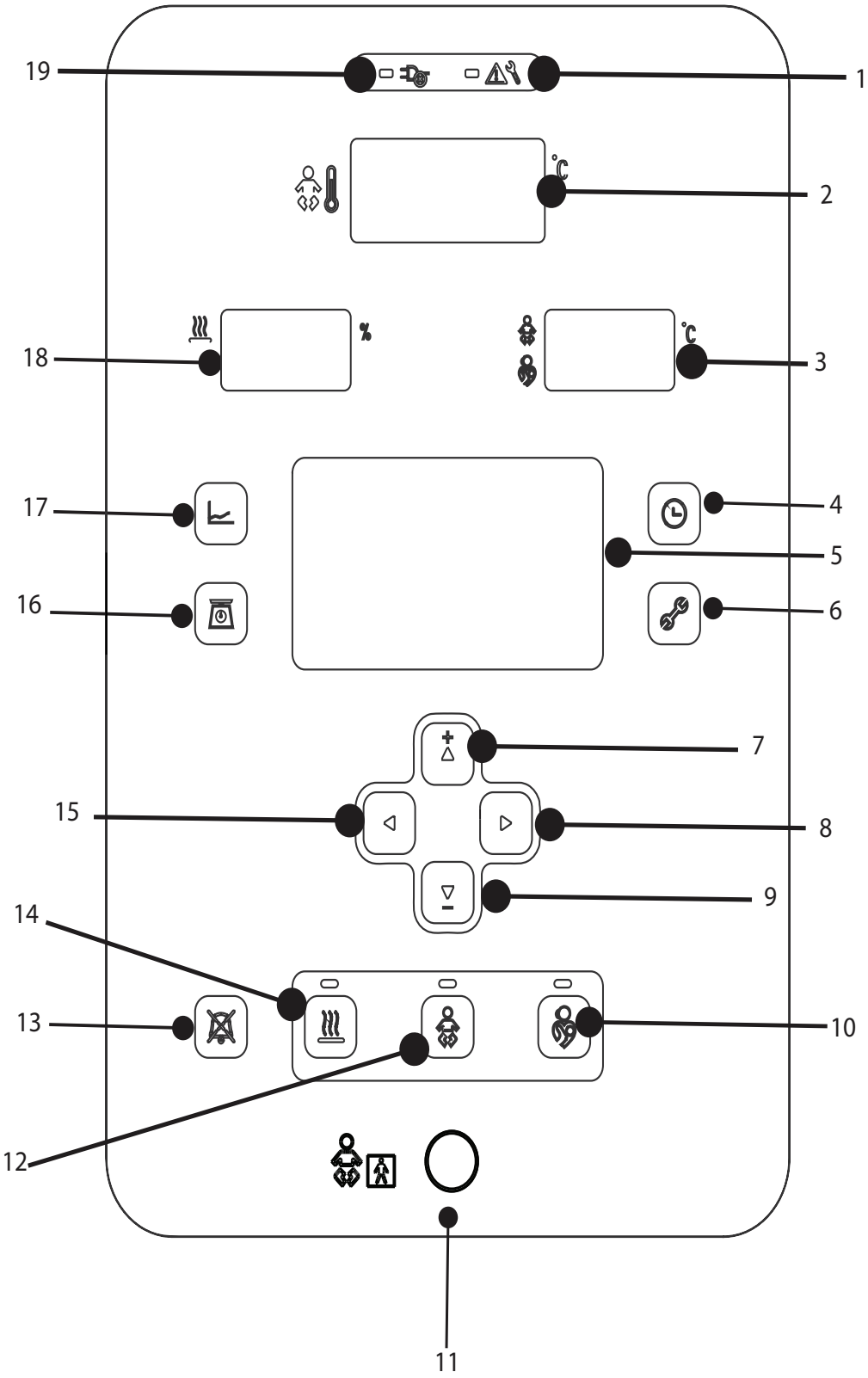
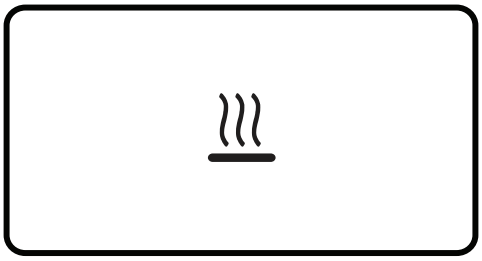
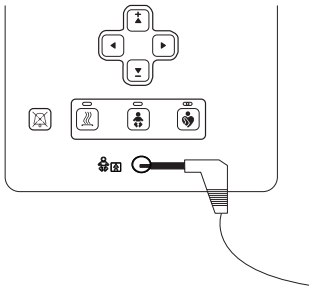
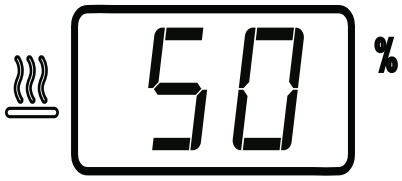


Figure 2-2 Warmer User Interface

The following summarizes the menu item functions:

No.	Menu Item	Symbol/Display Screen/Connecting Port	Function
(1)	System failure indicator		A red color indicator illuminates when the system failure alarm condition occurs.
(2)	Measured skin temperature numeric display		Displays measured skin temperature.
(3)	Set skin temperature numeric display		Displays the set skin temperature.
(4)	APGAR		Press the APGAR button to start the count-up timer that gives an audible alert at 1, 5, 10, and 20 minutes. The timer is seen in the Graphic display. Press the APGAR button again to stop the count-up timer.
(5)	Graphic display		Displays system information such as temperature, APGAR timer, settings, system messages, alarms and selected mode. It also displays error code in case of System Failure.
(6)	Settings		Press the Settings button to loop through the settings option to control the alarm volume, erase trend data, set date and time that is used during trending.
(7)	Increase button		Press the Increase button to increase, change or scroll a value of a parameter.
(8)	Forward selection button		Press the Forward selection button to select the next selection or to set a value.

No.	Menu Item	Symbol/Display Screen/Connecting Port	Function
(9)	Decrease button		Press the Decrease button to decrease, change or scroll a value of a parameter.
(10)	Standby mode		Press the Standby mode button to select this mode of operation of the device. This mode maintains the device in standby and relaxes alarm limits or turns OFF alarms. This mode facilitates supplementary care that requires the infant to be moved out of the device for varying durations. Note: Successful activation of this mode is indicated by illuminated indicator above mode button.
(11)	Skin temperature probe socket		Attach one end of the skin temperature probe to the infant and connect the other end to the probe socket. For details on attaching the skin temperature probe refer Chapter 4: Setup.
(12)	Skin temperature mode		Press the Skin temperature mode button to select this mode of operation of the device. This mode provides warming therapy to the infant based on measured skin temperature. Note: Successful activation of this mode is indicated by illuminated indicator above mode button.
(13)	Alarm silence button		Press the Alarm silence button to mute the alarm sounds. See Chapter 7: Alarms for details on Alarm silence time.

No.	Menu Item	Symbol/Display Screen/Connecting Port	Function
(14)	Manual temperature mode		Press the Manual temperature mode button to select this mode of operation of the device. This mode directly controls the heater output. This mode generates a 'Check baby alarm' 12 minutes after selection, If power is set above 25%. See Chapter 7: Alarms for details on Check baby alarm. Note: Successful activation of this mode is indicated by illuminated indicator above mode button.
(15)	Backward selection button		Press the Backward selection button to select the previous selection or to set a value.
(16)	Weight		Press the button to activate the in bed weighing scale that can be used to measure the weight of the infant.
(17)	View trend		Press this button to view temperature trend as a graph or weight trend (applicable only for NuBorne 510) as a table. Temperature trend data is stored for a maximum of 96 hours with each screen showing 24 hours of data. Last 30 weight measurements are stored with date and time stamp and displayed as a table with 5 entries in one screen.
(18)	Heater output numeric display		Displays the power output of the heater as percentage of full power. It also displays error code in case of System Failure.
(19)	Power failure indication		A red color indicator illuminates when the power failure alarm condition occurs.

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Chapter 3. Warnings, Cautions, Notes, and Symbols

Before using the NuBorne 500 device on an infant, familiarize yourself with the user manual, particularly the safety considerations listed. The NuBorne 500 manual is only for reference. It is not intended to supersede your institution's protocol regarding the safe use of a device.

Follow the operating instructions described in the manual for the safe use of the device. The NuBorne 500 shall only be operated by those who are trained and instructed in its operation under the supervision of qualified medical personnel familiar with the currently known risks and benefits associated with the use of a radiant warmer. Ensure that the NuBorne 500 is operated for its intended use only.

Warnings

General	Never use the device to transport the infant.
	Never use wet hands before connecting power cord, operating or accessing the control panel, or touching the probe cable. It may cause an electric shock. MR unsafe. Do not use the device during magnetic resonance imaging (MRI) scanning. Federal law (U.S.) restricts this device to sale or use by or on the order of a physician (or properly licensed practitioner).
Setup	Use only the power cord supplied with the device. Otherwise, a fire or an electric shock may result.
	Never install the device where it will be exposed to high temperature or excessive humidity (see Chapter 10: Technical Specifications for details on operating condition). It may cause a fire or an electric shock.
	Ensure that water does not drip into the vicinity of the radiant heater through the top air ventilation openings. It may cause an electric shock.
	The device is not intended to be used in an area where there is smoke.
	Never park the device on inclines more than 10° slope. Installing the device on inclines more than 10° may cause instability or toppling.
	Ensure that this device is connected only to a supply mains with protective earth. Never operate the device if you have a doubt about its protective earth connection. It may cause an electric shock.
	Electric equipment for medical use needs special precautions regarding Electromagnetic Compatibility (EMC). Install and place the electric equipment into service according to the EMC information provided in this manual, see Appendix A: EMC Information for details on EMC information.
	Use only International Biomedical temperature probe part # 108-4855 (reusable patient probe) with the NuBorne 500.
	Ensure use of a separate power outlet for each device. Also ensure the power outlet is located near the device to prevent accidental tripping over a trailing power cord.

Warnings

Operation	Never use the device in the presence of a flammable anesthetic gas. The device may cause an explosion or a fire if used in the presence of such a gas.
	Ensure the sidewalls are always locked. Stop using the device if the locking mechanism of the sidewall is found faulty. The infant may fall out and suffer serious injury.
	Ensure that the infant's clothing, probe lines, and IV lines are not caught in spaces between corner blocks and sidewalls during open/close operation. The infant may fall out and suffer serious injury.
	Never use a heated gel mattress in the NuBorne 500. Use of heated gel mattress in this device can increase the infant's temperature to dangerous levels.
	Ensure that the cords and tubes do not entangle the infant when managing the cords and tubes into or out of the device.
	Never leave the infant temperature unmonitored. The infant temperature may rise or fall unacceptably.
	Ensure that you monitor the infant's core temperature separately when using the device. You cannot differentiate the condition in which the infant's peripheral skin temperature is low, while its core temperature is high (fever), from the condition in which the infant's skin temperature is low, as well as core temperature is low (hypothermia).
	Never place an infant or an object weighing more than 10 kg on the mattress platform.
	Never use skin temperature probe to measure infant's rectal temperature.
	Ensure that the skin temperature probe is properly attached to the infant's abdominal wall for accurate skin temperature measurement.
	Ensure that the skin temperature probe is neither warmed by being covered with a blanket, diaper, or the infant's arm, nor is cooled by getting wet with the infant's urine, perspiration, or some medical fluid.
	Ensure that the skin temperature sensor is fixed without the possibility of being dislodged from infant's body. If the skin temperature probe is dislodged from infant's body it results in under heating or overheating of the infant.
	Ensure that your fingers are not pinched while inserting and removing under-surface phototherapy device.
	Ensure that you use caution when the heater hood is in swivel operation. It may cause collision of your head with the heater hood.
	Ensure that the cables attached to the infant are long enough when tilting the mattress platform.
	Ensure that free oxygen flow is at least 500 mm away from heater hood in a well-ventilated room. If the device is used in presence of oxygen sources the risk of explosion or fire will increase.
	Ensure that others' fingers are not pinched in the gaps during sidewall open/close operation.
	Ensure that others' fingers are not pinched in the space between heater hood and vertical pillar during hood swivel operation.

Warnings

Operation	Ensure that the device is not brought to a sudden stop from movement at speeds above 0.5 km/hr. You may injure your leg if the storage drawer slides open.
	Do not place the infant in the bed during warmup.
Alarms	Discontinue use of the equipment when the System and Power Failure Alarm displays. See Chapter 7: Alarms for details.
	Discontinue use of the device if the Graphic display or indicator fails. See Chapter 9: Troubleshooting for details.
Cleaning	Ensure that the device is disinfected before first use, between change of infants, and after maintenance.
	Ensure to turn the power OFF, remove the power plug from the power outlet, and allow the heater to cool down before cleaning and disinfecting the device.
Maintenance	Ensure that the infant is taken out of the device and the device is powered down before any servicing event.
	Always inspect the footswitch for any damage that may allow water ingress. This is to reduce the risk of electric shock.
	Never disassemble or modify the device. It may cause a fire, electric shock or injury.
	Ensure the power plug is disconnected from the power outlet before moving the device to another place or while not using the device for a long time.
	Never apply lubricants to joints or moving parts of the device except the caster wheel. Lubricants may be harmful to the infant.
EMC	When using the NuBorne 500 adjacent to or stacked with other equipment, observe the operation of the NuBorne 500 and the other equipment to ensure normal operation.
	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the NuBorne 500 and associated cables. Otherwise, degradation of the performance of this equipment could occur.
	Use only parts, accessories, transducers, and cables designated by International Biomedical for use with the NuBorne 500. Cables and accessories other than those supplied by International Biomedical may result in unacceptable operation of the NuBorne 500 and will void the equipment warranty.
	The use of devices which radiate high intensity electrical fields may affect the operation of the NuBorne 500. Constant assessment of the patient and all life support equipment is mandatory whenever interfering devices are operating on or near patient.
	Electrical shock, burns or electromagnetic interference are possible if high frequency surgical instruments or endocardial catheters are used in the area of this device.

Cautions

General	Always install the device in a location that is out of reach of small children.

Cautions

Setup	Ensure that the distance between heater and mattress is in the range of 790-830 mm.
	Never use unapproved mattress in NuBorne 500.
	Install the device at least 150 cm away from a room heater and in a location so that the device is not affected by external thermal conditions such as: • Direct sunlight • Heat emitted by a room heater • Airflow of an air conditioner • Cold wind from a window
	Install the device in such a way that the top surface of the hood is at least 50 cm below the ceiling as the heater hood radiates heat from the top surface of the hood.
	Install the device such that vertical pillar of the device is at least 40 cm away from the closest wall. Never block the air vents in the heater hood. This may lead to excessive heating of the heater hood.
Operation	Avoid excessive force to tilt the infant bed in the event of failure to the tilt actuation. For service contact International Biomedical representative.
	Avoid excessive force, if the device hood swivel ability is stuck or if the X-ray cassette is difficult to remove, place, or position on X-ray tray.
	Never hang anything heavy, place any heavy weight, or lean against the heater hood. It may cause a structural damage.
	Never use the tilt handle to move the device after installation. It may cause a structural damage.
	Never hang a cloth on the heater hood. It may catch a fire if the device is switched ON.
	Never stand, lean, or put full body weight on any part of device including base and footswitch. It may cause a structural damage or instability.
	Never get the power cord pinched or caught between the device and the wall, a shelf or the floor.
	Never place the power cord near a heating apparatus and never expose the power cord to heat.
	Never put anything heavy on the power cord.
	Never place weight beyond 7 kg on monitor stand mounted to accessory rail. It may cause instability.
	Never load more than 10 kg on one side of the accessory rail.
	Never overload the storage drawers beyond 5 kg of contents.
	Never store any heavy item in the space under the mattress.
	Ensure that the heater hood is adequately secured in the central position if the device requires to be transported in a road vehicle. It may cause unintended swivel of heater hood during transport.
	Infants should wear protective eyewear when observation light is being used.
	Always use a sheet or blanket to cover the mattress.
	Ensure the bed is level prior to initiating the weighing procedure.

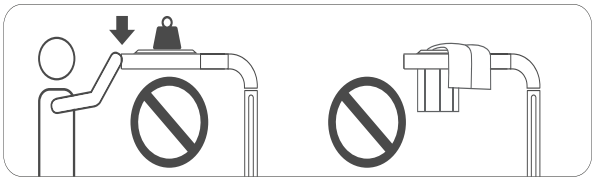
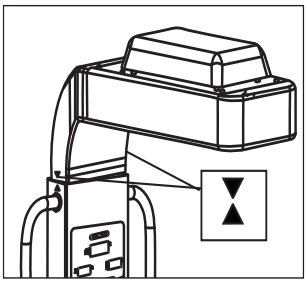
Cautions

Maintenance	Stop using the device and contact International Biomedical representative if you notice any unusual smell, unusual noise, unusual vibration, overheating, missing parts, or defective function in the inspection.
	Inspect the power cord for any damage. A damaged power cord may cause a fire or an electric shock.
	Inspect the device for damage if left unused in storage. If any damage is found, contact your International Biomedical representative.
	Always grasp the power plug with your hand to remove the power cord from the power outlet. A damaged power cord should be replaced with a new one.
	The device should be serviced only by qualified personnel.
	Never twist or pull the cords by force. If any defect is found, contact your International Biomedical representative.
	Clean and disinfect the device and its accessories before and after maintenance inspections and repairs, or before disposal.
Cleaning	After cleaning and disinfecting the device, dry completely before using the device.
	Never use unauthorized cleaning agents and do not scour or allow excess cleaning solutions to drip on to heater or electronics.
	Use only the approved disinfectants for NuBorne 500. See Recommended Disinfectant Solution in Chapter 8: Cleaning and Maintenance for appropriate concentration, contact time and handling.
	Assemble the removed parts and check that the device operates normally after cleaning and disinfecting.
	Never immerse removable parts in disinfectant or soap solution.
	Ensure that water or cleaning agents do not enter near electronics through vents on back of vertical pillar.

Notes

Setup	All materials used on continuous contact surfaces with infant are designed using biocompatible materials.
	Cover the mattress with a mattress sheet.
	The electrical rating of the device is: AC 230 V and 115 V, peak power consumption 750 VA (inclusive of height adjustment operation), frequency 50/60 Hz, and operating voltage range AC 230 V ± 10% AC and 115V ± 10%. Never connect the device to any other power source.
Cleaning	Clean and disinfect the device, as per the maintenance instructions, or whenever you notice any dirt or stain that may cause infection.
Maintenance	Medical institutions are responsible for performing routine maintenance as detailed in the user manual.

Symbols: Product Labels	
 (blue background)	Refer Accompanying Instructions For Use
	Ensure this device is disposed safely at end of life. (For guidance on safe disposal contact an International Biomedical representative).
	Date of Manufacture
	Warnings: • Do not Place the Infant on x-ray tray • Maximum Weight Capacity 3 kg
	• High voltage
	Warning: Hot Surface
	Potential Equalization Terminal
	Protective Earth Terminal
	Warning: Maximum Weight Capacity 1 kg
	Warning: Maximum Weight Capacity 5 kg
	Warning: Maximum Weight Capacity 7 kg
	Warning: Maximum Weight Capacity 10 kg
	Warning: Maximum Weight Capacity 15 kg

Symbols: Product Labels	
	Warning: • Maximum height 80 mm • Maximum weight capacity 5 kg on open shelf.
	Warning: • Do not attempt to touch heater
	Warning: • Do not Place Heavy Weight on Heater Hood • Do not Press Down on Heater Hood • Do not Hang Cloth on Heater Hood
	Caution: • Heater hood central alignment indication
 (blue background)	• Cover infant's eyes
	• Observation Light
CB	• Circuit Breaker Rating IEC 60127-1, T 10A, 240V

User Interface	
	Power Failure
	System Failure
	Skin Temperature
	Manual Temperature Mode
	Skin Temperature Control Mode
	Standby Mode
	View Temperature Trend
	Erase Trend
	APGAR Timer
	Settings
	Scale
	Increase Button
	Decrease Button
	Forward Selection Button
	Backward Selection Button

User Interface	
	Type BF Applied Part
	Observation Light
	Bed Motion
	Scale Warm-up Time
	Min Weight not Achieved
	Max Weight Exceeded
	Bubble Level Indicator
	Scale not Available
	Lift Baby
	Place Baby
	Scale Gravity Error
	Scale Communication Error
	Scale Zeroing Error

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Chapter 4. Setup

The Setup chapter provides instructions to setup the NuBorne 500. The following setup information is included:

- Installing the Device
- Locking the Caster Wheel
- Checking the Device
- Connecting Power Cord
- Using Potential Equalization Terminal
- Device Warm Up
- Warming Therapy Modes
- Warming in Manual Temperature Mode
- Warming in Skin Temperature Control Mode
- Transitioning to Standby Mode from Skin Mode

Installing the Device

Install the device on a horizontal surface, away from a room heater or a window, and in a room temperature of 18°C to 30°C.

Warning

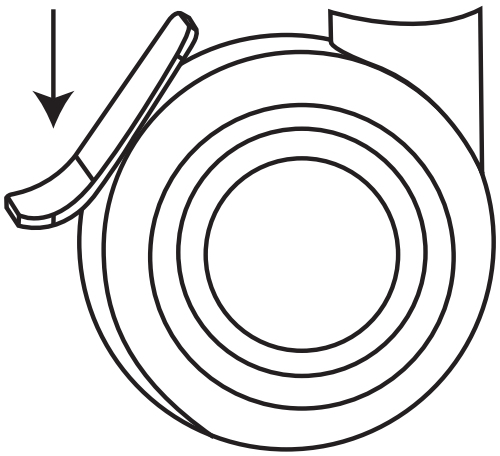
- The device should be used only by appropriately trained personnel and under the direction of qualified medical personnel who are familiar with currently known risks and benefits of radiant warmer use.

Cautions

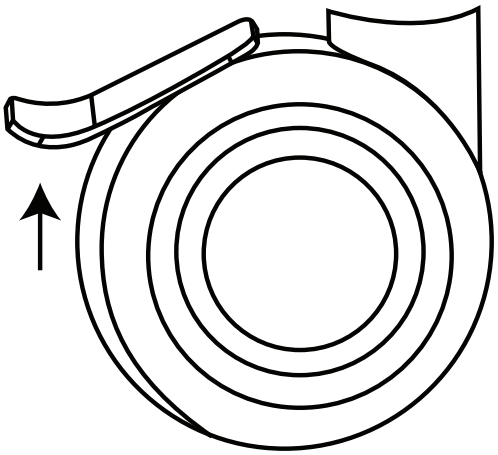
- Always install the device at least 150 cm away from a room heater and in a location so that the device is not affected by external thermal conditions such as:
  - Direct sunlight
  - Heat emitted by a room heater
  - Airflow of an air conditioner
  - Cold wind from a window
- Always install the device such that top surface of the hood is at least 50 cm below the ceiling as the heater hood radiates heat from the top surface of the hood.
- Always install the device such that the vertical pillar of the device is at least 40 cm away from the closest wall.
- Always use a sheet or blanket to cover the mattress.

Locking the Caster Wheel

1. Position the device in a desired location.
2. Lock the caster wheel by pressing down the foot press lever.



3. Unlock the caster wheel by raising the foot press lever.



Notes

- Lock all the caster wheels before using the device.
- Recommended speed of movement of device on casters is 0.5 km/hr.

Checking the Device

Check the device for any faults, contamination, missing parts, or defective parts to ensure safe use before using the device. See Chapter 8: Cleaning and Maintenance for details on inspection before every use.

Warnings

- Ensure that the device is cleaned and disinfected before first use, between change of infants, and after maintenance.
- Ensure that the sidewalls are always locked. Stop using the device if the locking mechanism of the sidewall is found faulty.

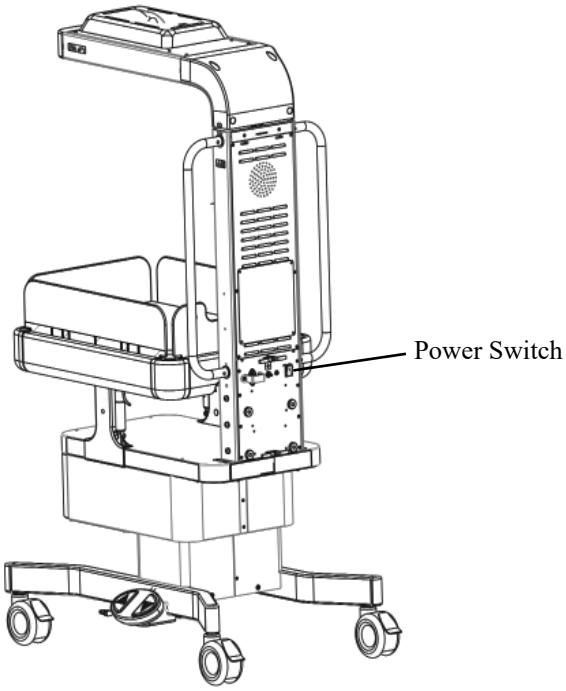
  The infant may fall out and suffer serious injury.

Connecting Power Cord

1. Connect the power cord to the wall outlet.

Note: The power cord may be attached to the device at the time of Installation and cannot be detached without the use of tools.

2. Turn ON the power switch in the rear panel of the device.



Warnings

- Ensure use of a separate power outlet for each device. Also ensure the power outlet is located near the device to prevent accidental tripping over a trailing power cord.
- Ensure that this device is connected only to a supply mains with protective earth. Never operate the device if you have a doubt about its protective earth connection.

  It may cause an electric shock.

Caution

- Ensure that the power cord complies with the country's requirement. If not contact your provider or International Biomedical representative.

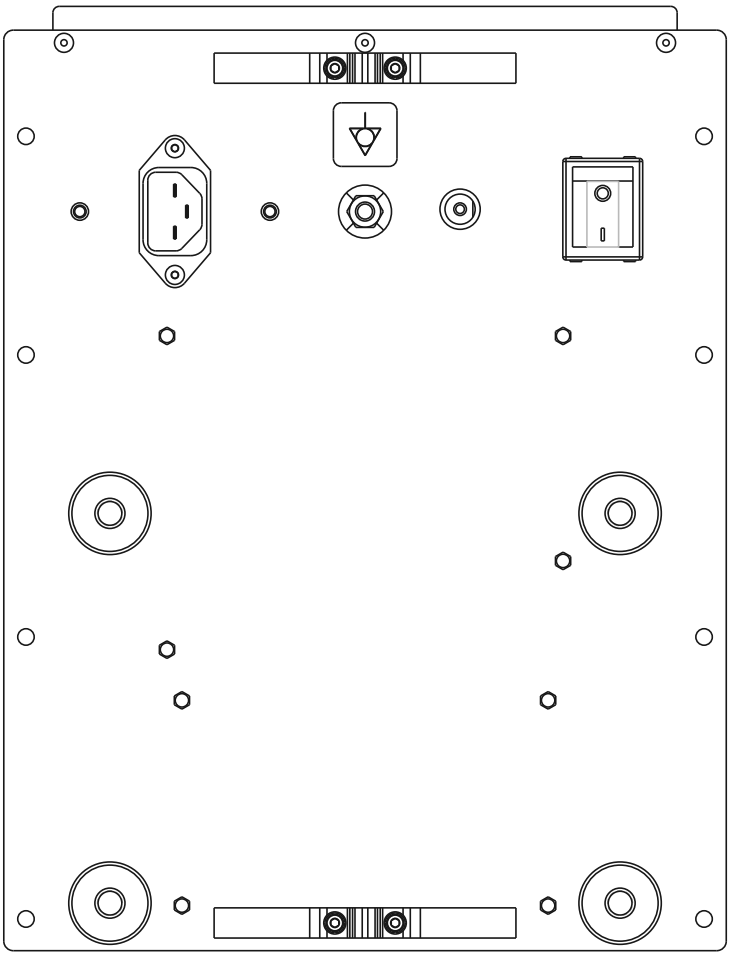
Notes

- Contact qualified personnel to service the device.
- The electrical rating of the device is: AC 230 V (115 V), peak power consumption 750 VA (inclusive of height adjustment operation), frequency 50/60 Hz, and operating voltage range AC 230 V (115 V) ± 10%.

Using Potential Equalization Terminal

1. Locate the potential equalization terminal on the rear panel,
2. Use a conducting wire rated for such use with a clip termination to connect the potential equalization terminal of this device to the hospital infrastructure intended for equalizing potential between medical devices.
3. Secure the potential equalization conductor by clipping onto the terminal.

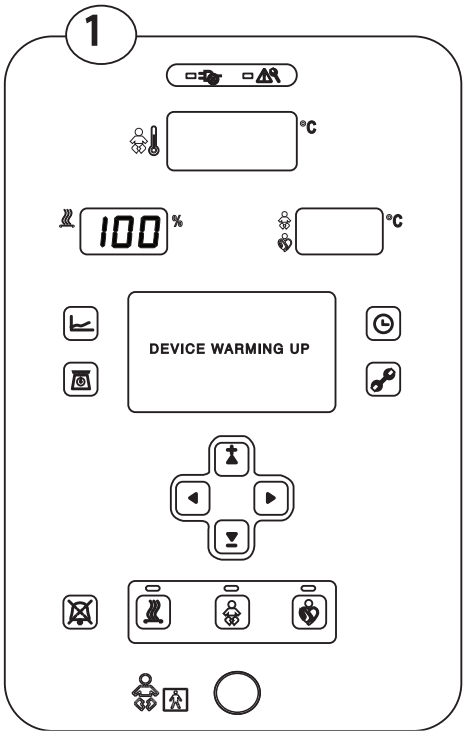
Note: When utilizing other medical equipment in conjunction with this device, it is recommended that both devices have their potential equalization terminals connected to the hospital infrastructure. Contact your International Biomedical provider for clarifications.



1. Potential equalization terminal

Device Warm Up

1. Turn ON the power switch. The following occurs:
   i. All the Indicators (except power failure alarm indicator), Numeric display and Graphic display panel lights up for a few seconds.
   ii. If skin probe is connected measured temperature is displayed.
   iii. The default heater output displays 100% and the Graphic display shows a message 'DEVICE WARMING UP...'. The heater output maintains warming state for 10 minutes.
2. After 10 minutes the heater output will reduce to 50% and remain there in warmup mode until the device is placed into one of the other three modes. Press one of the three mode buttons to interrupt device warming up and enter other modes.



Warnings

- Do not place infant in the bed during warmup.

Cautions

- Always use a sheet or blanket to cover the mattress.

Notes

- APGAR alarm/timer functionality as well as alarm conditions are not available during device warm-up.
- The previous settings are retained in the memory for a duration of 6 hours if the power supply is interrupted. After 6 hours of power down, the default settings are invoked when the device is restarted.
- Ensure that the mattress is not cold when infant is placed on the device for warming therapy.
- Ensure that Manual temperature or Skin mode is engaged when Warming therapy is administered to infants.
- Any adjustments made to the settings in warm-up mode are not saved if power is lost prior to entering normal operation.

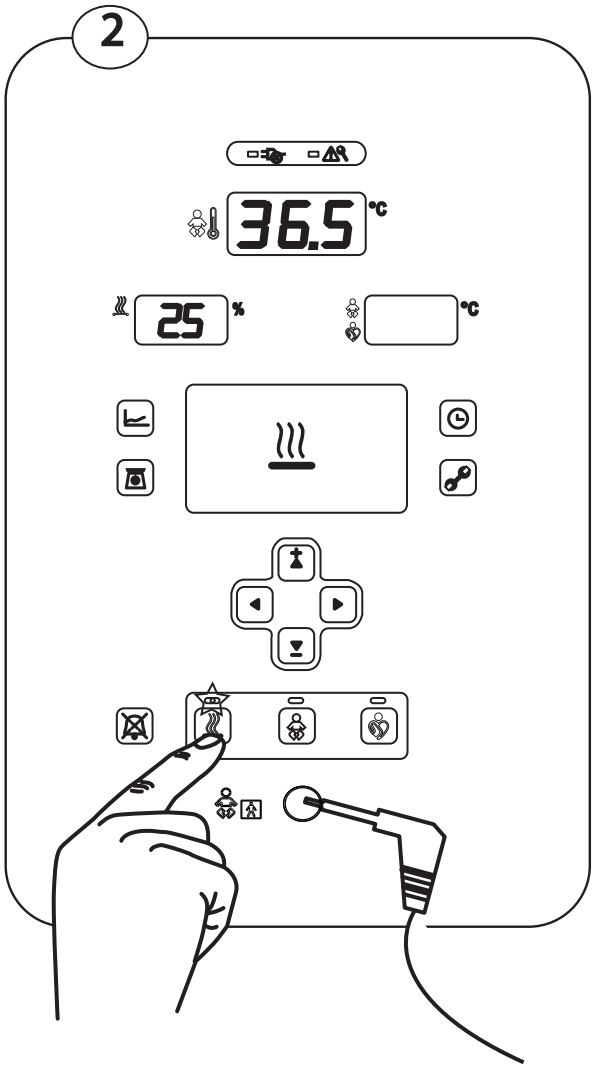
Warming Therapy Modes

Three modes of temperature control available in the device are Manual temperature mode, Skin temperature control mode, and Standby mode.

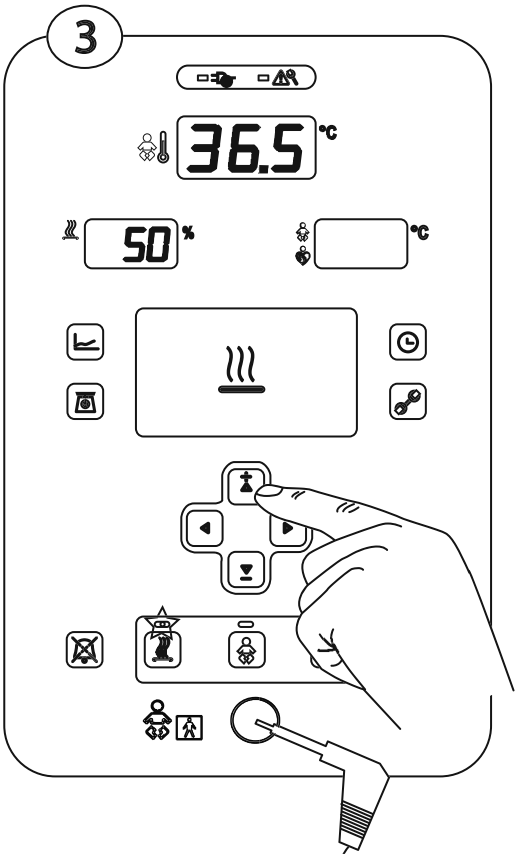
- In Manual temperature mode, you can control the heater power to achieve a selected output power level (%).
- In Skin temperature control mode, a skin temperature probe is attached to the infant and the heater output is controlled by the device. You can set the infant's skin temperature value.
- The Standby mode facilitates supplementary care requirements when the infant is lifted away from the device such as feeding, weighing, kangaroo care. The skin temperature probe is used to monitor the infant's skin temperature. The heater power is maintained at 25%. See Chapter 7: Alarms for details on alarms active in Standby mode and their thresholds.

Warming in Manual Temperature Mode

1. If desired, insert the plug of the skin temperature probe cable into the skin temperature probe connecting port and attach the other end to the infant. (Optional)
2. Press . The following occurs:
   i. The indicator lights up.
   ii. The numeric display for heater output flashes for 5 seconds and displays 25%.



3. Press the ⇧ button to increase the heater output by 5% and press the ⇩ button to decrease the heater output by 5%. The selected value is displayed in the heater output display and the heater functions at the set level.



4. With no interaction for 5 seconds, the new value will be accepted. If any button is pressed other than increase, decrease, forward, and backward button before 5 second of idle time, value will be accepted immediately.

Warnings

- Never leave the infant temperature unmonitored.

  The infant temperature may rise or fall unacceptably.

- Never use a heated gel mattress in the NuBorne 500.

  Use of heated gel mattress in this device can increase the infant's temperature to dangerous levels.

- Never leave the infant unmonitored when using a phototherapy device at the same time.

  The heat addition by the phototherapy device may increase the infant's skin temperature.

- Never leave the infant unmonitored during thermoregulation therapy.

  The infant may experience increased insensible water loss during thermoregulation therapy in the NuBorne 500.

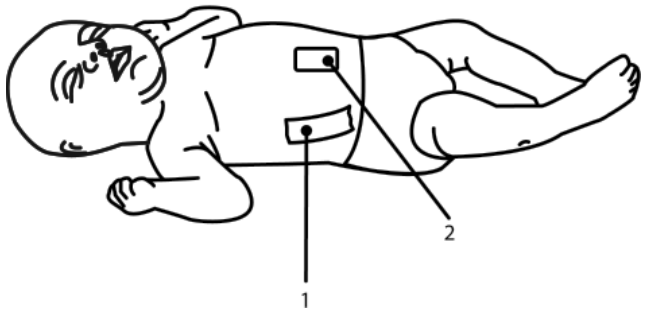
Notes

- If the power setting is greater than 25% after 12 minutes in Manual temperature mode the Check baby alarm is activated. To continue Manual temperature mode operation re-initiate from Step 2 or press or or within 2 minutes from the Check baby alarm initiation to reset alarm and allow manual mode operation for 12 more minutes. If Check baby alarm is not attended to, within 2 minutes, the heater power is cut OFF with continued audible and visual indication of the Check baby alarm. If heater is OFF, re-engage in desired mode.
- If the measured skin temperature exceeds 40°C, Max Skin Temperature Alarm is triggered and heater power is cut-off.

Warming in Skin Temperature Control Mode

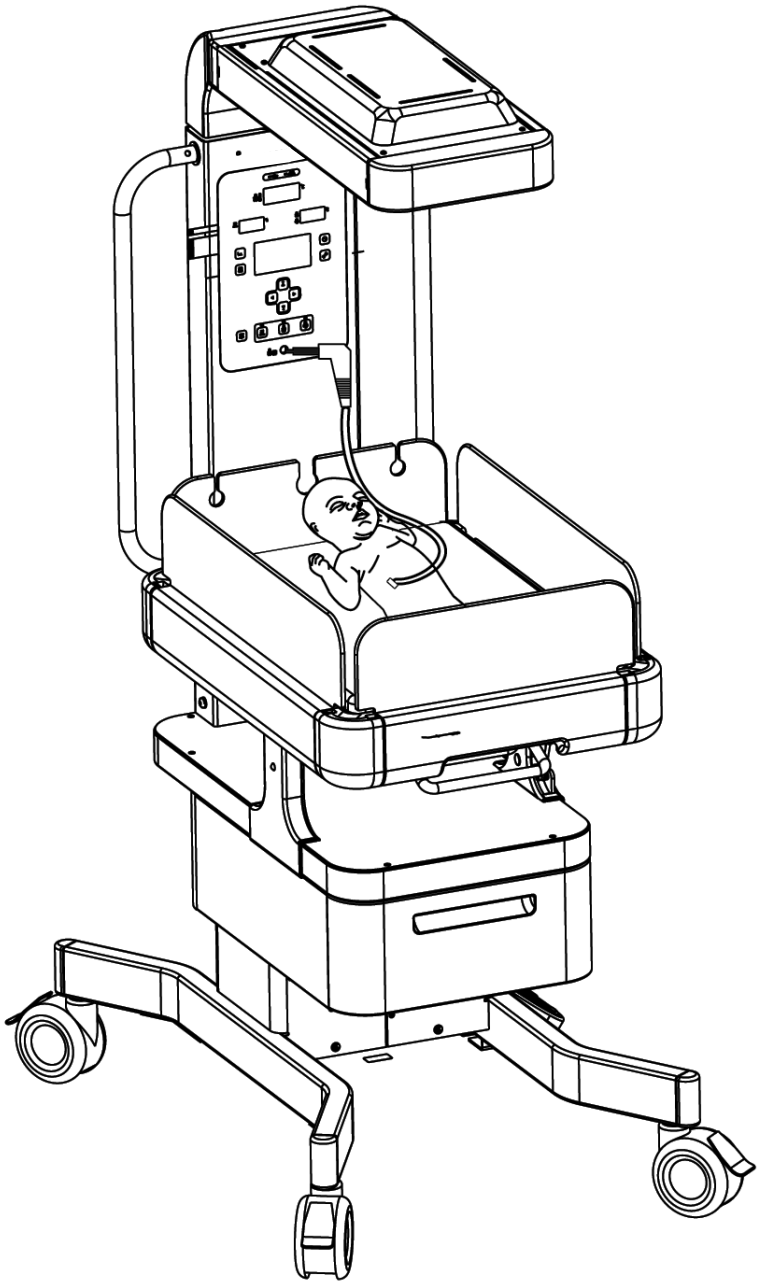
Attaching the Skin Temperature Probe

1. Clean the site of attachment with alcohol or lukewarm water before attaching the skin temperature probe to the infant.
2. Attach the skin temperature probe using a tape on infant's anterior abdominal wall.
3. Affix a piece of tape at a short distance from the tip of the probe and fix the probe to the skin.



1. Tape
2. Skin temperature probe

4. Insert the plug of the skin temperature probe cable into the skin temperature probe connecting port. The temperature detected by the skin temperature probe is displayed on the measured temperature display.



5. Monitor skin temperature for 1 to 2 minutes after connecting the skin temperature probe to allow the temperature reading to stabilize.

Notes

- The measured temperature is displayed in the range of 25.0°C to 40.0°C in 0.1°C increments on the Measured temperature display.
- Temperature Low alarm is displayed if the Measured temperature is below Set temperature by 1°C or less and Temperature High alarm is displayed if Measured temperature is above Set temperature by 1°C or more.
- If the measured skin temperature exceeds 40°C, Max Skin Temperature Alarm is triggered and heater power is cut-off.
- Follow the physician's instructions or hospital protocol as to the site of attachment of the skin temperature probe.

Warnings

- Ensure that you monitor the infant's core temperature separately when using the device.

  You cannot differentiate the condition in which the infant's peripheral skin temperature is low while its core temperature is high (fever) from the condition in which the infant's skin temperature is low as well as core temperature is low (hypothermia).
- Ensure that the skin temperature probe is properly attached to the infant's abdominal wall for accurate skin temperature measurement.
- Ensure that the skin temperature probe is neither warmed by being covered with a blanket, diaper, or the infant's arm, nor is cooled by getting wet with the infant's urine, perspiration, or some medical fluid.
- Use only International Biomedical accessory part #108-4855.
- Never use skin temperature probe to measure infant's rectal temperature.

Setting Skin Temperature

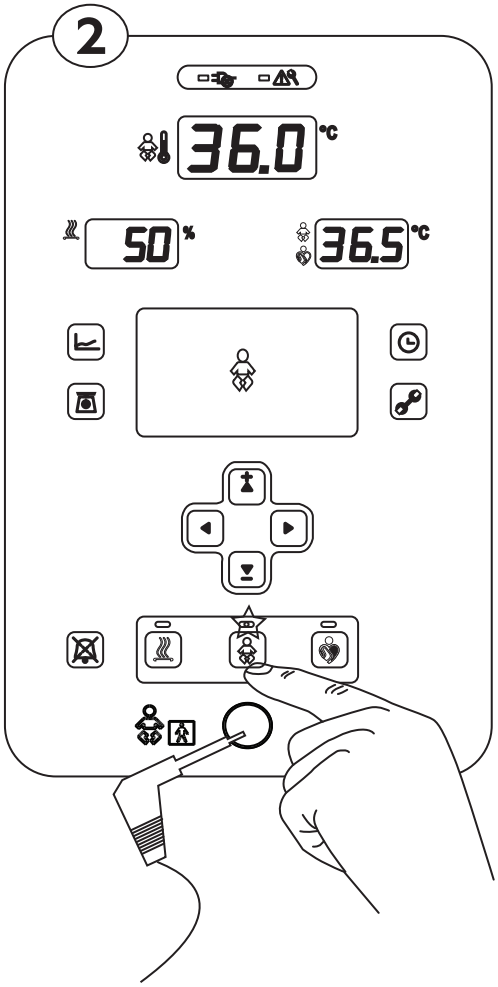
In Skin temperature control mode, the heater output is controlled using measured skin temperature. The infant's skin temperature is detected with a skin temperature probe attached to the infant's skin and the device maintains the optimum thermal environment through feedback control. In skin mode, the heater output is controlled to maintain the infant's skin temperature at a constant level (that is, the set temperature). If the infant's skin temperature is lower than the set temperature, the heater output increases. If the infant's skin temperature is higher than the set temperature, the heater output decreases.

Notes

- Skin temperature control operation is recommended unless Manual temperature mode is needed.
- Check firm attachment of temperature probe to the skin for optimal warming.

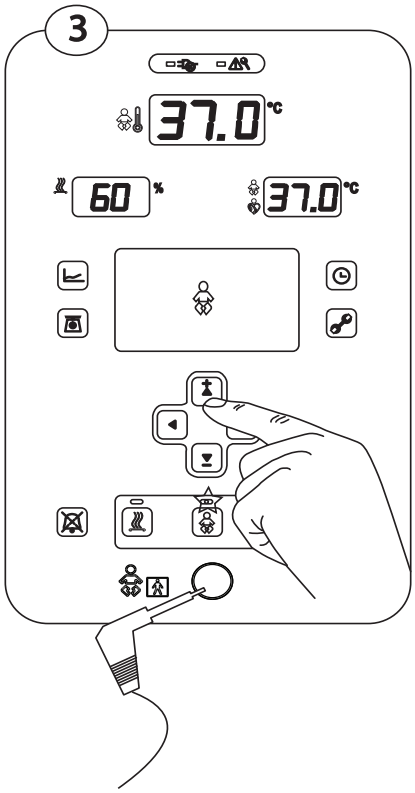
In Skin temperature control mode the heater output is controlled to maintain the infant's skin temperature at a level preselected by the clinician and is corrected for such environmental effects.

1. Insert the plug of the skin temperature probe cable into the skin temperature probe connecting port and attach the other end to the infant.
2. Press . The following occurs:
   i. The indicator lights up.
   ii. The numeric display for set temperature flashes showing '36.5°C'.
   iii. The is displayed on the Graphic display.

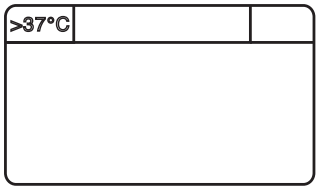


3. Press the ⇧ button or press the ⇩ button to set the skin temperature to a desired level. The skin temperature is set in the range of 33°C to 38°C in 0.1°C increments. The following occurs:

   i. The set skin temperature is set to the displayed level and the heater output is controlled so that the measured skin temperature reaches and maintains the set level.



   ii. The set temperature can be increased up to 38°C. For all set temperatures above 37°C, a >37°C symbol appears on the Graphic display.



4. With no interaction for 5 seconds, the new value will be accepted. If any button is pressed other than increase, decrease, forward, and backward button before 5 second of idle time, value will be accepted immediately.

Warning

- Ensure that you monitor the infant's core temperature separately when using the device.

  You cannot differentiate the condition in which the infant's peripheral skin temperature is low while its core temperature is high (fever) from the condition in which the infant's skin temperature is low as well as core temperature is low (hypothermia).

Transitioning to Standby Mode from Skin Mode

Monitoring Skin Temperature in Standby Mode

In Standby mode, the heater output is maintained at 25% independent of the measured skin temperature. The infant's skin temperature is detected with a skin temperature probe attached to the infant's abdomen. The Standby mode facilitates supplementary care requirements when the infant is lifted away from the device such as feeding, weighing, kangaroo care. The skin temperature probe is used to monitor the infant's skin temperature. See Chapter 7: Alarms for details on alarms active in Standby mode and their thresholds.

1. Insert the plug of the skin temperature probe cable into the skin temperature probe connecting port and attach the other end to the infant.
2. Press the button. The following occurs:
   i. The indicator lights up.
   ii. Provide input reference temperature with respect to which alarm conditions are inferred. By default numeric display for set temperature flashes showing '– – –' for 5 seconds.
   iii. Press or to set the reference temperature as desired.

Notes

- If or is not pressed within 5 seconds, the device reactivates previous mode.
- If or is pressed within 5 seconds set temperature display shows increment or decrement from 36.5°C indicating that Standby mode is activated with the input reference temperature.
- With no interaction for 5 seconds after Setting temperature, the new value will be accepted. If any button is pressed other than increase, decrease, forward, and backward button before 5 second of idle time, value will be accepted immediately.

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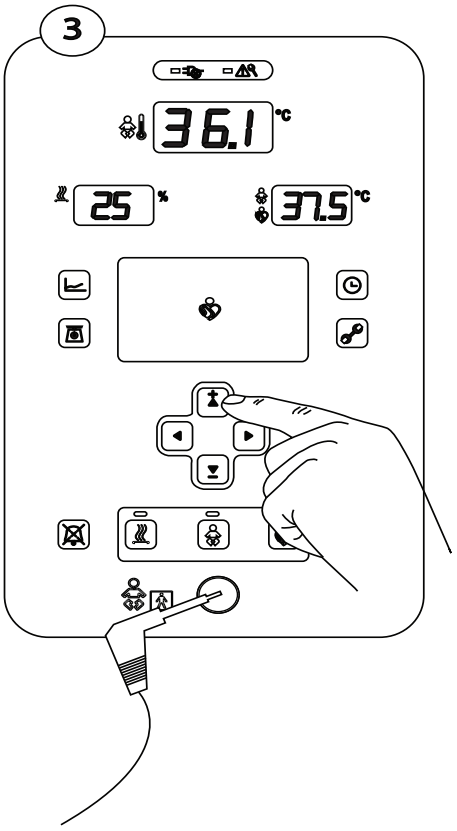
   iv. The Graphic display shows the reference and measured skin temperature, as well as heater power.
   v. Heater output is held constant at 25%.

3. If the infant is returned to the device before the Standby mode expires (60 minutes) ensure that Skin or Manual temperature mode is engaged.



Notes

- The Standby mode times out in 60 minutes and returns to Manual temperature mode with heater output at 25%. Check baby alarm triggers on entering the Manual temperature mode.
- If the Standby mode is to be extended beyond 60 minutes re-engage the Standby mode.
- All alarm conditions are inferred from the reference temperature input when Standby mode is engaged. Temperature Low alarm is displayed if the difference between Measured and Set temperature is below 2.5°C and Temperature High alarm is displayed if the difference between Measured and Set temperature is above 1°C. See Chapter 7: Alarms for more details on alarms.
- If the temperature is above 40°C the heater power is cut OFF.

Warning

- Ensure that the Standby mode is not active when the infant is in the device and that the Standby mode is activated only when intended.

Chapter 5. Operation

This chapter provides instructions on various operating procedures for the NuBorne 500:

- Adjusting the Bed Height
- Tilting the Infant Bed
- Opening and Closing the Sidewalls
- Preparing Device for X-Ray
  - Swivelling the Hood
  - Preparing Device for X-Ray
- Opening and Closing the Storage Drawer
- Assembly of IV Pole
  - Instructions to Assemble IV Pole on Accessory Rail
- Assembly of Monitor Stand
  - Instructions to Assemble Monitor Stand on Accessory Rail
- Assembly of Oxygen Cylinder Holder
  - Instructions to Assemble the Oxygen Cylinder Holder on Device (Rear View)
- Assembly of UPS
  - Instructions to Assemble the uninterruptable power supply
- Additional Operation Procedures
  - Using In-bed Weighing Scale
  - Setting the APGAR Timer
  - Viewing Trend
  - Configuring the Settings
- Turning On/Off the observation light

Adjusting the Bed Height

1. Turn ON the device.
2. Actuate the footswitch using feet.

Cautions

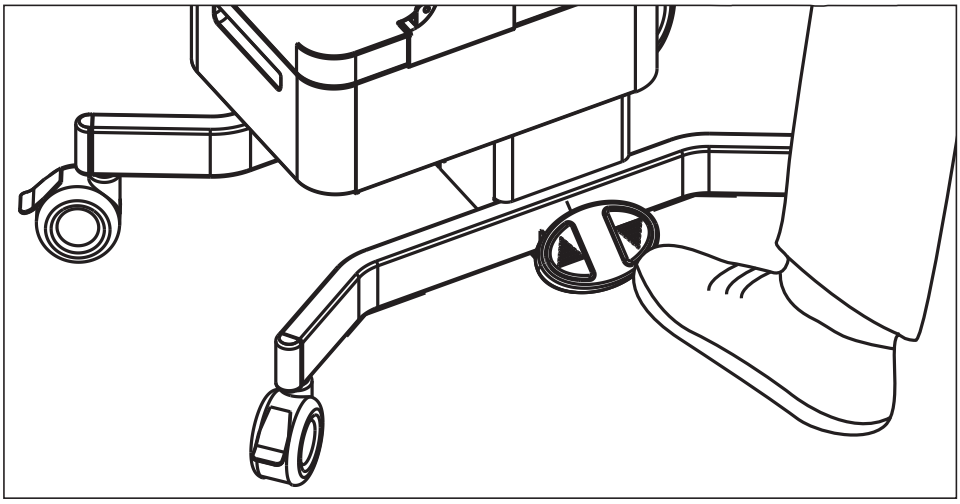
- Ensure that the cords and lines have sufficient slack when the mattress is raised or lowered.
- Never stand, lean, or put full body weight on any part of device including base and footswitch.

  It may cause a structural damage or instability.
- Ensure that the device is brought to its lowest height when moving the device.

1. Continuously press the side of the footswitch marked ▲ to raise the bed mattress until a desired height is achieved. Continuously press the side of the footswitch marked ▼ to lower the bed mattress until a desired height is achieved.

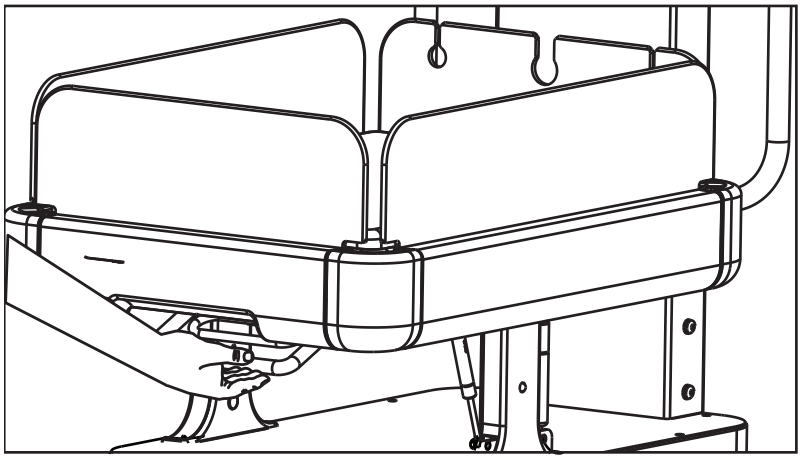
Notes

- Never pulse the footswitch.
- The electrical height adjustment is intended for intermittent operation, but to ensure full life of electrical height adjustment wait at least 20 minutes before re-energizing.
- The lowest position of the mattress is 900 mm above the ground and the highest position of the mattress is 1100 mm from the ground.



Tilting the Infant Bed

1. Grip and compress the double lever to release the tilt lock.
2. Raise the mattress platform up or down to achieve the tilt angle.
3. Release the double lever to lock the mattress in a desired position.
4. Reverse Steps 1 through 3 to return the mattress to its original position.



Warnings

- Ensure to lock the sidewalls when tilting the mattress platform.

  The infant may fall out and suffer serious injury.
- Ensure that the infant's clothing, probe lines, and IV lines are not caught in spaces between corner blocks and sidewalls during open/close operation.

  The infant may fall out and suffer serious injury.
- Never place an infant or an object weighing more than 10 kg on the mattress platform.
- Ensure that the cables attached to the infant are long enough when tilting the mattress platform.

Caution

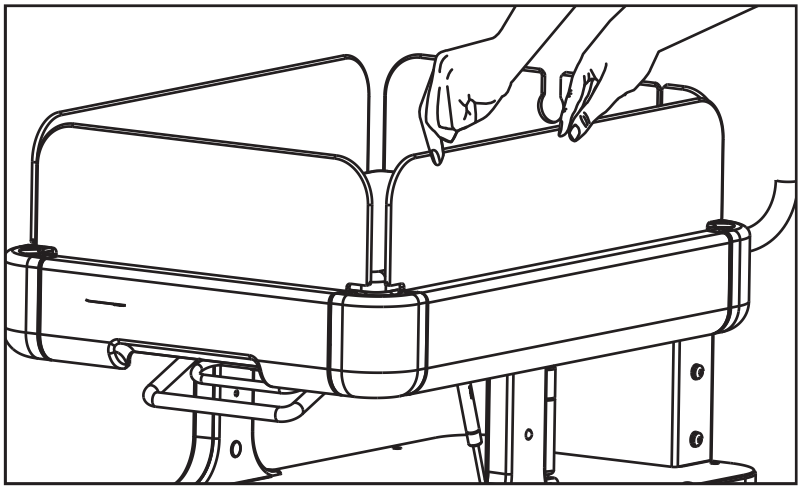
- Avoid excessive force to tilt the infant bed in the event of failure to the tilt actuation. For service contact International Biomedical representative.

Notes

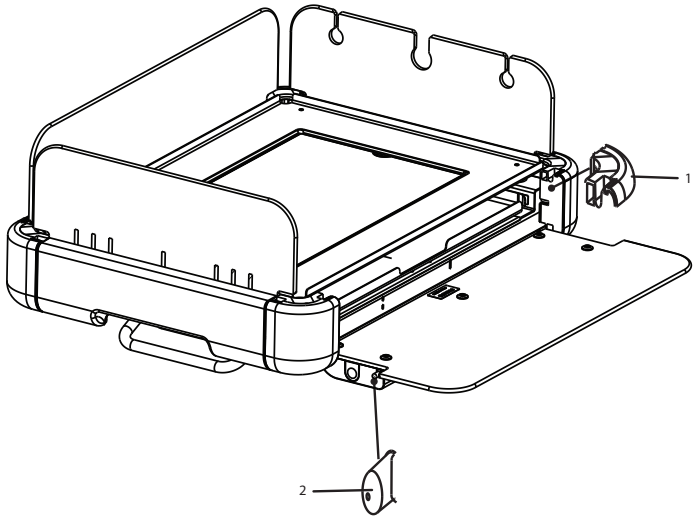
- Uniformity of warming the infant on mattress is dependent on whether the mattress is horizontal or tilted.
- The mattress platform can be tilted up to ±12° in either direction.
- If optional scale is installed, a bubble level indicator is located under the mattress on the base of the bedframe adjacent to the right sidewall when standing at the foot of the bed.

Opening and Closing the Sidewalls

1. Hold the edges of the sidewall and lift the sidewall with both hands so that the sidewall comes out of the hinge sockets on the sides. The sidewall can be lowered and hangs down.



2. To close the sidewall, lift the sidewall with both hands so that the sidewall becomes vertical and the hinge pin drops into the hinge pin slot on the sides.



1. Hinge pin slot 2. Hinge pin

3. Lock the sidewall firmly into the hinge slot on the sides.

Warnings

- Ensure the sidewalls are always locked. Stop using the device if the locking mechanism of the sidewall is found faulty.

  The infant may fall out and suffer serious injury.
- Ensure that the infant's clothing, probe lines, and IV lines are not caught in spaces between corner blocks and sidewalls during open/close operation.

  The infant may fall out and suffer serious injury.
- Ensure that others' fingers are not pinched in the gaps during sidewall open/close operation.

Cautions

- Always lower the sidewall gently to prevent any damage to the sidewall.
- Never lean on the sidewall.

Notes

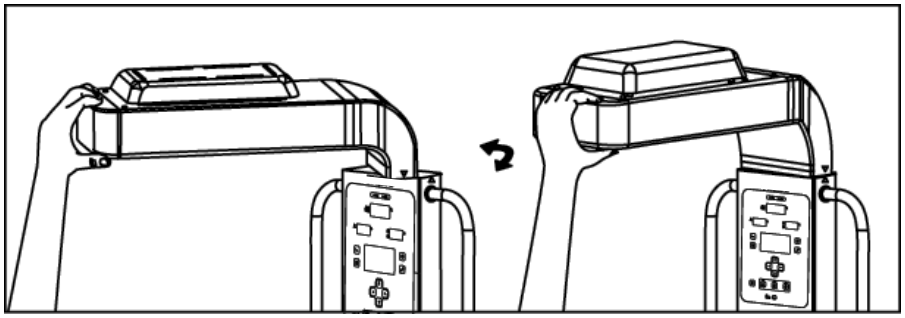
- All the sidewalls except for the short sidewall with tubing slot can be folded down.
- The short sidewall with tubing slot has a central opening for ventilator or CPAP tubings and tubing slots on either side of the central opening.
- The two short sidewalls may be interchanged as needed to facilitate tube management.
- The sidewalls can also be completely removed for cleaning. See Removing the Sidewall section in Chapter 8: Cleaning and Maintenance.

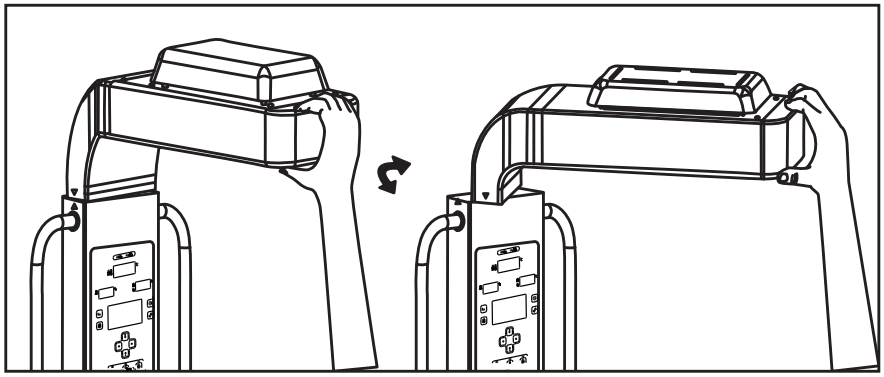
Preparing Device for X-Ray

Swiveling the Hood

Heater hood pivoted at the vertical pillar can be swivelled away. Swivel the hood ±90° so that it does not get in the way of x-ray.

When heater is swivelled to any one side by at least 20° from the center, the heater power is cut-off. Indication of the same is shown in the Graphic display and the heater output numeric display shows a heater power of 0%.





Warnings

- Ensure that the sidewalls are locked when taking x-ray.

  Otherwise, the infant may fall out.
- Ensure that heater hood is realigned to central position to resume thermoregulation therapy. A misaligned position is likely to result in uneven warming of infant bed.
- Ensure that others' fingers are not pinched in the space between heater hood and vertical pillar during hood swivel operation.

Caution

- Never hang anything heavy, place any heavy weight, or lean against the heater hood.

  It may cause a structural damage.
- Never hang a cloth on the heater hood.

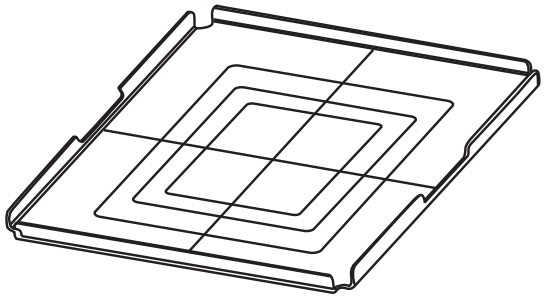
  It may catch a fire if the device is switched ON.

Note: Realignment to the central position is accomplished by aligning the markings ⧗ as shown in the graphics.

Preparing Device for X-Ray

X-Ray Cassette Tray

An optional X-ray cassette tray is available as an accessory. Confirm the part of the infant's body to be radiographed. Use the aligned markings on the X-ray cassette tray and sidewalls to place the cassette directly below the infant to minimize the need to reposition the infant. The marking on the X-ray cassette tray is shown in the following Figure.

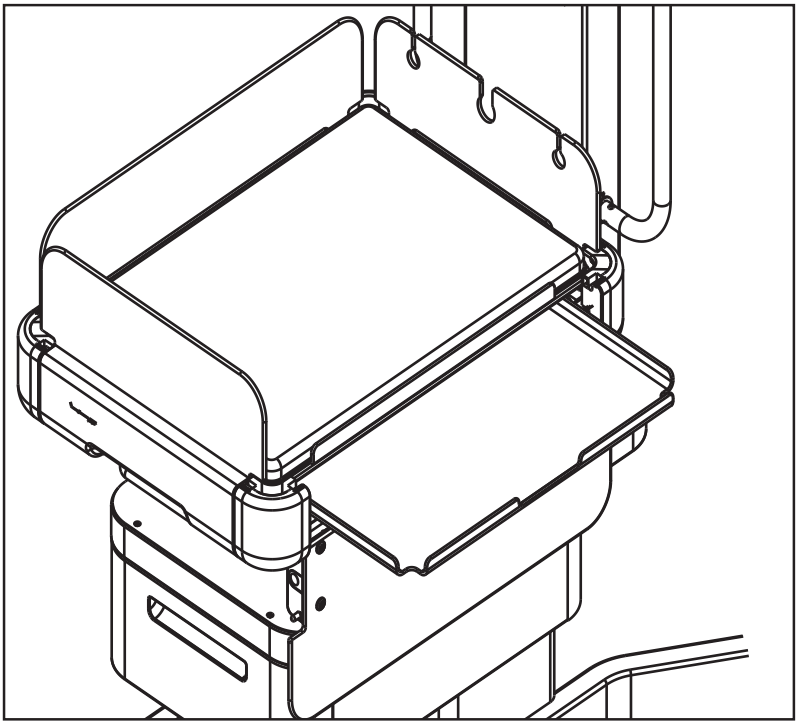


Caution

- Never place an infant or object weighing more than 3 kg on x-ray cassette tray.

1. To take x-ray open the sidewall, draw out the x-ray cassette tray and set an X-ray cassette on it.

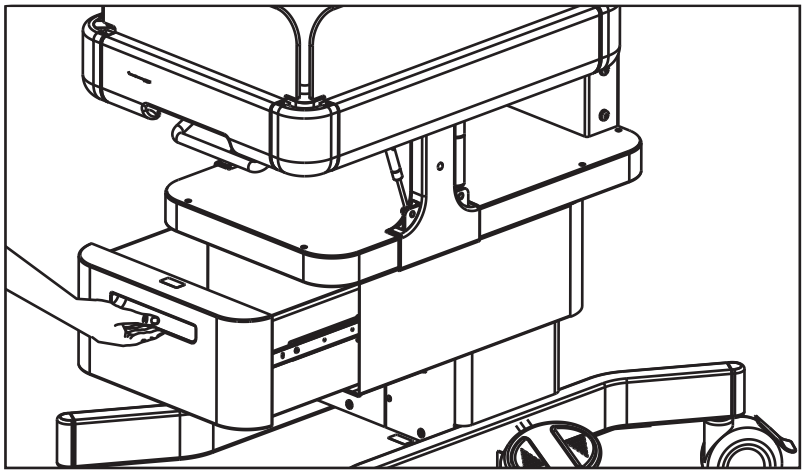
2. Push in the X-ray cassette tray to its fully inserted position and close the sidewall.



Opening and Closing the Storage Drawer

The storage drawer system consists of a slide out storage drawer, which provides convenient and easy storage for items such as sheet, blankets, and diapers.

1. Place your fingers in the shaped slot on the storage drawer and pull to slide it out.



2. Push back the storage drawer to its original position to close it.

Caution

- Never overload the storage drawer beyond 5 kg of contents.

Notes

- Ensure that the storage drawer is pushed enough for the catch to engage and hold the storage drawer closed.
- The storage drawer can also be completely removed for cleaning. See Removing the Storage Drawer section in Chapter 8: Cleaning and Maintenance.

Assembly of IV Pole

Instructions to Assemble IV Pole on Accessory Rail

The procedure for attaching the IV pole assembly on accessory rail is shown in the following figure and is described as follows:

1. Loosen the accessory knob so that the movable mounting block on the IV pole assembly opens.

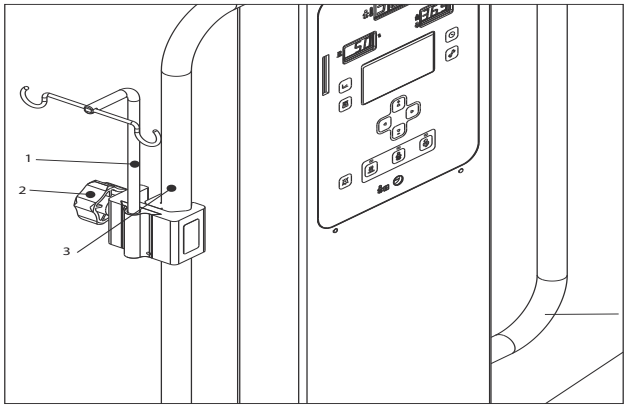
2. Orient and position the IV pole assembly at a desired height on the accessory rail.

3. Rotate the accessory knob in clockwise direction to attach the IV pole assembly to the accessory rail.

4. Tighten the accessory knob fully to ensure movable mounting block does not slide or move on the accessory rail.

Warning

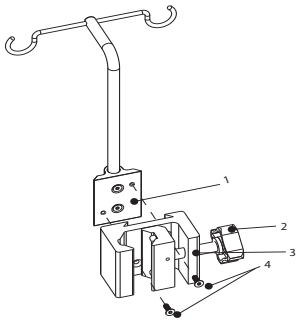
- Ensure to position the accessory knob facing away from the infant for infant's safety.



1. IV pole assembly
2. Movable mounting block
3. Accessory rail

Instructions to Assemble IV Pole on Other Side of Device

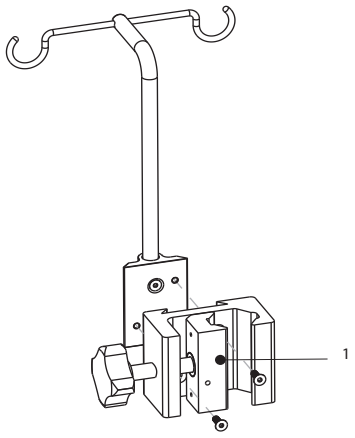
1. Unfasten the fasteners (M4 Hexagon Socket Countersunk Head Screws (x2)) from dovetail part using 2.5 mm Allen Wrench (Hex key) as shown in the following figure



1. Dovetail part
2. Accessory knob
3. Movable mounting block
4. Fasteners

Note: The fasteners are fixed on the dovetail part that remains covered with movable mounting block. Rotate the accessory knob to adjust the position of the movable mounting block for better access of the screws.

2. Reverse the orientation of movable mounting block as shown in the following figure and then reassemble the dovetail part using the same fasteners.



1. Reversed orientation of movable mounting block

Note: Apply one drop of Loctite 242 on screws threading before fastening.

3. Loosen the accessory knob so that the mounting block on the IV pole assembly opens.

4. Orient and position the IV pole assembly at a desired height on the accessory rail.

5. Rotate the accessory knob in clockwise direction to attach the IV pole assembly to the accessory rail.

6. Tighten the accessory knob fully to ensure movable mounting block does not slide or move on the accessory rail.

Note: For repositioning the IV pole, loosen the accessory knob and position at a desired height.

Warning

- Never slide or rotate the movable mounting block for repositioning the IV pole.

  The block may come out and injure the infant.

Assembly of Monitor Stand

Instructions to Assemble Monitor Stand on Accessory Rail

The procedure for attaching the monitor stand assembly on accessory rail is shown in the following figure and is described as follows:

1. Loosen the accessory knob so that the movable mounting block on the monitor stand assembly opens.

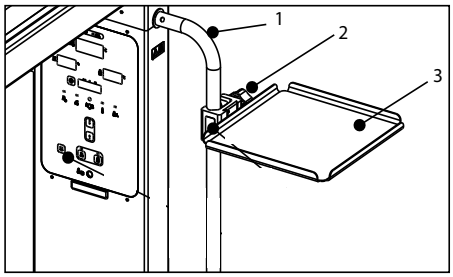
2. Orient and position the monitor stand assembly at a desired height on the accessory rail.

3. Rotate the accessory knob in clockwise direction to attach the monitor stand assembly to the accessory rail.

4. Tighten the accessory knob fully to ensure mounting block does not slide or move on the accessory rail.

Warning

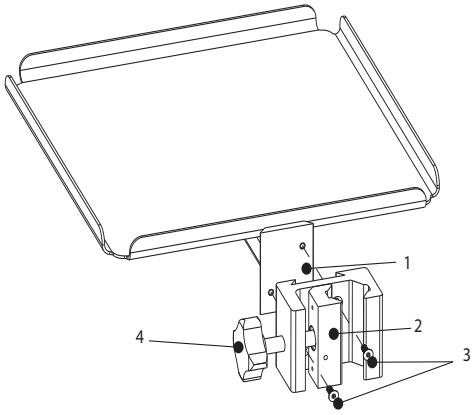
- Ensure to position the accessory knob facing away from the infant for infant's safety.



1. Accessory rail
2. Movable mounting block
3. Monitor stand

Instructions to Assemble Monitor Stand on Other Side of Device

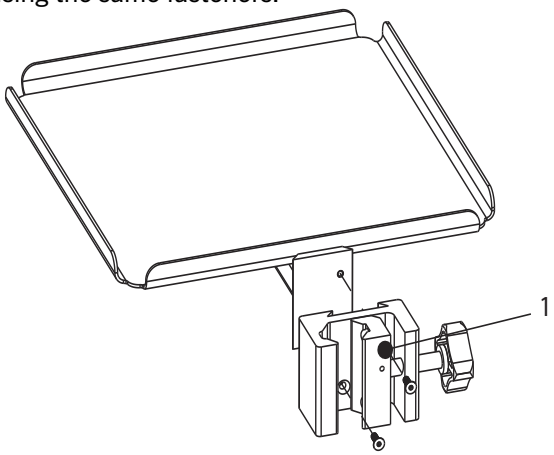
1. Unfasten the fasteners (M4 Hexagon Socket Countersunk Head Screws (x2)) from dovetail part using 2.5 mm Allen Wrench (Hex key) as shown in the following figure.



1. Dovetail part
2. Movable mounting block
3. Fasteners
4. Accessory knob

Note: The fasteners are fixed on the dovetail part that remains covered with movable mounting block. Rotate the accessory knob to adjust the position of the movable mounting block for better access of the screws.

2. Reverse the orientation of movable mounting block as shown in the following figure and then reassemble the dovetail part using the same fasteners.



1. Reversed orientation of mounting block

Note: Apply one drop of Loctite 242 on screws threading before fastening.

3. Loosen the accessory knob so that the movable mounting block on the monitor stand assembly opens.

4. Orient and position the monitor stand assembly at a desired height on the accessory rail.

5. Rotate the accessory knob in clockwise direction to attach the monitor stand assembly to the accessory rail.

6. Tighten the accessory knob fully to ensure movable mounting block does not slide or move on the accessory rail.

Note: For repositioning the monitor stand assembly, loosen the accessory knob and position at a desired height.

Warning

- Never slide or rotate the movable mounting block for repositioning the monitor stand assembly.

  The block may come out and injure the infant.

Assembly of Oxygen Cylinder Holder

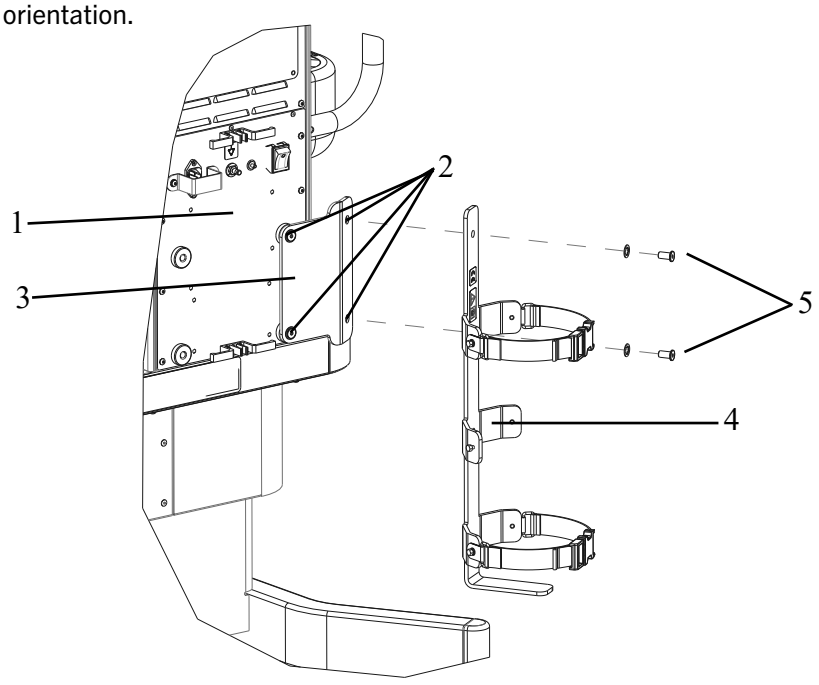
Instructions to Assemble the Oxygen Cylinder Holder on Device (Rear View)

The procedure for fixing the cylinder holders to the rear side of the device is shown in the following figure and is described as follows:

Note: If both cylinder holders are available mount one cylinder holder as described in following procedure and the other cylinder holder as described in Instructions to Assemble Oxygen Cylinder Holder on Other Side of Device (Rear View).

---

1. Align the cylinder holder bracket on the mounting holes provided on the device in correct orientation.



1. Vertical pillar
2. Mounting holes
3. Cylinder holder bracket
4. Cylinder holder
5. Mounting hardware

2. Fix the cylinder holder bracket on the vertical pillar and fasten the fasteners (M8 Hexagon Socket Button Head Cap Screws (x2) using 4 mm Allen Wrench (Hex key)).

3. Fix the cylinder holder to the cylinder holder bracket and fasten the fasteners (M8 Hexagon Socket Button Head Cap Screws (x2) using 4 mm Allen Wrench (Hex key)).

Note: Ensure while tightening the screw, the spring washer is fully compressed.

---

4. Place the cylinder into the cylinder holder from top and fasten it with webbing belt.

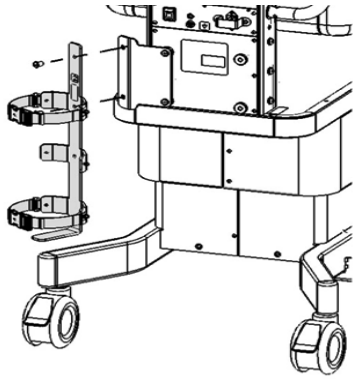
5. Use strap buckles (x2) to secure cylinders (straps can be moved to alternate locations to accommodate cylinder size).

Instructions to Assemble Oxygen Cylinder Holder on Other Side of Device (Rear View)

1. Reverse the orientation of cylinder holder bracket as shown in the following figure.

2. Fix the cylinder holder bracket on the vertical pillar and fasten the fasteners (M8 Hexagon Socket Button Head Cap Screws (x2) using 4 mm Allen Wrench (Hex key)).

Note: Ensure while tightening the screw, the spring washer is fully compressed.



1. Reversed orientation of cylinder holder bracket

3. Fix the cylinder holder to the cylinder holder bracket and fasten the fasteners (M8 Hexagon Socket Button Head Cap Screws (x2) using 4 mm Allen Wrench (Hex key)).

4. Place the cylinder into the cylinder holder from top and fasten it with webbing belt.

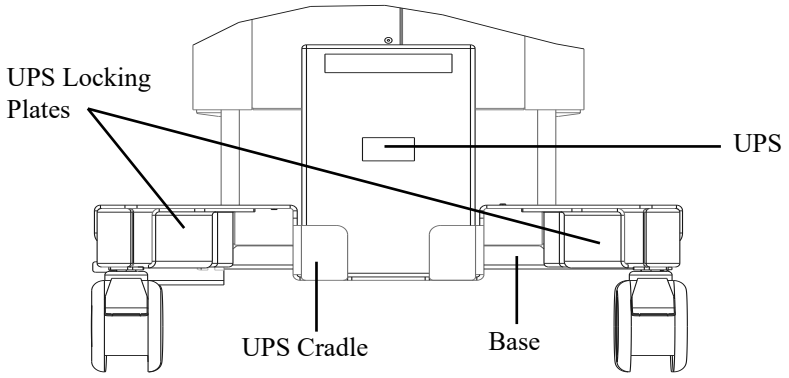
5. Use strap buckles (x2) to secure cylinders (straps can be moved to alternate locations to accommodate cylinder size).

Assembly of the UPS

Instructions to Secure the UPS to the NuBorne 500 Infant Warmer

The procedure for securing the UPS assembly on the NuBorne 500 Infant Warmer is shown in the following figures and is described as follows:

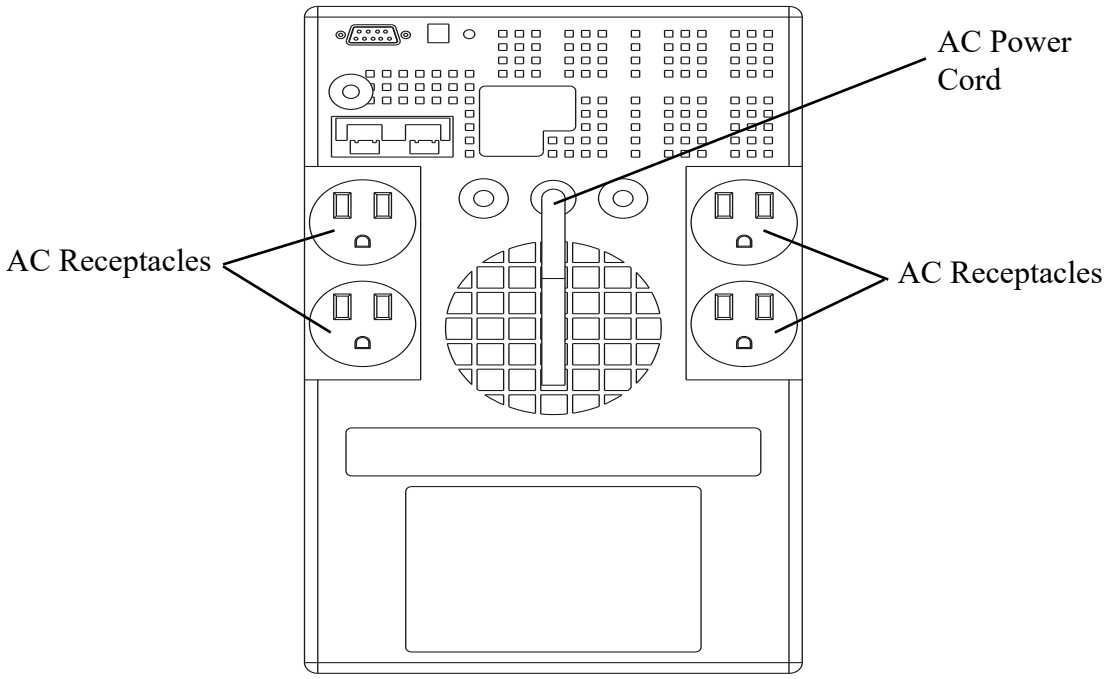
1. Place the UPS cradle bracket across the rear portion of the base assembly.



2. Carefully place the UPS in the cradle of the UPS support bracket with the power receptacles oriented towards the warmer.

For 115 VAC UPS Option:

1. Remove and save the power inlet bracket and hardware which secures the AC power cord to the warmer. Remove and discard the AC power cord provided with the warmer.



2. Replace the power inlet bracket by only fastening 1X of the M3x8 screws. Position the inlet bracket 90^0 to the “unlocked” position to provide access to the AC input receptacle and tighten the hardware. Fasten the remaining M3x8 screw back in its original location for later use.

3. Connect the expandable AC power cord (supplied with the UPS option) from the warmer to one of the AC receptacles on the rear of the UPS. The expandable AC power cord has an integrated strain relief within the connector to the warmer.

4. Slide the two UPS locking plates outwards towards the base into the locked position. Tighten the four M5 lock nuts to secure the UPS cradle bracket.

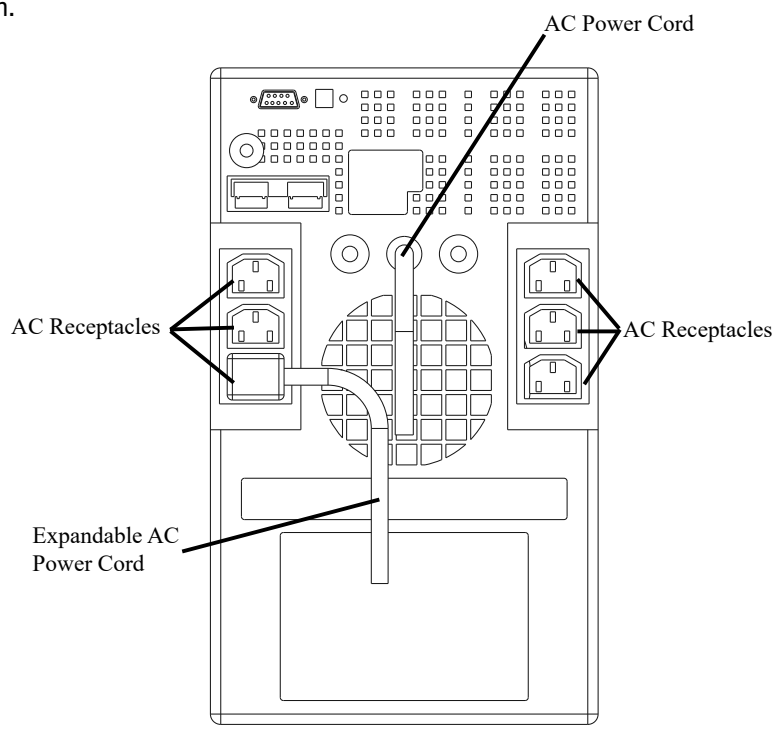
5. Connect the power cord from the UPS to the wall outlet.

6. Power on the UPS and wait 10 seconds to initialize the UPS. Power on the warmer and confirm normal operation. The power switch is located on the front of the UPS.

For 230 VAC UPS Option:

1. Remove and save the power inlet bracket and hardware which secures the AC power cord to the warmer. Remove and save the AC power cord provided with the warmer.

2. Replace the power inlet bracket by only fastening 1X of the M3x8 screws. Position the inlet bracket 90^0 to the unlocked position to provide access to the AC input receptacle. Fasten the remaining M3x8 screw back in its original location.



3. Connect the expandable AC power cord (supplied with the UPS option) from the warmer to one of the AC receptacles on the rear of the UPS. The expandable AC power cord has an integrated strain relief within the connector.

4. Slide the two UPS locking plates outwards towards the base into the locked position. Tighten the four M5 lock nuts to secure the UPS cradle bracket.

5. Connect the original power cord provided with the warmer to the short AC inlet jumper located on the rear of the UPS. Connect the remaining end to the AC wall outlet.

6. Power on the UPS and wait 10 seconds to initialize the UPS. Power on the warmer and confirm normal operation. The power switch is located on the front of the UPS.

Additional Operation Procedures

Using Optional In-bed Weighing Scale

1. Level the bed
2. Press the button

Notes

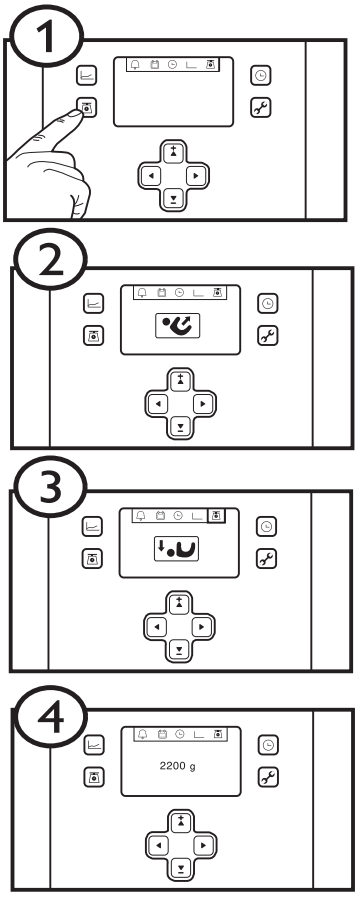
- The in-bed weighing scale is an option for the NuBorne warmer. Pressing on NuBorne 500 without the optional scale or during pre-warm results in a message, 'Weighing not available.'
- If there is an alarm condition during weighing, an alarm symbol appears on the top right corner of graphic display. As weight measurement screen is time bound, after the measurement is done the alarm is displayed in the graphic display.

3. Lift the infant when the main display shows lift infant symbol and weighing tones sound.

Note: Progress of execution is shown through gradual filling of lift baby symbol.

The device now measures the offset weight value during 10 sec period.

4. Place the infant when the place infant symbol is displayed and weighing tones sound. The device now measures the weight of the infant.
5. The measured weight of the infant is displayed on the screen.
6. The screen of weight measurement exits to main screen within 25 seconds of confirmation of measured weight or any error.



Notes

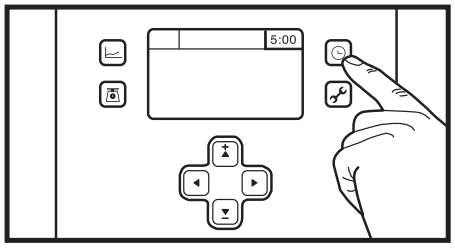
- Ensure the bed is in a horizontal position by using the bed bubble level when using the weighing function.
- When standing at the foot of the bed, the bubble level indicator is located under the mattress along the right hand sidewall adjacent to the ▲■■■▲ label.
- Every successful weight measurement is stored with date and time in the device memory. The stored data is viewed using the View trend button.
- If the total weight on the bed is less than 250 grams or more than 24 kg an error message is displayed ⚠ or ⚠ .
  < >

Scale Alerts	
	Scale Gravity Error
	Scale Communication Error
	Scale Zeroing Error
	Scale Motion
	Scale Warm Up
	Scale Not Available
	Min Weight Not Achieved
	Max Weight Not Achieved

Setting the APGAR Timer

APGAR Timer is a user-initiated, count-up timer displayed on the graphic display with an audio alert.

1. Press the button to start the count-up timer. The graphic display shows the timer. An audible alert sounds at the completion of 1st, 5th, 10th, and 20th minute sound for a duration of 10 seconds.



2. Record required vital signs when audible alert sounds.
3. Pressing the button, when the APGAR timer is ON, interrupts and deactivates the timer.

Notes

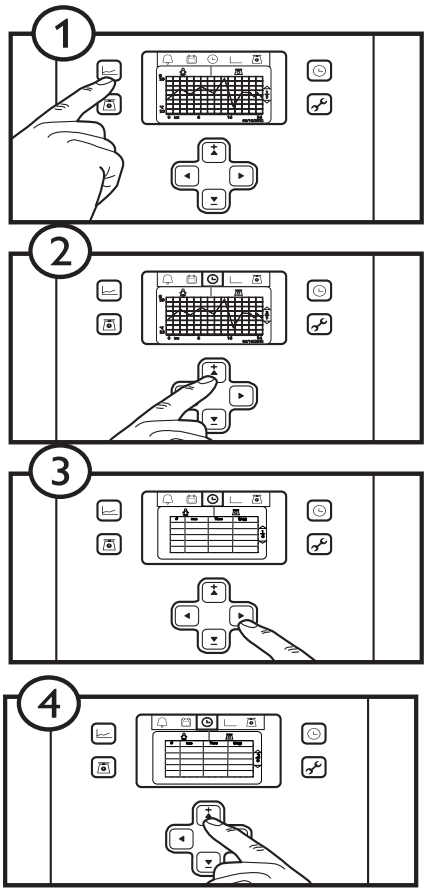
- APGAR times is unavailable during device warm up.
- Upon completion of the 20th minute, no further audible alerts are triggered. The timer counts up until the 60th minute and then deactivates automatically.
- If an alarm condition coincides with an APGAR audio alert, the alarm audio signature takes priority over the APGAR audio signature.

Audio Signature

Note: Each pulse represents a beep and each gap between the pulse represents silence duration.

Viewing Trend

1. Press the button to view the skin temperature trend graph or weight trend table.
2. Press the button or press the button to change the pages to view temperature trend prior to most recent 24 hours.
3. Press the ▷ button to select the weight trends.
4. Press the button or press the button to change the pages to view entries prior to most recent five entries.



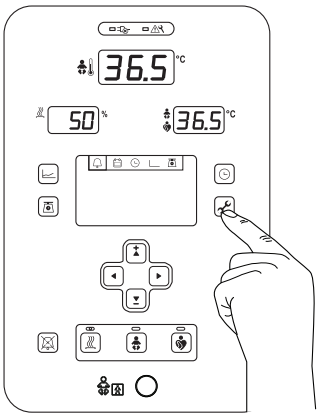
5. From temperature trend graph, if forward button is pressed twice, the screen comes out of the trend screen to previous screen. From weight trend graph, if forward button is pressed once, the screen comes out of the trend screen to previous screen. If the keypad is inactive for 15 seconds, then the screen exits to main screen.

Notes

- Trend data is erased if the device is in power OFF condition for more than 6 hours.
- Set temperature trend data is shown in green color and measured temperature trend data is shown in red color.
- Temperature trend data is stored for a maximum of 96 hours with each screen showing 24 hours of a day.
- Weight trend data is stored for last 30 successful weight measurements.
- If there is an alarm condition while the viewing trend screen is ON, an alarm symbol appears in the top right corner.

Configuring the Settings

1. Press the button to enter the Settings tab in the following order:
   - Alarm volume
   - Date
   - Time
   - Erase data trends



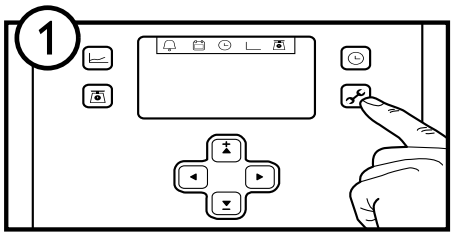
2. Press the ▷ or ◁ button to navigate the Settings tab (alarm volume, date, time, erase data trends).
3. Press the button to increase or press the button to decrease a value within a selection.
4. If the keypad is inactive for 15 seconds, then the screen exits to main screen within next 10 seconds. Maximum timeout for screen in idle condition is 25 seconds.
5. Re-initiate the settings change by restarting from Step 1 if the graphic display returns to displaying active mode.

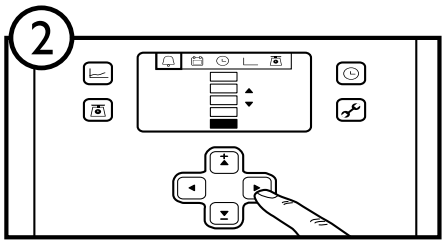
Note: If there is an alarm condition while changing settings an alarm symbol appears on the top right corner of graphic display below the Settings tab. On exiting the settings screen, the alarm screen is displayed in the graphic display.

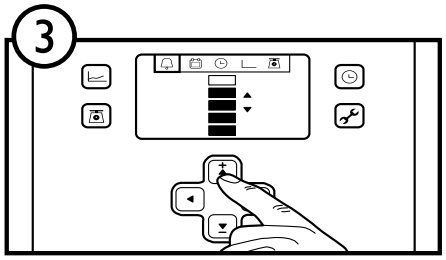
Setting Alarm Volume

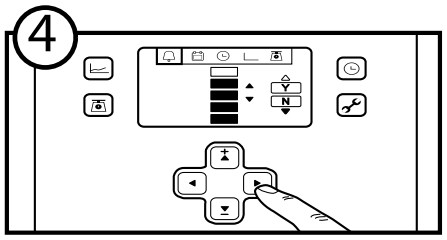
i. Press the button to enter the Settings tab to enter the alarm volume settings.
ii. Press the button to increase or press the button to decrease the alarm volume as required. A beep sounds at the corresponding volume level as volume is adjusted.
iii. Press the ▷ button to move to 'Y/N' screen to confirm setting.
iv. Press the button so that 'N' (default setting) changes to 'Y'.
v. The graphic display shows the confirmation screen upon successful completion of input.
vi. If the keypad is inactive for 15 seconds, then the screen exits to main screen within next 10 seconds. Maximum timeout for screen in idle condition is 25 seconds.

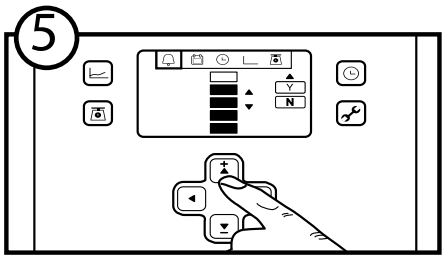
Note: Alarm volume cannot be adjusted if any audible alarm is active or silenced.

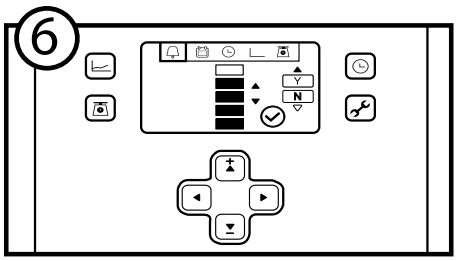

1


2


3


4
Y
N


5
Y
N


6
Y
N

Setting Date

i. Press the button to enter the Settings tab.

ii. Press the ▷ button to navigate the Settings tab to enter the date settings.

iii. Press the button to increase or press the button to decrease a value within a selection.

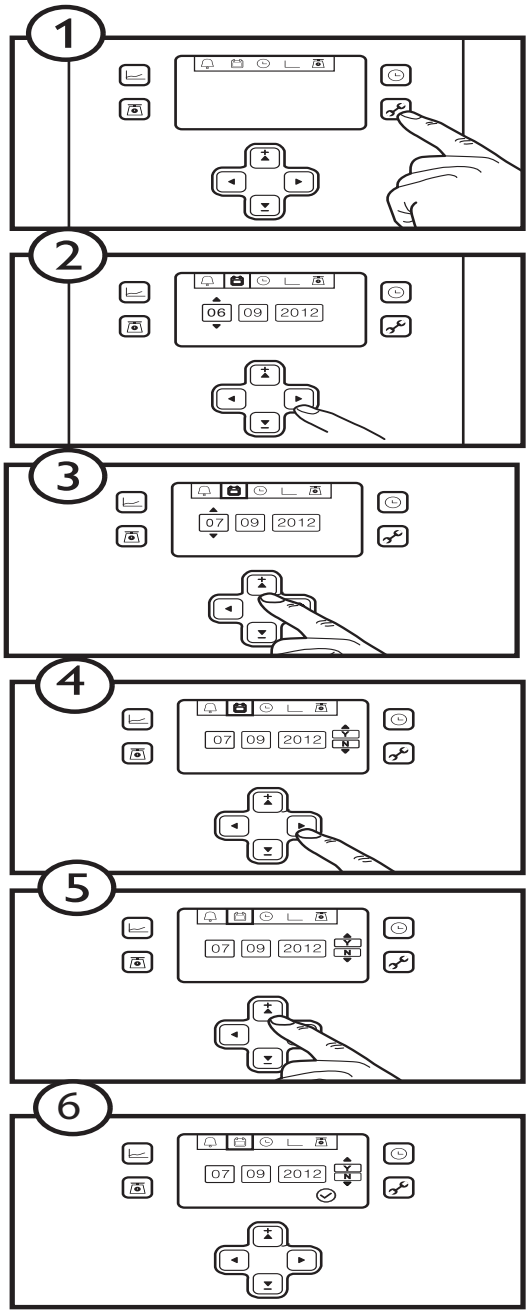
iv. Press the ▷ or ◁ button to toggle between the selection of date, month, year, or 'Y/N' screen. The selected value is displayed on the main display with the top and bottom arrow buttons .

v. Press the button so that 'N' changes to 'Y'.

vi. The graphic display shows the confirmation screen upon successful completion of input.

vii. If the keypad is inactive for 15 seconds, then the screen exits to main screen within next 10 seconds. Maximum timeout for screen in idle condition is 25 seconds.

Note: Stored trend data is erased if date settings are altered.



Setting Time

i. Press the button to enter the Settings tab.

ii. Press the ▷ button to navigate the Settings tab to enter the time settings.

iii. Press the button to increase or press the button to decrease a value within a selection

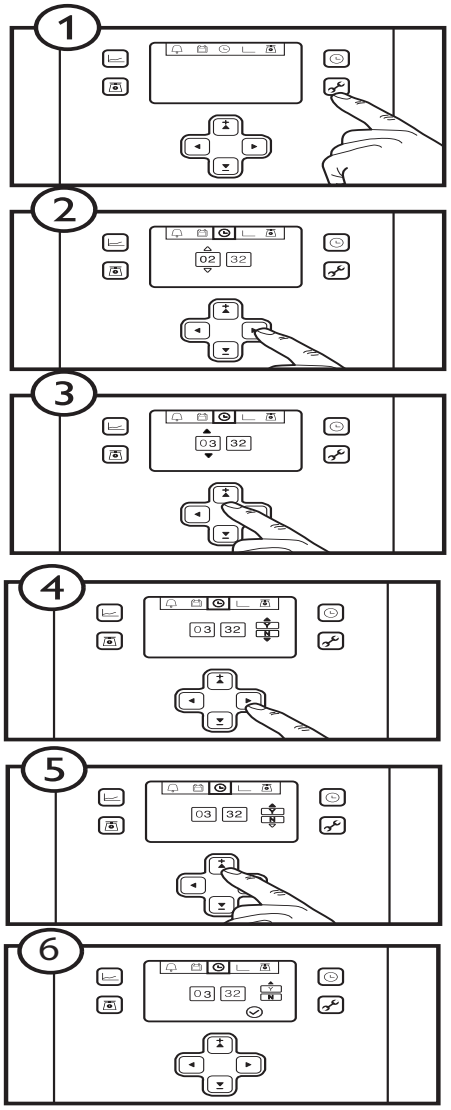
iv. Press the ▷ or ◁ button to toggle between the selection of minutes, seconds, or 'Y/N' screen. The selected value is displayed on the main display with top and bottom buttons

v. Press the button so that 'N' changes to 'Y'.

vi. The graphic display shows the confirmation screen upon successful completion of input.

vii. If the keypad is inactive for 15 seconds, then the screen exits to main screen within next 10 seconds. Maximum timeout for screen in idle condition is 25 seconds.

Note: Stored trend data is erased if time settings are altered.



Erasing Data

i. Press the button to enter the Settings tab.

ii. Press the ▷ button to move to 'Y/N' screen to confirm setting.

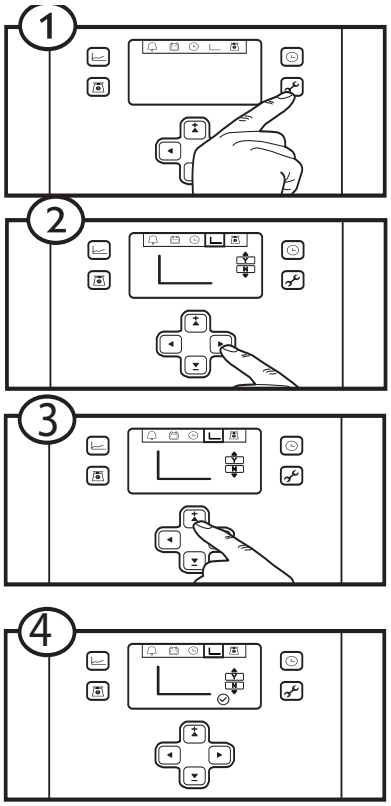
iii. Press the button so that 'N' changes to 'Y'.

iv. The graphic display shows the confirmation screen upon successful completion of input.

v. If the keypad is inactive for 15 seconds, then the screen exits to main screen within next 10 seconds. Maximum timeout for screen in idle condition is 25 seconds.

Notes

- Stored trend data is erased if date or time settings are altered.
- Trend data is erased if the device is in power OFF condition for more than 6 hours.
- Ensure that trend data is erased between change of infants.



Turning On/Off the Observation Light

1. Locate the on/off knob for the observation light on the underside of the heater head near the vertical pillar.
2. Rotate the knob counterclockwise to turn the observation light on and increase intensity.
3. Rotate the knob clockwise to decrease the intensity and turn the observation light off.

Cautions

- Infants should wear protective eyewear when observation light is being used.

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Chapter 6. Shut Down and Transport

The Shut down and transport chapter provides instructions to safely shut down and to safely transport the NuBorne 500.

Shutting Down the Device

Follow the physician's recommendations if the infant needs to be transferred to another device for continued thermoregulation therapy. Note any required information from temperature and weight trend data if the device is to be shut down for more than 6 hours.

Note: Temperature trend data are automatically erased if the device is shut down for more than 6 hours.

1. Ensure that the device is brought to its lowest height by using footswitch.
2. Turn OFF device main power switch.
3. Disconnect the power cord from the wall outlet.

Preparing Device for Transport

The following steps are recommended to transport the device within the hospital.

1. Ensure that the storage drawer is emptied of its contents.
2. Ensure that sidewalls are securely locked.
3. Ensure the heater hood is in central position.
4. Disconnect any connection to the potential equalization terminal.
5. Remove any accessories mounted to the device.
6. Unlock all caster wheels.
7. Push the device using accessory rail.

Note: Ensure that your vision of the path for transporting the device is not blocked when pushing the device.

Warning

- Ensure that the device is not brought to a sudden stop from movement at speeds above 0.5 km/hr.

  You may injure your leg if the storage drawer slides open.

Caution

- Ensure that the heater hood is adequately secured in the central position if the device requires to be transported in a road vehicle.

  It may cause unintended swivel of heater hood during transport.

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Chapter 7. Alarms

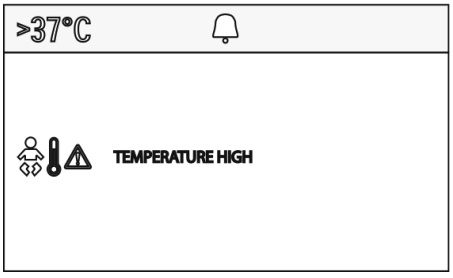
In the NuBorne 500 if any of the following alarm condition occurs, check for a possible cause of the alarm. Take appropriate measures to remove possible causes for the alarm condition.

Warning

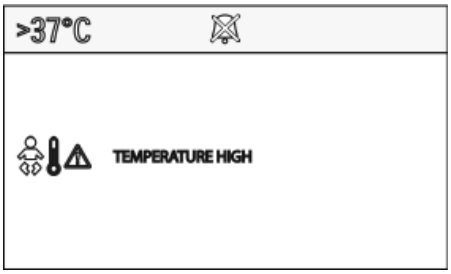
- Discontinue use of the device if the Graphic display or indicator fails.

Alarm Indication

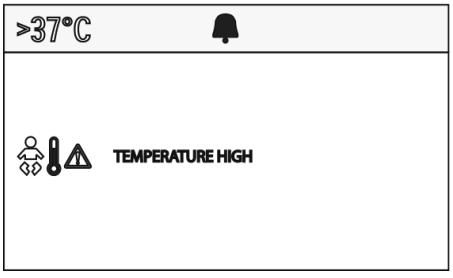
In case of any alarm condition, the alarm symbol is displayed in the top bar of the Alarm Screen as shown in the following figure, and the bar is shown in red color to indicate the urgency to attend on priority.



In the case where an alarm is active, but silenced the bell icon will appear with an X.



In the case where an alarm is active, but the volume is reduced from the factory set point, the bell will be colored blue.



The audible alarm will sound between 54dB and 69dB

Alerts

Alerts	Visual Indication	Condition	Response	Mode
Measurement Error - Low		Occurs if the total weight is less than 250 grams.	Repreat weighing. Ensure weight is in the specified range.	All
Measurement Error - High		Occurs if the total weight is greater than 24 kg.	Repreat weighing. Ensure weight is in the specified range.	All
Weighing not Available		Occurs if in-bed weighing scale button is pressed on a device without the scale option installed.	No response required as weighing functions is an option.	All
Heater cut-off	 HEATER OFF	Occurs if the heater is swiveled to at least 20° from the central position.	Realign the swivled heater to the central position.	All
Scale Gravity Error		Gravity compensation not enabled.	Recalibrate scale.	All
Scale Communication Error		Communication with scale failed.	Weigh again. If problem persists, inspect cabling and connectors.	All
Scale Zeroing Error		Issue zeroing scale.	Recalibrate scale.	All
Scale Motion		Occurs if excessive motion is detected during the weighing process.	Repeat weighing. Ensure motion on the bed is stable.	All.
Scale Warm Up		Occurs if the scale was not given enough time to warm-up.	Wait 1 minute. Repeat weighing process.	All

Patient Alarms

Alarm	Visual Indication		Condition	Response	Alarm silence time	Heater status	Priority*	Mode
	Graphic Display	Indicator						
Check Baby Alarm		No change	• Occurs when device is in manual temperature mode after 12 minutes and power is greater than 25%. • Occurs when the device transitions into manual temperature mode after 60 minutes in Standby mode.	• The alarm is reset when you press alarm silence button within 2 minutes. • If heater is OFF, re-engage in desired mode.	• 12 minutes if reset within 2 minutes. • Not mutable if heater is OFF.	Heater OFF if mode is not reset within 2 minutes of activation of alarm.	High	Manual
High Skin Temperature Alarm		The measured skin temperature indicator blinks	Occurs if the measured temperature is above set temperature by 1°C or more.	The alarm is reset automatically when the measured temperature is within 1°C of the set temperature.	12 minutes	Heater OFF	High	Skin/ Standby
Max Skin Temperature Alarm	  HEATER OFF	Heater output indicator blinks	Occurs if the measured temperature is above 40°C.	The alarm will be reset when the skin temperature falls to 40°C or lower.	3 minutes	Heater OFF	High	All
Skin Temperature Probe Disconnected		The measured temperature displays (---)	Occurs if the skin temperature probe is unplugged.	The alarm is reset when the skin temperature probe is plugged in.	3 minutes	Heater OFF	High	Skin/ Standby

Patient Alarms

Alarm	Visual Indication		Condition	Response	Alarm silence time	Heater status	Priority*	Mode
	Graphic Display	Indicator						
Skin Temperature Probe Failure		The measured temperature displays (---)	Occurs if the skin temperature probe is not functional.	The alarm is reset when the defective probe is replaced with a functional probe.	3 minutes	Heater OFF	High	All
Low Skin Temperature Alarm		The measured skin temperature indicator blinks	Occurs if the measured temperature is below set temperature by 1°C or more.	The alarm will be reset automatically when the measured temperature is within 1°C of the set temperature.	12 minutes	Heater ON	High	Skin
Low Skin Temperature Alarm		The measured skin temperature indicator blinks	Occurs if the measured temperature is below set temperature by at least 2.5°C.	The alarm will be reset automatically when the measured temperature is within 2.5°C of the set temperature.	12 minutes	Heater ON	High	Standby
Note: * High alarm priority indicates audio signature ,  where each pulse represents a beep and each gap between pulses represents silence duration.								

System Alarms

- The indicator is ON to indicate the alarm condition.
- There is no message displayed on the Graphic display screen.

Alarm	Visual Indication		Condition	Response	Alarm silence time	Heater status	Mode
	Graphic Display	Indicator					
System Failure Alarm*	⚠ ERROR CODE XX	In case of system failure, the system failure indicator glows red. Additionally, the error code is shown in the heater output numeric display indicator.	Failure of any system component required for thermoregulation therapy.	If the alarm persists when the power is turned ON, the device is considered to be defective and cannot be used.	Not mutable and continuous sound	Heater OFF	All
Power Failure Alarm		In case of power failure, the power failure indicator glows red.	Power Switch is ON but no Mains power.	Automatically resets when mains power is restored. If alarm is not reset even upon restoration, switch OFF main power, the device is defective and cannot be used.	Not mutable and continuous sound for 10 minutes	Heater OFF	All

Notes:

- * The error code is shown in both the graphic display and in the heater output numeric display indicator to handle single point failures. xx in the error code is replaced by any of the System Failure error code such as 1, 2, 3, 4, 5, 6, 7, 9, 30, 31, or 53.
- For the power failure alarm activation for full 10 minutes, the device must be connected to the recommended power source and operated for 24 hours to recharge Super Capacitor.

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Chapter 8. Cleaning and Maintenance

Warnings

- Ensure to turn the power OFF, remove the power plug from the power outlet, and allow the heater to cool down before cleaning and disinfecting the device.
- Ensure that the device is cleaned and disinfected before first use, between change of infants, and after maintenance.

Cautions

- After cleaning and disinfecting the device always dry completely before using the device.
- Ensure that water or cleaning agents do not enter near electronics through vents on back of vertical pillar.
- Assemble the removed parts and check that the device operates normally after cleaning and disinfecting.

Cleaning

Use a soft cloth and mild soap/water to clean the device prior to disinfection to remove soil.

Recommended Disinfectant Solution

Use a soft clean cloth and a disinfectant solution for disinfection. After each patient use, follow the hospital's infection control procedures for equipment disinfection. Wipe down the surfaces of the device with a soft cloth dampened with a disinfectant solution. Always follow the disinfectant solution-manufacturer's direction for use. Wipe all surfaces with a damp, soft cloth to remove any cleaner residue.

Approved disinfectant solutions are:

- Soap and water
- Ethanol 96%
- IPA 90% (max concentration)
- Cavicide

Inspection

- After cleaning and disinfection, always inspect the cleaned area for thoroughness.
- If the device doesn't appear adequately clean, repeat the cleaning process.

Notes

- Never use disinfectant solutions at concentrations above recommended values.
- Never use any abrasive cloth or unapproved cleaning solution for disinfection.
- Never autoclave removable parts.
- Follow standard hospital cleaning/disinfecting procedures/protocol.
- Clean and disinfect the device as per the maintenance instructions or whenever you notice any dirt or stain that may cause infection.
- Always use small cotton buds to wipe and disinfect any unreachable area of the device.
- Visual inspection of device for cleanliness requires adequate lighting.

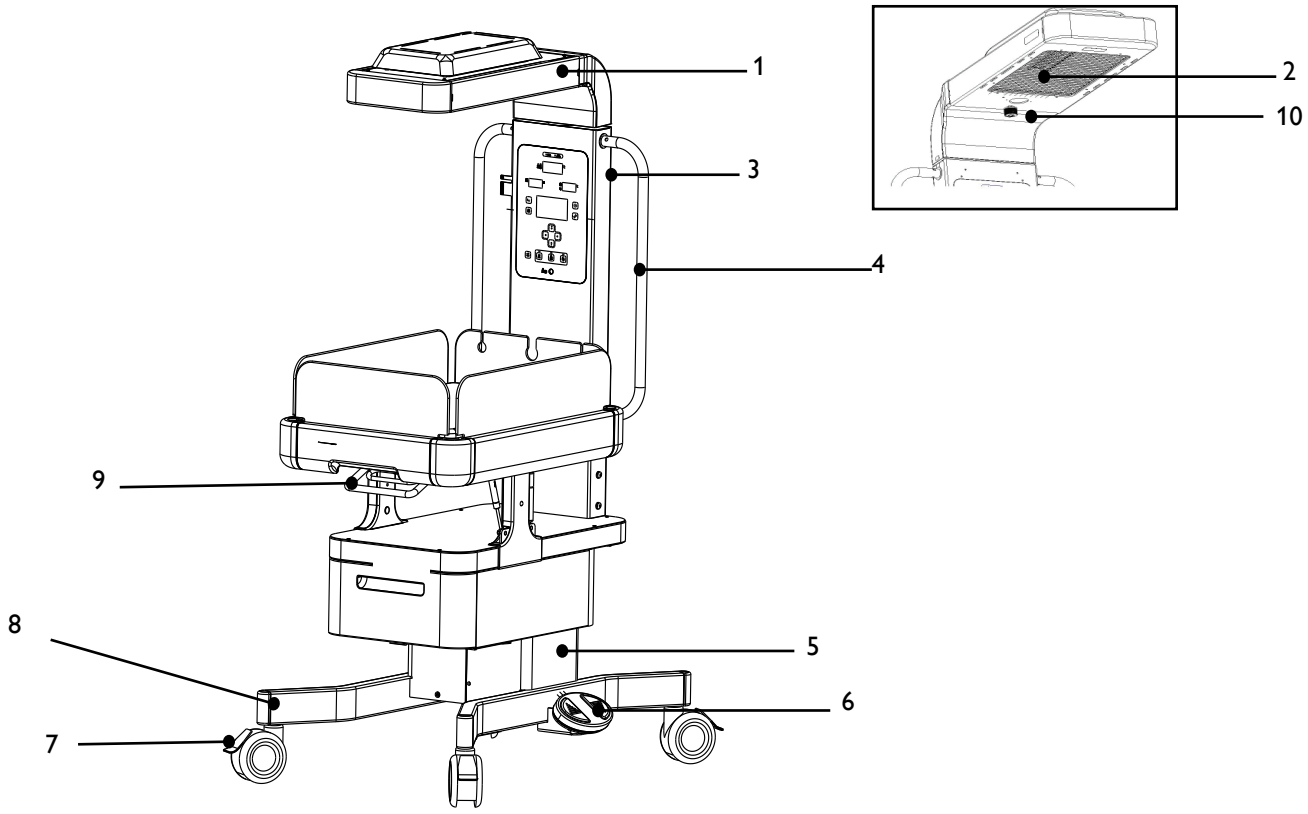
Caution

- Never use alcohol, ammonia, or acetone-based cleaning solutions.

  It can damage the parts that are cleaned.

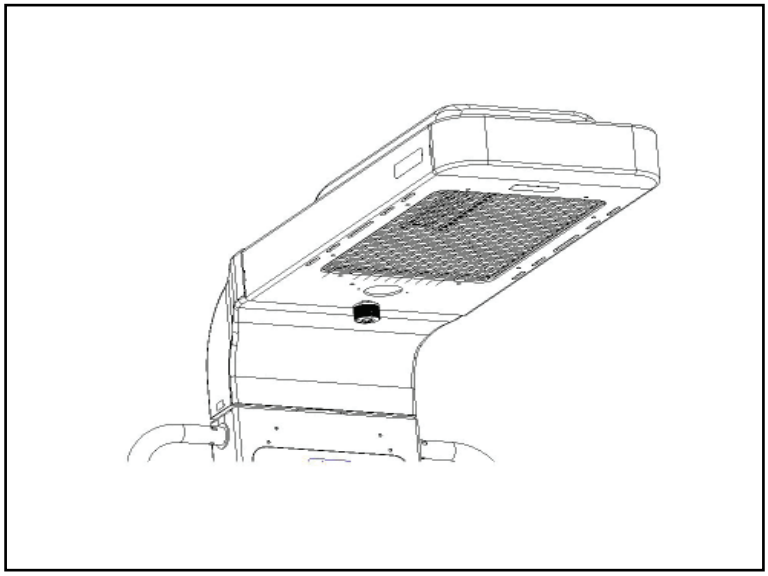
Main Body

The main body of the device includes the parts displayed in the following figure:



#	Name
(1)	Heater Hood
(2)	Heater Grill
(3)	Vertical Pillar
(4)	Accessory Rail
(5)	VHA Cover
(6)	Footswitch
(7)	Caster Wheels
(8)	Pedestal
(9)	Bed Tilt Handle
(10)	Observation Light

1. Clean the main body and the heater hood by wiping with a soft cloth dampened with a disinfectant solution.
2. Clean the heater grill of the heater hood with a clean dry cloth, or a piece of absorbent cotton dampened with soap solution.

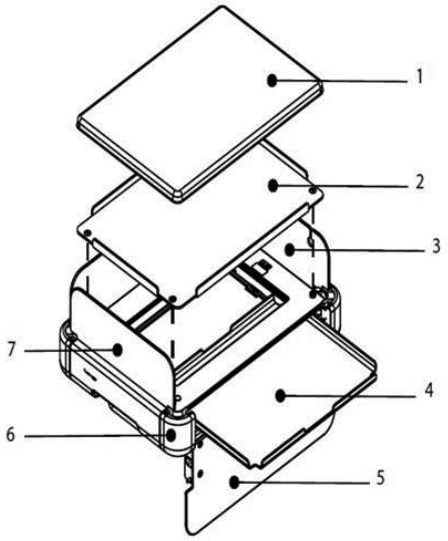


Warning

- Ensure to turn the heater OFF and allow the heater to cool down before cleaning the heater hood.

Bed Compartment

Clean the bed compartment by wiping with a soft cloth dampened with a disinfectant solution. The bed compartment of the device includes the parts displayed in the following figure:



#	Name
(1)	Mattress
(2)	Bed Acrylic Tray
(3)	Short sidewall with tubing slots
(4)	X-ray cassette tray (optional)
(5)	Long Sidewall
(6)	Corner Block
(7)	Short Sidewall

Caution

- Never immerse removable parts in disinfectant or soap solution.

Mattress

Clean the mattress with a soft cloth dampened with a disinfectant solution.

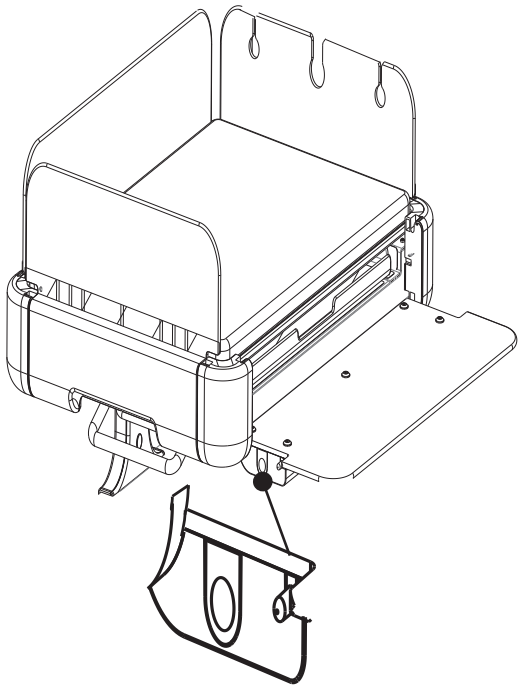
Visually inspect the inside of the mattress for contamination and discontinue use if internal contamination found.

Note: If the cover is torn or damaged discontinue use of the mattress and contact International Biomedical representative.

Sidewalls

Removing the Long and Short Sidewall

1. Open the sidewalls as mentioned in Opening and Closing the Sidewalls section in Chapter 1: Operation.
2. Press the side button to remove the sidewall completely.



Note: Each sidewall can be removed completely in this way except for short sidewall with tubing slots.

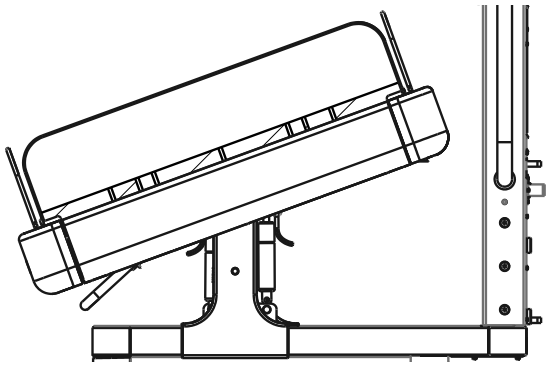
3. Reverse the order of operations to restore the sidewall.

Cautions

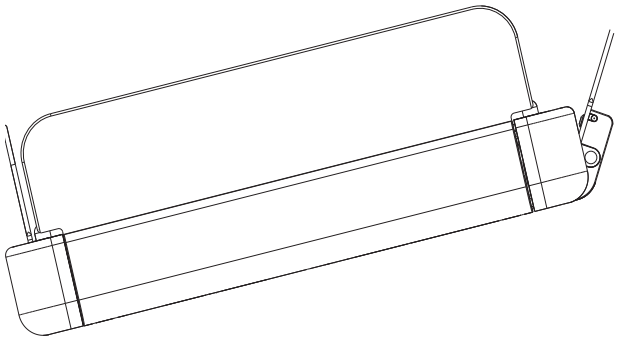
- Never immerse removable parts in disinfectant or soap solution.
- Always clean the sidewalls with a soft cloth dampened with a disinfectant solution.

Removing the Short Sidewall Beside Vertical Pillar

1. For removing the short sidewall beside vertical pillar, tilt the bed until there is enough distance for the sidewall to open.



2. Open the sidewall as mentioned in Opening and Closing the Sidewalls section in Chapter 5: Operation.
3. Press the side button to remove the sidewall completely.



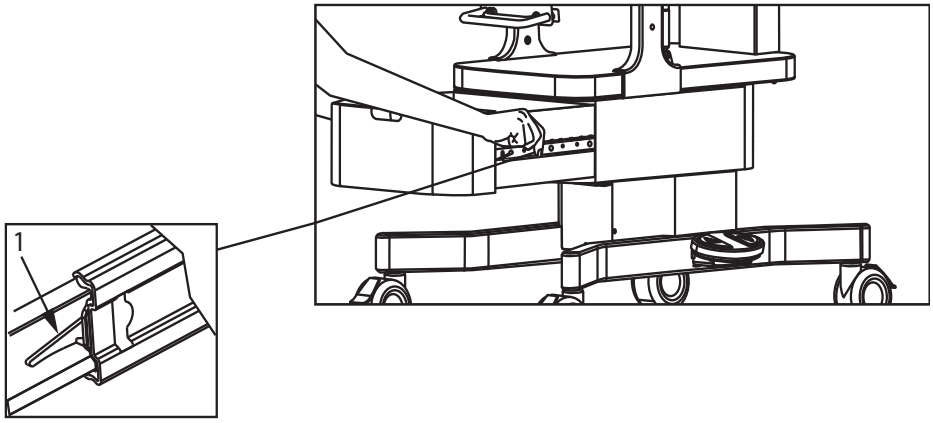
4. Reverse the order of operations to restore the sidewall.

Storage Drawer

Removing the Storage Drawer

1. Open the storage drawer following the steps in Opening and Closing the Storage Drawer section in Chapter 1: Operation.
2. Press the tab on both sides and pull out the storage drawer to remove the storage drawer completely.

Note: Press down the tab on the right side and press up the tab on the left side.



3. Clean the storage drawer by wiping with a soft cloth dampened with a disinfectant solution.

Caution

- Never immerse removable parts in disinfectant or soap solution.

4. Align the storage drawer on the sides and push the storage drawer to its original position to close it.

Note: Ensure that the storage drawer is pushed enough for the catch to engage and hold the storage drawer closed.

Skin Temperature Probe

Wipe a used skin temperature probe lightly with a soft dry cloth. Wipe and disinfect the heat-sensing portion with a soft cloth dampened with a disinfectant solution.

After disinfection, rinse the skin temp probe with a clean, damp cloth to remove any residual residue.

Caution

- Never immerse skin temperature probe in disinfectant or soap solution.

Maintenance Inspection

In order to use the device safely for a longer period, perform the maintenance inspections described below:

Operator Maintenance

- Inspection before use

  Check the basic functional operation of each part of the device every time before using the device.

- Quarterly inspection

  Check the operation of each function of the device every three months.

Service Maintenance

- Annual inspection

  Device needs to be inspected for routine maintenance every year. Perform the electrical safety procedures as described in Service Manual. Contact International Biomedical representative for annual inspection.

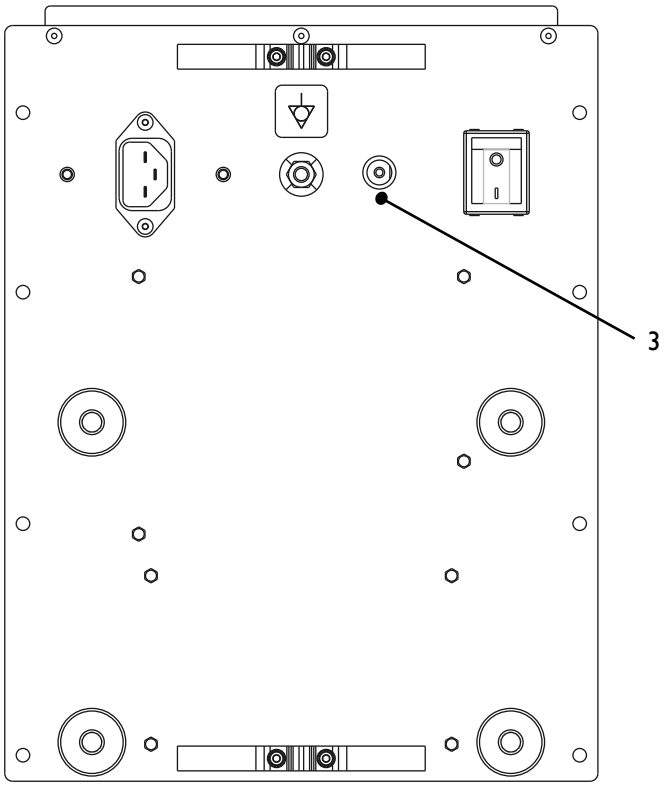
Cautions

- Inspect the device for damage if left unused in storage. If any damage is found, contact your International Biomedical representative.
- Clean and disinfect the device and its accessories before and after maintenance inspections or repairs or before disposal.

Note: Medical institutions are responsible for performing routine and periodic maintenance. Contact your International Biomedical representative for annual service inspection information.

- Main Breaker Reset

1. Switch OFF the device.
2. Locate the resettable breaker (1) on the rear power panel.



3. Push button on breaker to reset.
4. Switch ON the device and check basic functionality.

Inspection Before Every Use

Caution

- Stop using the device and contact International Biomedical representative if you notice any unusual smell, unusual noise, unusual vibration, overheating, missing parts, or defective function in the inspection.

Check the following points regularly before using the device.
If you notice any defect, contact International Biomedical representative.

1. Check the following points before connecting the power cord.

Item to check	Expected test result
Appearance	No part of the main body is broken.
Power cord	The plug is not deformed. The cord is not damaged.
Power connection	The power connections are clean with no medical fluid stains.
Caster wheel	The caster wheels rotate smoothly. They are locked reliably.
Sidewall	The sidewalls are attached securely to the mattress platform. No hinges are broken.
Mattress platform tilting mechanism	The mattress platform locks in a tilted position.
Probe socket	The area around the probe connecting port is clean and not damaged.
Heater hood swivel mechanism	The heater hood swivels away to either side of the vertical pillar smoothly.

2. Check the following points after connecting the power cord.

Item to check	Expected test result
Height adjustment mechanism	The mechanism operates smoothly without making any unusual sound.
Display panel	All the indicators on the Display panel comes on along with an audible alarm sound when the power switch is turned ON.
Skin temperature probe	A temperature value between 33°C to 38°C is displayed when the skin temperature probe is connected and the tip of the probe is held with your hand.

Quarterly Inspection

Check the following points every three months.
If any trouble is detected, indicate on the device that it is out of order and contact International Biomedical representative immediately.

Item to check	Procedure	Expected test result
Skin temperature control	Set the skin temperature to 36°C in the Skin temperature control mode. Warm the skin temperature probe by exposing the skin temperature probe closer to the heater.	• The heater output percentage decreases when the displayed skin temperature is 36°C or higher • The heater output percentage increases when the displayed skin temperature is below 36°C.
High/Low skin temperature alarm	Set the skin temperature to 36.5°C in the Skin temperature control mode. Warm the skin temperature probe by exposing the skin temperature probe closer to the heater.	The set temperature alarm indicator comes on and an audible alarm sound is heard when the displayed skin temperature deviates from 36.5°C ± 1.0°C.
Max temperature limit alarm	Set the heater output to 100% in the Manual temperature mode. Warm the skin temperature probe by exposing the skin temperature probe closer to the heater.	The set temperature alarm indicator comes on and an audible alarm is heard when the displayed skin temperature becomes 40°C or higher.
Check baby alarm	Set the heater output to 100% in the Manual temperature mode.	The check baby alarm indicator comes on and an audible alarm is heard in 12 minutes with 2 minutes of alarm activation.
Power failure alarm	• Switch ON device power switch. Set to Manual temperature mode. Switch OFF mains power to device at wall outlet. • Repeat by setting Skin and Standby mode.	The power failure alarm indicator comes on and audible continuous alarm sound is heard.

Disposal

The medical institution concerned is responsible for proper disposal of the main body, old parts past their expected life span, and disposables in accordance with applicable waste disposal laws and regulations. For details on guidance for safe disposal see Appendix B: Product Disposal.

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Chapter 9. Troubleshooting

Warning

- Stop using the device if it is defective, indicate on the device that it is out of order, and contact your provider or International Biomedical representative.

Check the following points before requesting repair service.

Trouble	Action to take
System does not turn ON	• Check that the device is connected securely to the power source. • Check if there is a problem with the main breaker. Reset the main breaker as mentioned in Main Breaker Reset section of Chapter 8: Cleaning and Maintenance.
Nothing is displayed on the Display panel when the power switch is turned ON, and the power failure alarm activates.	• Check that the device is connected securely to the power source. • Check that the wall socket is delivering power by connecting another electric device to the power outlet used for the device.
The temperature on the mattress does not rise.	• Check that the heater output is not set too low. • Check that the supply voltage is not low. (The device should not share a power outlet with another device). • Check that the ambient temperature is not low. (The ambient temperature should be 18°C to 30°C). • Check the alarm conditions that switches OFF the heater power.
The temperature on the mattress rises too high.	• Check that the heater output is not set too high. • Check that the device is not exposed to direct sunlight or affected by a heating apparatus nearby.
The temperature on the mattress does not stabilize.	• Check that the ambient temperature is stable. (The ambient temperature should be 18°C to 30°C). • Check that the device is not exposed to an excessive draft.
The skin temperature display does not show the infant's skin temperature accurately.	• Check that the plug of the skin temperature probe is connected securely to the skin temperature probe connecting port. • Check that the heat-sensing portion of the skin temperature probe is attached properly to the infant's abdominal wall. • If problem persists replace the temperature probe.

Trouble	Action to take
Height adjustment (VHA) does not function	• Check that the actuation of footswitch is easy • Check that there is no loose connector near the footswitch
No response upon key press	• Check if the indicators in the keypad are glowing when power is ON. • Check if all the keys or only few keys on keypad are not functioning.
Device cannot be moved	• Release the caster brake if the caster brake is locked • Check that the caster is not damaged
Infant bed cannot be positioned in tilted condition	• Check that there is no obstruction to tilting bed • Check if the bed tilt mechanism is stuck
Graphic display/indicator does not work	• Check that the device is connected securely to the power source.
Note: If any other faults not listed in the table occur, or in case device does not respond as expected, take unit out of service. Contact your provider or International Biomedical representative.	

Chapter 10. Technical Specifications

Parameters/Conditions	Values/Description
230 VAC Power Requirements	• Rating: AC 230 V; peak power consumption (including electrical height adjustment operation) 750 VA; frequency 50/60 Hz • Operating voltage range: AC 230 V ± 10% • Breaker: 10 A, 230 V IEC 60934
115 VAC Power Requirements	• Rating: AC 115 V; peak power consumption (including electrical height adjustment operation) 750 VA; frequency 50/60 Hz • Operating voltage range: AC 115 V ± 10% • Breaker: 10 A, 230 V IEC 60934
Classification	• Type of protection: Class 1 equipment • Degree of protection: Type BF applied part – Not for use in an environment of air and flammable anesthetic gas mixture or an oxygen/nitrous oxide and flammable anesthetic gas mixture. • Mode of operation: Continuous operation – The electrical height adjustment is intended for intermittent operation.
Operating Conditions	• Ambient temperature: 18°C to 30°C • Relative humidity: 30% to 75% • Ambient air velocity: < 0.3 m/s • Atmospheric Pressure: 70 kPa~106 kPa
Packed Storage Conditions	• Ambient temperature: -25°C to 50°C • Relative humidity: 10% to 95% (non-condensing)
Regulatory Standards	• IEC60601-1: General requirements for basic safety and essential performance. • IEC60601-1-2: Electromagnetic compatibility. • IEC60601-1-6: Medical electrical equipment - General requirements for basic safety and essential performance - Collateral standard: Usability • IEC60601-1-8: Medical electrical equipment - General requirements for basic safety and essential performance -- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems • IEC60601-1-10: Medical electrical equipment - General requirements for basic safety and essential performance - Collateral standard: PCLC • IEC60601-2-21: Particular requirements for basic safety and essential performance of infant radiant warmers.
Device Operation Modes	Manual temperature control/Skin temperature control/ Standby mode.
Maximum Heater Wattage at 100% Setting	650 W at 230 V or 115 V, 50/60 Hz.
Maximum Bed Irradiance	• Total Spectrum is less than 60 mW/cm^2 • 760 nm to 1400 nm is less than 10 mW/cm^2

Parameters/Conditions	Values/Description
Skin Temperature Display Range	18.0°C to 45.0°C: Resolution 0.1°C, Accuracy ± 0.3°C
Graphic Display Characteristics	• Pixel Resolution: 480 pixels by 272 pixels {10.9 cm (4.3') TFT (Thin Film Transistor)}, 16 M Colors
Skin Temperature Setting Range	33.0°C to 38.0°C (in 0.1°C increments)
Heater Output Setting Range	0% to 100% (in 5% increments)
Heater Output Indication	Numeric display 0% to 100%, resolution 1%
APGAR Timer	10 second beep at 1 minute, 5 minutes, 10 minutes, and 20 minutes.
Observation Light	Variable with intensity range of 0 - 1000 lux (max)
Alarms	Low skin temperature, high skin temperature, check baby, power failure, system failure, skin temperature probe disconnected, and skin temperature probe failure.
Alarm Volume	Max: 69dB Min: 54dB
Mattress Platform Tilting	Continuous horizontal tilt of ± 12°(freely adjustable and lockable)
Dimensions	• Main body: 85(W) x 117(D) cm Height 180 to 200 cm (mattress surface 90 to 110 cm in height) • Mattress: 47(W) x 67(D) x 2.5(H) cm
Maximum Weight Without Accessories	105 kg
Storage	1 storage drawer 5 kg Max load
Bed Load Capacity	Infant weight up to 10 kg
Scale (Optional)	• Measuring Range: 250 g - 8,000g (0.55 to 7.6 lb) • Accuracy: 10 g • Resolution: 10 g

Chapter 11. Accessories

The following International Biomedical accessories are available for use with the NuBorne 500.

Name	International Biomedical Part Number
Reusable Patient Probe (x1)	108-4855
Foam Mattress (not available in U.S.)	109-1451
Pressure Diffusing Mattress	736-1120
Acrylic Mattress Platform	110-3829
Acrylic X-Ray Tray	110-3830
IV Pole	110-3833
Monitor Stand	110-3834
Oxygen Cylinder Holder	332-0005
115 V Power Cord NEMA 5-15P	711-0028
230 V Power Cord CEE 7/7	110-3494
UPS Option 115V AC	017-0048
UPS Option 230V AC	017-0047

Contact your provider or International Biomedical representative for the latest accessories list for the NuBorne 500.

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Appendix A. EMC Information

EMC Warnings

When using the device adjacent to or stacked with other equipment, observe the operation of the device and the other equipment to ensure normal operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the device and associated cables. Otherwise, degradation of the performance of this equipment could occur.

Use only parts, accessories, transducers, and cables designated by International Biomedical for use with the device. Cables and accessories other than those supplied by International Biomedical may result in unacceptable operation of the device and will void the equipment warranty.

The use of devices which radiate high intensity electrical fields may affect the operation of the device. Constant assessment of the patient and all life support equipment is mandatory whenever interfering devices are operating on or near patient.

Guidance and Manufacturer's Declaration - Emissions

The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted Emissions CISPR 11	Class B	The device is suitable for use in all establishments, other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Immunity

This device is intended for use in the electromagnetic environment specified below. The customer or user of the device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	± **8 kV Contact** ± **15 kV Air**	± **8 kV Contact** ± **15 kV Air**	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2 kV Mains ±1 kV I/Os	±2 kV Mains ±1 kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5/1 kV Differential ± 0.5/1/2 kV Common	± 0.5/1 kV Differential ± 0.5/1/2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	100% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25/35 Cycles 100% Dip for 250/350 Cycles	100% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25/35 Cycles During the 5 Second event, the device will enter power fail.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruption, it is recommended that the device be powered from an uninterruptible power supply.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power Frequency magnetic fields should be that of a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz (AC/DC) 6 Vrms (in ISM Bands between 150kHz and 80MHz) 3 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz (AC/DC) 6 Vrms (in ISM Bands between 150kHz and 80MHz) 3 V/m 80 MHz to 2.7 GHz (V1) Vrms (E1) V/m	Portable and mobile communications equipment should be separated from the device by no less than the distances calculated/listed below: $D = (3.5)/V_1 \sqrt{P}$ $D = (3.5)/E_1 \sqrt{P}$ 80 to 800 MHz $D = 7/E_1 \sqrt{P}$ 800 MHz to 2.7 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.
Proximity fields from RF Wireless Communication Equipment IEC61000-4-3	See IEC 60601-1-2 8.10	See IEC 60601-1-2 8.10	This equipment should be placed no closer than 30cm from the nearest RF Wireless communication device.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and this Device

The device is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the device as recommended below, according to the maximum output power of the communications equipment.

MAX OUTPUT POWER (WATTS)	Separation (m) 150 kHz to 80 MHz $D= (3.5)/V_1 \sqrt{P}$	Separation (m) 80 to 800 MHz $D= (3.5)/E_1 \sqrt{P}$	Separation (m) 800 MHz to 2.5 GHz $D= (7)/E_1 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance D in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

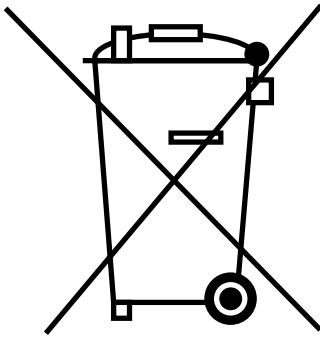
Appendix B Product Disposal

Environmental Requirements

International Biomedical is concerned about protecting the natural environment and helps to ensure continued safe and effective use of this product through proper support, maintenance, and training. International Biomedical equipment is therefore designed and manufactured to comply with relevant guidelines for environment protection. As long as the equipment is properly operated and maintained, it presents no risk to the environment. However, the equipment may contain materials which could be harmful to the environment if disposed of incorrectly. Use of such materials is essential for the implementation of certain functions and for meeting certain statutory and other requirements.

Final Disposal

Final disposal is when you dispose of the equipment or system in such a way that it can no longer be used for its intended purpose.



Warning

- Never dispose of this product (or any parts of it) in industrial waste or domestic waste. The system may contain materials hazardous substances that can cause serious environmental pollution. The system also contains privacy sensitive information. It is advisable to contact your International Biomedical representative before disposing of this product.

International Biomedical gives support for:

- Recovery of reusable parts
- The recycling of useful materials by competent disposal companies
- Safe and effective disposal of equipment
  - For advice and information, contact your International Biomedical Service Organization

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Appendix C Essential Performance

Risk Assessment – Loss of the Alarm annunciation would constitute an unacceptable risk. The alarm is annunciated in both visual and audible means. The operation of the Alarm buzzer and the Display are considered essential performance for this device.

Alarm/ Alert Condition	Activation Criteria	Action on Actuator	Audible Signal Type	Mode
High Skin Temp	Sensed Temp 1°C above set temp	Heater Off	High Priority	Skin, Standby
Low Skin Temp	Sensed Temp 1°C below set temp	None (Heater ON)	High Priority	Skin
Low Skin Temp	Sensed Temp 2.5°C below set temp	None	High Priority	Standby
Check Baby	1.Device transitions from Standby mode to manual mode 2.Manual mode operational for more than 12 minutes above 25% heater power	Heater off if alarm unattended for 2 mins.	High Priority	Manual
Max Skin Temp	Skin Temp Above 40°C.	Heater Off	High Priority	All
Skin Temp Probe Disconnected	Skin Probe Unplugged	Heater Off	High Priority	Skin/ Standby
Skin Temp Probe Failure	Open or Shorted	Heater Off	High Priority	All
System Failure	Electronics failures detected by the device	Heater Off	Continuous Sound	All
Power Failure	Power Switch On but no Mains power	Heater Off	Continuous Sound	All

60601-2-21 (Warmer):

With the Infant Radiant Warmer working in the Baby Controlled Radiant Warmer operation with horizontal mattress orientation in Normal Condition, the temperature as measured by the Skin Temperature Sensor shall not differ from the Control Temperature by more than 0.5°C.

60601-2-21 (Warmer):

After Steady Temperature Conditions have been achieved, any sensed temperature deviation exceeding +/- 1°C compared with the Control Temperature shall cause an auditory and visual alarm to operate, and the Infant Radiant Warmer heater shall switch off when the sensed temperature exceeds the Control Temperature by 1°C. (**See High Skin Temp and Low Skin Temp alarms above**)

60601-1-8 (Alarms): None

60601-1-10(Closed loop controllers): None

Proprietary Information

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