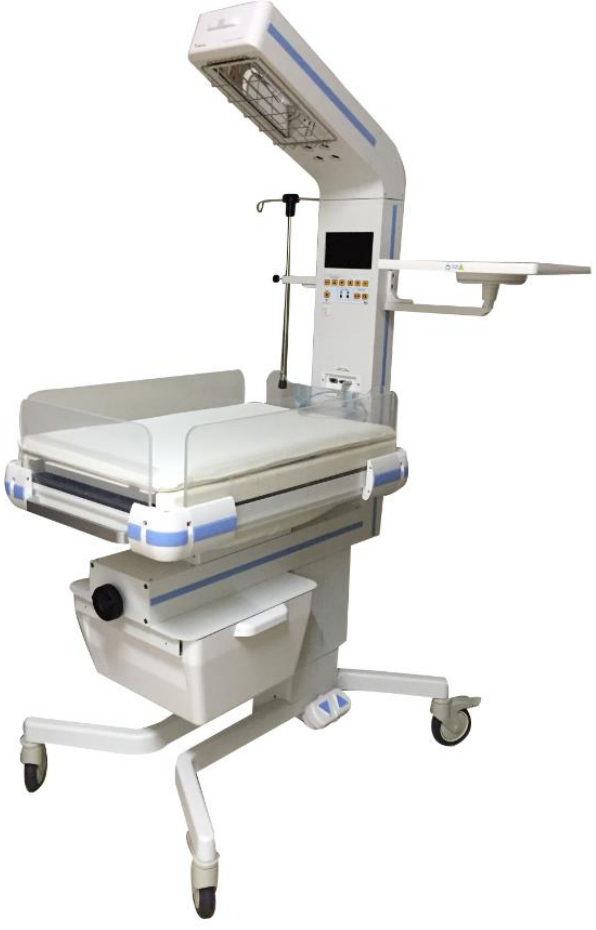
BT-550
Operation Manual



Keep this manual for future reference

P/N : 550-ENG-OPM-EUR-R03

Proprietary Material

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Contents

0 Safety information

Before using BT-550 Infant warmer, read this entire manual and be fully understood the following safety information to prevent injury of patient and user.

Symbols Used

The following symbols identify all instructions that are important to safety. Failure to follow these instructions can lead to injury or damage to the infant warmer. When used in conjunction with the following words, the symbols indicate:

WARNING	Can lead to serious injury or death.
CAUTION	Can lead to minor injury

The following symbols are placed on product, label, packaging and this manual in order to stand for the information about:

Used to identify safety information.
Be well-known this information thoroughly before using BT-550.
During the operation, do not disconnect any cable.

Indicate the warning for hot surface.

IPX0 IPX0 Non-protected against ingress of water with harmful effects.

IPX1 IPX1 Protected against the vertically dripping water (Skin temperature sensor_2EA)

IPX2 IPX2 Protected against the dripping water (SpO_2 sensor)

IPX6 IPX6 Protected against the powerful jetting (Foot switch_2EA)

Refer to operation manual. Read manual before placing the device.

Indicates the weight limit

This symbol indicates the manufacturer.

SN This symbol indicates the serial number of the device.

EC REP This symbol indicates the authorized representative in the European Community of manufacturer.

This symbol indicates a type BF applied part.

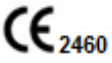
This symbol indicates to keep the device dry.

This symbol indicates the device is fragile.

This symbol indicates the temperature limitation for operation, transport and storage.

This symbol indicates the humidity limitation for operation, transport and storage.

This symbol indicates the packing material is recyclable.



This symbol indicates the compliance with the essential requirements and provisions of the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.

This symbol indicates to not dispose the device together with unsorted municipal waste(for EU only). The solid bar symbol indicates that mains adapter is put on the market after 13 August 2005.

DISPOSAL

	In order to comply with EU Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE): This product may contain material which could be hazardous to human health and the environment. DO NOT DISPOSE of this product as unsorted municipal waste. This product needs to be RECYCLED in accordance with local regulations, contact your local authorities for more information. This product may be returnable to your distributor for recycling - contact the distributor for details.

0.1 General precautions, warnings and cautions

- Examine the warmer and any accessories periodically to ensure that the cables, line cords and instruments do not have visible evidence of damage that may affect patient safety or performance. The recommended inspection interval is once per week or less. Do not use the warmer if there is any visible sign of damage.
- Only the AC line cord supplied with the BT-550 is approved for use with the Unit.
- Do not attempt to service the BT-550 infant warmer. Only qualified service personnel by Bistos Co. Ltd., should attempt any needed internal servicing.
- The BT-550 is not specified or intended for operation during the use of defibrillators or during defibrillator discharge.
- The BT-550 is not specified or intended for operation in the presence of electrosurgical equipment.
- The BT-550 is not specified or intended for operation in conjunction with any other type of equipment except the specific devices that have been identified for use in this Operator's Manual.

- Perform periodic safety testing to insure proper patient safety. This should include leakage current measurement and insulation testing. The recommended testing interval is once per year.

- Do not operate the BT-550 infant warmer if it fails to pass the power on self-test procedure.

Side effect

- The exposure to heat in a dry state is a method to raise body temperature effectively, but the incentive water loss may be appeared to a patient.

- Some patients may require more frequent inspection, such as patients with perfusion disorders or sensitive skin, because persistent and prolonged monitoring may increase unpredictable skin changes, such as allergies, redness, blistering, or pressure necrosis.

⚠ WARNING

- Infant warmer may increase the patient's insensible water loss. Keep the water balance of patient properly.

- Thoroughly read and understand the manual prior to use of the BT-550. Failure to do so could result in personal injury or equipment damage.

- Infant warmer misuse may result in harm to an infant. Only properly trained personnel should use the infant warmer as directed by an appropriately qualified attending physician aware of currently known risks and benefits.

- Use of accessories other than those listed and approved for use with this product may result in increased emissions or decreased immunity.

- Use only certified accessories with the appropriate International Electrotechnical Commission (IEC) 60601 harmonized national standard.

- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. In addition, portable and mobile RF communications equipment can affect medical electrical equipment.

- The equipment shall not be used adjacent to other devices unless verification of normal operation in the configuration in which it is to be used can be achieved.

- For proper operation of the infant warmer, use only skin temperature sensor from Bistos Co. Ltd. Using other sensor could result in personal injury or equipment damage.

- Never place the skin temperature sensor under the infant's body or use it rectally. Personal injury could occur.

- The skin temperature sensor must be in direct contact with the skin to provide

accurate measurement of the infant's skin temperature. Failure to maintain direct skin contact can result in overheating. Routinely check the infant's condition for correct sensor attachment, and feel the infant's skin for signs of overheating.

- Do not use in the presence of flammable anesthetics. Personal injury or equipment damage could occur.
- Keep matches, and all other sources of ignition, out of the room in which the infant warmer is located. Textiles, oils, and other combustibles are easily ignited and burn with great intensity in air enriched with oxygen. Personal injury or equipment damage could occur.
- Small quantities of flammable agents, such as ethyl and alcohol, left on the infant warmer may cause a fire in connection with oxygen. Personal injury or equipment damage could occur.
- A fire and explosion hazard exists when performing cleaning or maintenance procedures in an oxygen-enriched environment.
- To avoid overheating the infant due to direct radiation, do not position the infant warmer in direct sunlight or under other sources of radiant heat.
- To prevent accidental disconnection when adjust the height, ensure that all patient leads, infusion lines, and ventilator tubing have sufficient excess length.
- For infant's safety, do not leave the infant unattended. Personal injury could occur.
- Never place objects taller than the top of the wheel casters beneath the infant warmer stand. Personal injury of equipment damage could occur.
- For optimum stability, always lock all stand wheels. Do not leave the device unattended when parking on an incline. Failure to do so could result in personal injury or equipment damage.
- Prior to placing the infant in the infant warmer, pre-warm the BT-550 to the temperature prescribed by the attending physician, or according to nursing protocol.
- Only one monitor shelf should be used per infant warmer. When using the monitor shelf, always place the monitor in the center of the shelf, ensure that the monitor fits within the border of the shelf, and avoid stacking monitors on the shelf. Personal injury or equipment damage could occur.
- Attach the infant warmer to the stand using the bolts provided. Failure to do so could result in the infant warmer separating from the stand if sufficiently tilted. Personal injury or equipment damage could occur.

- This product has been validated with the accessories and options listed in this manual and found to comply with all relevant safety and performance requirements applicable to the device. It is therefore the responsibility of that person or organization who makes an unauthorized modification, or incorporates an unapproved attachment to the device.
- An operator may only perform maintenance procedures specifically described in this manual.
- Do not remove the covers of a BT-550 yourself to avoid damage to the equipment and unexpected electrical shock. Only qualified Bistos service engineer must repair or replace components.
- Check the rating of power source compatible with the input voltage rating of BT-550.
- The UART port is for debugging purposes only. It does not allow connections with other devices.
- Take off the metallic materials such as watch and ring and touch only the insulated plastic part of BT-550
- When the measured value is not completed, then the "---" is displayed.
- During long time continuous monitoring of a patient, check the position of SpO2 sensor once every 2 hours, and move properly when the skin changes or every four hours.

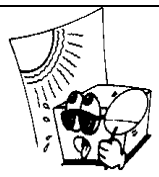
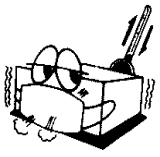
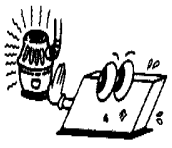
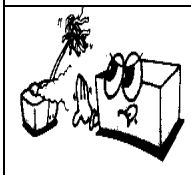
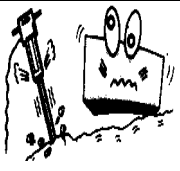
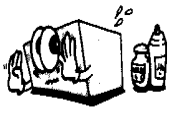
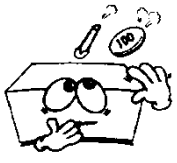
0.2 Shock hazards

⚠ WARNING

- Unplug the unit from its power source prior to cleaning or maintenance to prevent personal injury or equipment damage.
- Some chemical cleaning agents may be conductive and leave a residue that may permit a build-up of conductive dust or dirt. Do not allow cleaning agents to contact electrical components and do not spray cleaning solutions onto any of these surfaces. Personal injury or equipment damage could occur.
- To ensure grounding reliability, plug the AC power cord only into a properly grounded 3-wire hospital-grade or hospital-use outlet. Do not use extension cords. If any doubt exists as to the grounding connection, do not operate the equipment. Personal injury or equipment damage could occur.
- Do not expose the unit to excessive moisture that would allow for liquid pooling. Personal injury or equipment damage could occur.
- Do not touch the patient and signal input/output parts simultaneously
- Due to the risk of electrical shock hazard, only qualified personnel with appropriate service documentation should service the unit.
- The total power of all equipment connected to the convenience outlet strip on the stand must be within the electrical requirements shown on the rear of the stand. Otherwise, personal injury or equipment damage could occur.
- Make sure the building power source is compatible with the electrical specifications shown on the column of the stand and on the infant warmer. Failure to do so could result in personal injury or equipment damage.
- To prevent equipment damage or accidental power disconnections, do **not** plug a BT-550 power cord directly to an AC wall socket when the BT-550 is mounted on a pedestal /stand. Always provide power to the BT-550 by using the power cord coming directly from the pedestal /stand.

0.3 General precautions on environment

Do not keep or operate the equipment under the environment listed below.

	Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.		Avoid exposure to direct sunlight
	Avoid placing in an area where high variation of temperature exists. Operating temperature ranges from 18℃ ~ 30℃. Operating humidity ranges from 0 % ~ 95 %.		Avoid in the vicinity of electric heater.
	Avoid placing in an area where there is an excessive humidity rise or ventilation problem.		Avoid placing in an area where there is an excessive shock or vibration.
	Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.		Avoid dust and especially metal material enter into the equipment
	Do not disjoint or disassemble the device. Bistos Co., Ltd. does not have liability of it.		Power off when the equipment is not fully ready to operate. Otherwise, the equipment could be damaged.

1 System basics

1.1 Intended use

The BT-550 Infant Warmer is intended to emit controlled, evenly distributed overhead heat to the body of premature infant and other newborns that cannot effectively regulate their body temperature. This device can be used before any treatment or operation of an infant. The device has two operating functions; the baby mode and the manual mode. In the baby mode, the temperature is controlled by the infant's skin temperature. The infant's skin temperature is compared to the temperature setting. If the measured skin temperature is lower than a temperature setting value, the warmer operates to increase the skin temperature of an infant. In the manual mode, the warmer operates for a predefined time.

The device has the option for weighing scale and SpO2 measuring functions. Weight and SpO2 of infant can be measured using the options. In the SpO2 measurement, the sensor is place at the end of a finger. By measuring the intensity of reflected light, depending on the concentration of dissolved oxygen in the blood determines the oxygen concentration.

1) Intended patient population

- Newborns, Premature infant, Low birth weight infant
- Age up to 3 months
- Weight up to 10 Kg

2) Intended user profile

- Nursing staff or physicians who is qualified personnel
- Basic experiences or knowledge on medical field, especially on obstetrics
- Trained or requested to read IFU before use

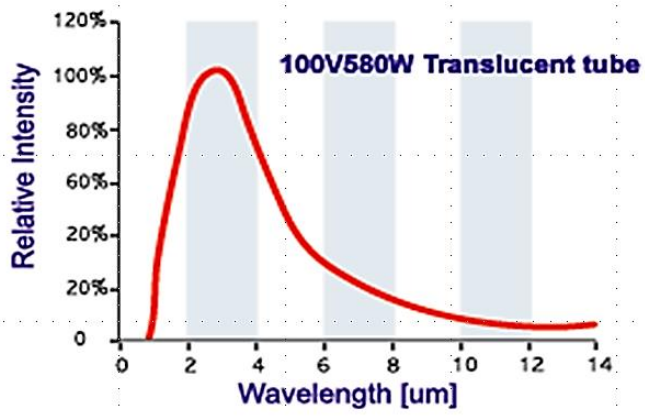
3) Environment of use

- Hospital (birthing center, delivery rooms), Neonatal intensive care unit (NICU)
- Requirements: Stable power source

1.2 Operating principle

The BT-550 infant warmer is electrically powered device with a radiant heating source intended to maintain the thermal balance of an infant by direct radiation of energy in the infrared region of the electromagnetic spectrum. The maximum irradiance level at any point on the mattress is 100% heater output, 28 ㎽/㎠±20% in the total infrared spectrum.

The following graph shows the emissivity data of infrared radiation used for the BT-550 Infant Warmer. It has the specific frequency band of 2 ~ 11㎛.



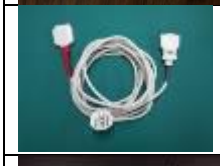
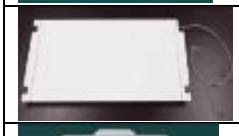
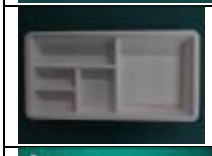
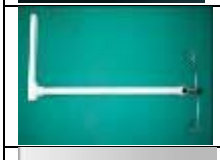
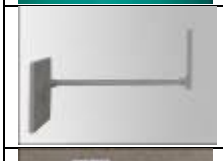
1.3 System configurations

Basic configuration of BT-550

- Main body with fixed height stand
- Mattress & Power cable
- 2 skin temperature sensor

Options of BT-550

- Motor-driven height adjustable stand (Lift stand)
- Intravenous(IV) pole
- IV Plate for auxiliary equipment
- Basket(Drawer)
- Basket partition
- Weighing scale
- Bed tilting mechanism
- SpO_2
- Extension for SpO2 sensor

Picture	Name	Description	Qty
	Fixed Stand (Standard)	Movable warmer cradle with wheels	1ea
	Mattress (Standard)	Accommodate infant stably with bouncy mattress	1ea
	Skin temperature sensor (Standard)	Measures infant's skin temperature Model: W0001C	2ea
	AC power code (Standard)	AC Power cord(AC Power cord for operating the equipment)	1ea
	Masimo SpO2 sensor probe (Optional)	Measures infant's SpO2 Model: Masimo M-LNCS series	1ea
	Masimo Extension for SpO2 sensor (Optional)	Extend sensor cable Model: Masimo SET M-LNC Patient Cable M-LNC-10	1ea
	Weighting Scale (Optional)	Measures Infant's weight	1ea
	Basket (Optional)	Store medical equipment and items which infant needs	1ea
	Basket Partition (Optional)	Partition of Basket	1ea
	IV-pole (Optional)	IV hanger	1ea
	IV plate (Optional)	Plate to place items which infant needs	1ea
	Lift Stand (Optional)	Movable warmer cradle with wheels (VHA- Variable Height Adjustable)	1ea

1.4 Product outlook

Basic configuration Configuration with full Options

Figure1-1: Front view

Figure1-2 : Side view

1.5 Description of System components

Figure1-3: System components

	Name	Description
①	Head	Equipped with infrared radiating light source and can be rotated up to 90° to left and right each and totally 180°.
②	Column	Supporting head part and equipped with electronic circuits to operate BT-550 inside. The electronic circuits are composed with power supply part, display and user interface. The IV pole and plate for auxiliary equipment attached on the side of column when the option has been selected.
③	Stand	Supporting the whole BT-550 system. Basic stand has fixed height. Height adjustable stand is available as option. It has equipped with caster to move the BT-550 easily and can be fitted with drawer and bed tilting mechanism when options are selected.
④	Bed	Equipped with mattress and protective barriers to prevent the patient from falling off the mattress. X-ray cassette tray is located under the bed for X-ray procedure. Weighing scale plate can be placed beneath the mattress as option. Protective barriers can be opened or removed from the bed for easy access to infant patient.

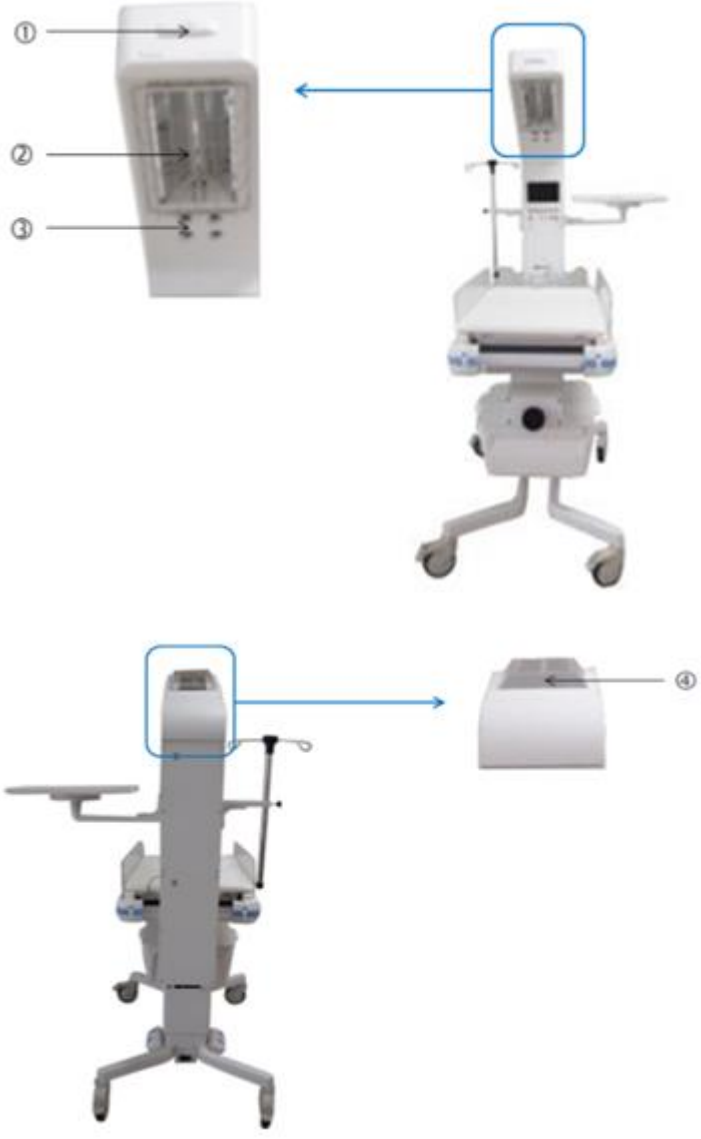


Figure1-4: Head

	Name	Description
①	Alarm light	Flashing red light in alarm status
②	Heat source	Composed with heating element, reflecting plate and protection guard to prevent touch the heating element
③	Examination lamp	Provide added illumination of the mattress area
④	Ventilation hole	To ventilate the heated air around the heating element

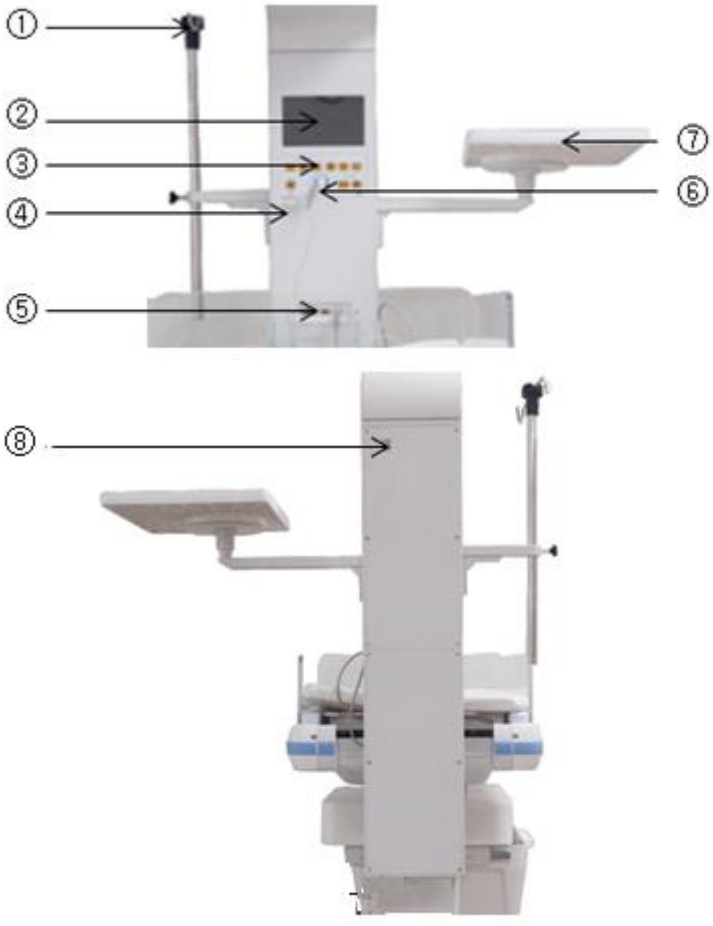
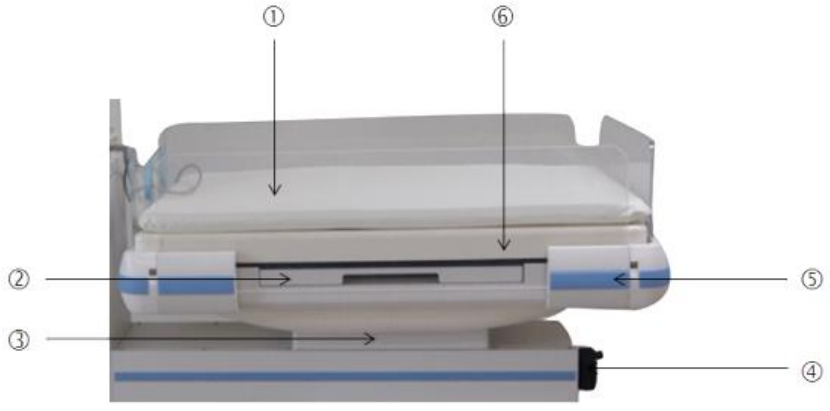


Figure1-5: Column

① IV Pole
② Display LCD
③ Buttons
④ Power switch
⑤ Connector for SpO_2 sensor and weighing scale
⑥ Connector for Skin temperature sensor
⑦ Plate for auxiliary equipment (IV Plate)
⑧ Speaker

⚠ WARNING

- The maximum permitted load of IV pole is 5 kg. Do not hang heavy object on the pole.
- The maximum permitted load of plate for auxiliary equipment is 11 kg. Do not place heavy object on the plate.

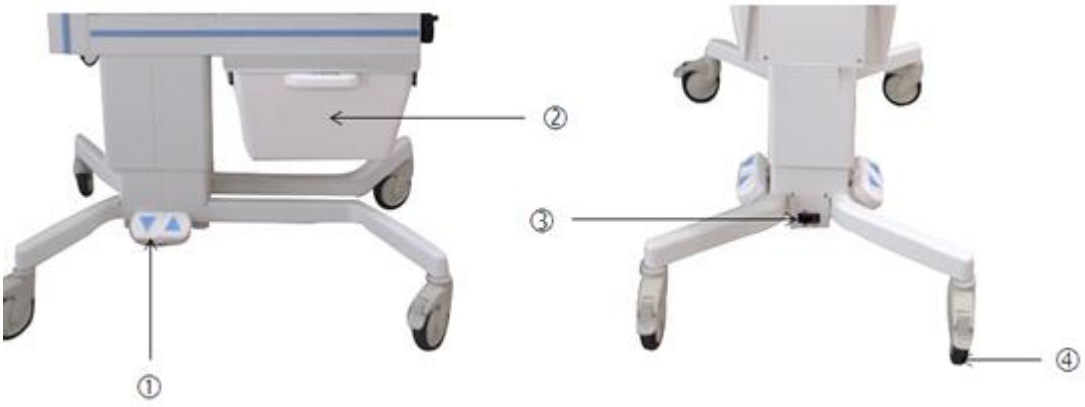


① Mattress
② X-ray cassette tray
③ Bed tilting mechanism
④ Tilting handle
⑤ Protective barriers
⑥ Weighing scale

Figure1-6 : Bassinet

⚠ WARNING

- Do not place heavy objects on the X-ray cassette tray to prevent the device falling down.
- Do not place any object under the bed while taking the X-ray radiation.
- Do not place infant on the X-ray cassette tray directly.
- Do not move the infant warmer while X-ray cassette tray expelled.
- The maximum permitted load of X-ray cassette tray is 1.5 kg. Do not place heavy object on the tray.



① Foot switch
② Drawer
③ AC power socket inlet
④ Caster

Figure 1-7: Stand part (Height adjustable stand)

⚠ WARNING

- Do not place any items taller than the caster diameter of device to prevent any disturbance of stability of stand and damage to the device
- Keep vacant surrounding stand about 30 cm.
- When adjusting the height of stand, place one hand on the infant warmer to keep the balance of operator.
- Be sure that auxiliary equipment or items are removed from the moving path when adjusting the height of stand. Before adjusting the height, secure the safe of infant and other connections.
- The maximum permitted load of drawer is 10 kg. Do not place heavy object in the drawer.

1.6 Understanding the display

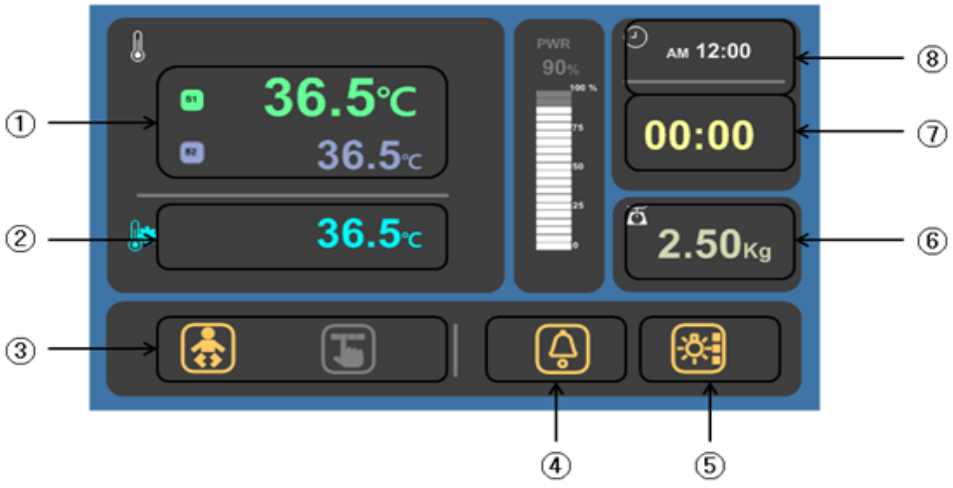


Figure 1-8: Display when SpO_2 option not installed

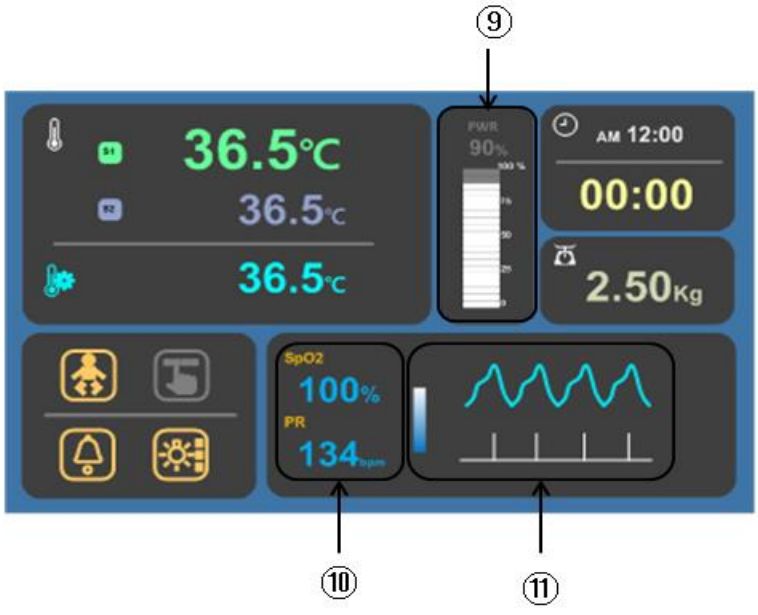


Figure 1-9: Display when SpO_2 option installed

① Measured temperature
② Set temperature
③ Selected operation mode
④ Alarm mute indicator
⑤ Examination lamp status indicator
⑥ Weight measured
⑦ APGAR timer
⑧ Current time
⑨ Heater power output indicator
⑩ Blood oxygen saturation, pulse rate
⑪ Photo plethysmograph and Signal IQ® (Signal Identification and Quality indicator)

1.7 Buttons

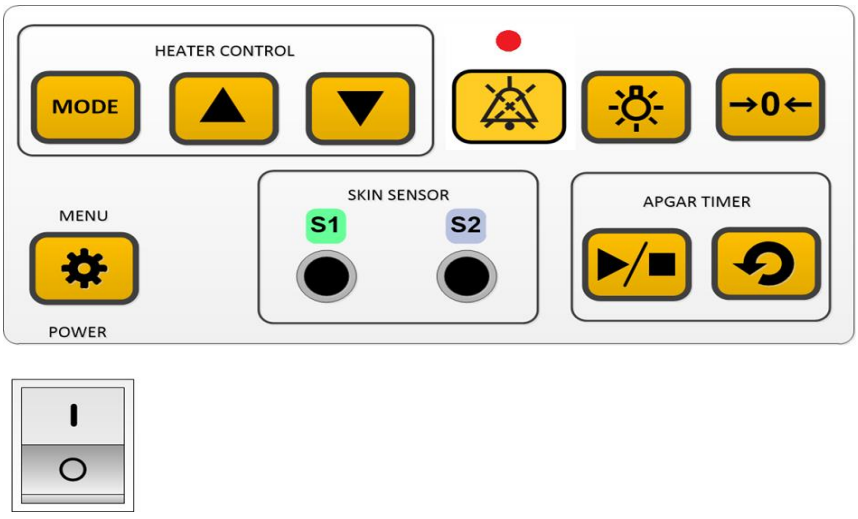
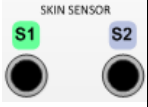


Figure1-10 Buttons

Button	Name	Description
MODE	[MODE]	Button for mode selection.
▲	[UP]	Button for increment of temperature set value in baby mode and heater output in manual mode. And can be used to move cursor upward or change the set value in setting mode.
▼	[DOWN]	Button for decrement of temperature set value in baby mode and heater output in manual mode. And can be used to move cursor downward or change the set value in setting mode.
	[ALARM MUTE]	Alarm mute button. Push the button makes the audible alarm muted for about 5, 10, 15 minutes. The red LED lighted when alarm muted.
	[LAMP]	Button for lamp control. Lamp brightness changed in Low → Medium → High → OFF sequence when press the button.
→0←	[ZERO]	Button to set the scale to zero.
	[SETUP]	Button for set-up. Press this button to enter set-up menu
▶/■	[APGAR*]	Button for APGAR Timer Start and Stop. *The APGAR timer provides tones at 1, 5 and 10 mins set intervals to prompt the assessment on infants nursed under the BT-550 infant warmer.

	[APGAR RESET]	Button for APGAR Timer Reset.
	Skin temperature sensor connectors	S1 : The first sensor to be attached to the abdomen of infant (*The heater power in baby mode is controlled by the temperature measure from S1.)* S2 : The second sensor to be attached to the foot or ear lobe of infant
	Power switch	A switch that serves to change between the on state and the off state.

1.8 Alarm and Error indication

The audio alarm signal varies with the alarm priority.

① High alarm priority

The patient is in critical condition that should be immediately rescued. The device has a serious mechanical or electrical failure or malfunction, which means the patient is putting into the unintended environment or the device is unable to monitoring and control the environment.

- Alarm light: Red, flashes
- Audible alarm: Beep-beep-beep--beep-beep----beep-beep-beep--beep-beep
- Alarm information: Red

② Medium alarm priority

The device is in an abnormal condition including a mechanical or electrical failure or malfunction, which means the device does not a normal operation.

- Audible alarm: Beep-beep-beep
- Alarm information: Yellow

③ Low alarm priority

The device detects an abnormality that might lead to critical condition.

- Audible alarm: Beep
- Alarm information: Yellow

Alarm message	Priority	Description
POWER FAIL	High	• When the supply power are interrupted the 'POWER FAIL' warning message are displayed in white and red and audio alarm stays for 10 minutes

<table>
<tr><td>SENSOR DISABLE</td><td>High</td><td>• Alarms are activated when skin temperature sensor did not connect to S1 connector.</td></tr>
<tr><td>S1 TEMP LOW
S1 TEMP HIGH
S2 TEMP LOW
S2 TEMP HIGH</td><td>High</td><td>• High Temperature: Alarm activated when the measured temperature is higher than set temperature value by 1.0 ℃ in baby mode or 38 ℃ in manual mode.
• Low temperature: Alarm activated when the measured temperature is lower than set temperature value by 1.0 ℃ in baby mode or 30 ℃ in manual mode.</td></tr>
<tr><td>BABY CHEK</td><td>High</td><td>• In manual mode, the alarm activated after 12 minutes and the heater output reduced to 25 % after 15 minutes.
• In baby mode, the heater output set to 100 %, the alarm activated after 12 minutes and the heater output reduced to 25 % after 15 minutes.</td></tr>
<tr><td>Head Rotation</td><td>Medium</td><td>• When the head is rotated more than 20 degree, the heater output reduced to 0% and alarm activated.</td></tr>
<tr><td>Masiomo-check alarm
Masimo Alarm message</td><td>High</td><td>• Alarm will be activated upon following situations:
<table>
<tr><th>Alarm message</th><th>Situation</th></tr>
<tr><td>Open LEDs</td><td>LED opened</td></tr>
<tr><td>Shorted LEDs</td><td>LED shorted</td></tr>
<tr><td>Interference detected</td><td>Interference between transmitting LED and detector</td></tr>
<tr><td>Low SpO2</td><td>Measured SpO_2 value is lower than low limit setting</td></tr>
<tr><td>No cable</td><td>SpO_2 cable was not connected</td></tr>
<tr><td>Sensor off patient</td><td>Sensor was not connected to the patient</td></tr>
<tr><td>Unrecognized sensor</td><td>The system cannot recognize the sensor</td></tr>
<tr><td>Bad sensor ID offset</td><td>Not supported sensor connected</td></tr>
<tr><td>Shorted detector</td><td>The detector diode shorted</td></tr>
<tr><td>High pulse rate</td><td>Measured pulse rate is higher than high limit setting</td></tr>
<tr><td>Low pulse rate</td><td>Measured pulse rate is lower than low limit setting</td></tr>
<tr><td>No adhesive sensor</td><td>Not supported adhesive sensor connected</td></tr>
<tr><td>No sensor connected</td><td></td></tr>
<tr><td>Too much ambient light</td><td></td></tr>
<tr><td>Low perfusion</td><td>Perfusion index is low</td></tr>
<tr><td>Low signal IQ</td><td>Signal IQ® is low</td></tr>
<tr><td>Masimo board failure</td><td>Masimo board failure and failure code</td></tr>
<tr><td>Diagnostic failure</td><td>Diagnostic failure and failure code</td></tr>
<tr><td>PROCAL FAILURE</td><td>ProCal failure</td></tr>
</table>
• To see the alarm situation pressing down the [ALARM MUTE] button until the message pop-up displayed.</td></tr>
</table>

CAUTION ⚠ FALL BACK Mode

- The following operation of device considered as fall back mode (mode of operation (or state) into which the Physiological Closed Loop Control System) transitions when the PCLC (Physiological Closed Loop Controller) stops operating due to detection of a fault).
  - · Sensor disable
  - · Skin temperature high/Low
  - · Head rotation
  - · Baby check

1.9 Essential performance

1) Accuracy of baby mode operation
The temperature as measured by the skin temperature sensor shall not differ from the control temperature by more than 0.5 ℃.

2) Accuracy of measurement

The skin temperature measurement accuracy is ± 0.3 ℃.

If the module is equipped, the SpO2 measurement accuracy is ± 3 % in range of 70 – 100 %.

If the module is equipped, the Pulse rate measurement accuracy is ± 3 bpm in range of 25 to 240 bpm.

3) Display
The warmer displays the measurement value of skin temperature, and if the module is equipped, the SpO2 and pulse rate measurement value.

4) Generation of visual and audible alarm
After steady temperature condition have been achieved, any sensed temperature deviation exceeding ±1°C compared with the control temperature shall cause an auditory and visual alarms to operate, and the infant radiant warmer heater shall off when the sensed temperature exceeds the control temperature by 1℃.
If the device cannot get a stable power supply, technical alarm occurs.
If the module is equipped, alarm for low SpO2, high and low pulse rate occurs based on the set limit.

2 Operation of BT-550

2.1 Precautions

CAUTION ⚠

- Use the BT-550 in the environment temperature 18 ~ 30 ℃ and humidity 0 ~ 95%(non-condensing).
- Be sure the power cord securely connected.
- Do not connect several cords to one socket outlet.
- Place the device on the flat floor.
- Do not use the power cord which can cause the electromagnetic noise
- Avoid the impact on the device.
- Use the device in the place free from dust or flammable agent
- Be sure to lock the caster before use.
- The device shall 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 infant warmer use.
- BT-550 should not be used adjacent to or stack with other equipment.
- The AC power plug is a means to isolate its circuits electrically from the supply mains on all poles simultaneously. Do not place the device in an area when there is difficult to disconnect from the supply mains.
- To avoid overheating or underheating, observe the infant constantly and monitor the temperature using the skin temperature sensor supplied with the equipment or other electronic thermometer. It is important to note that the skin temperature alarms are not functional during manual operation. Therefore, the operator should use baby mode whenever possible.

2.2 Assembling BT-550

2.2.1 Repositioning the column

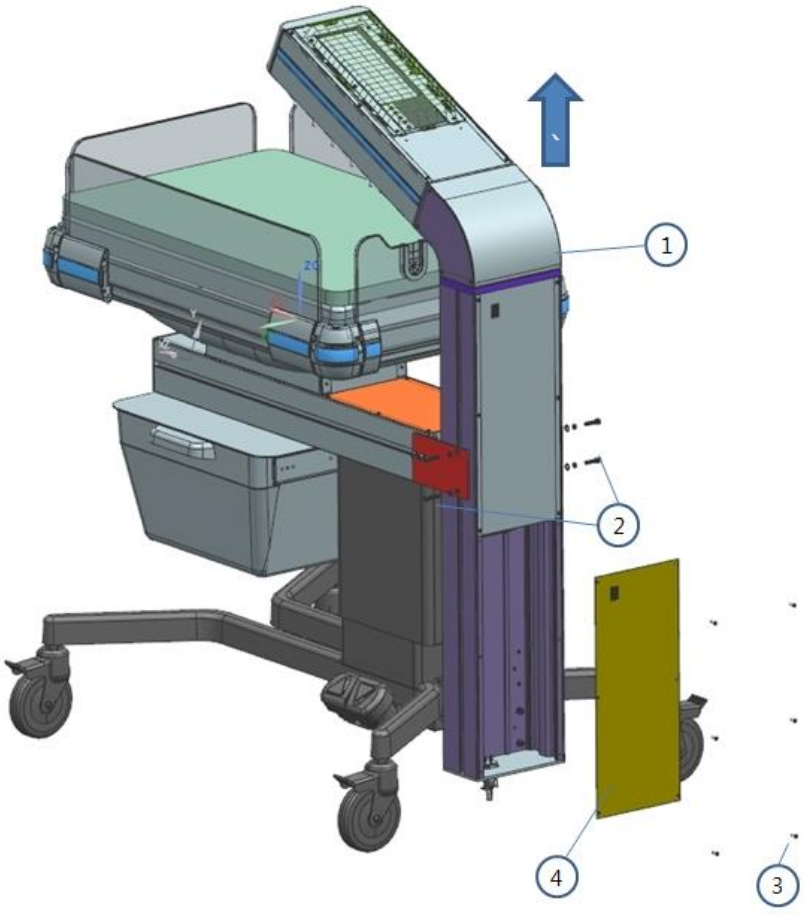


Figure 2-1: Repositioning the Column (1)

1. Remove the package.
2. Remove the four M6X25 Hexagon head bolt (number ② in figure) from column (hold the column securely to prevent declining) with 5 mm hexagon wrench enclosed.
3. Remove the six M4x8 machine screws (number ③ in figure) and detach the back cover (number ④ in figure) from column.

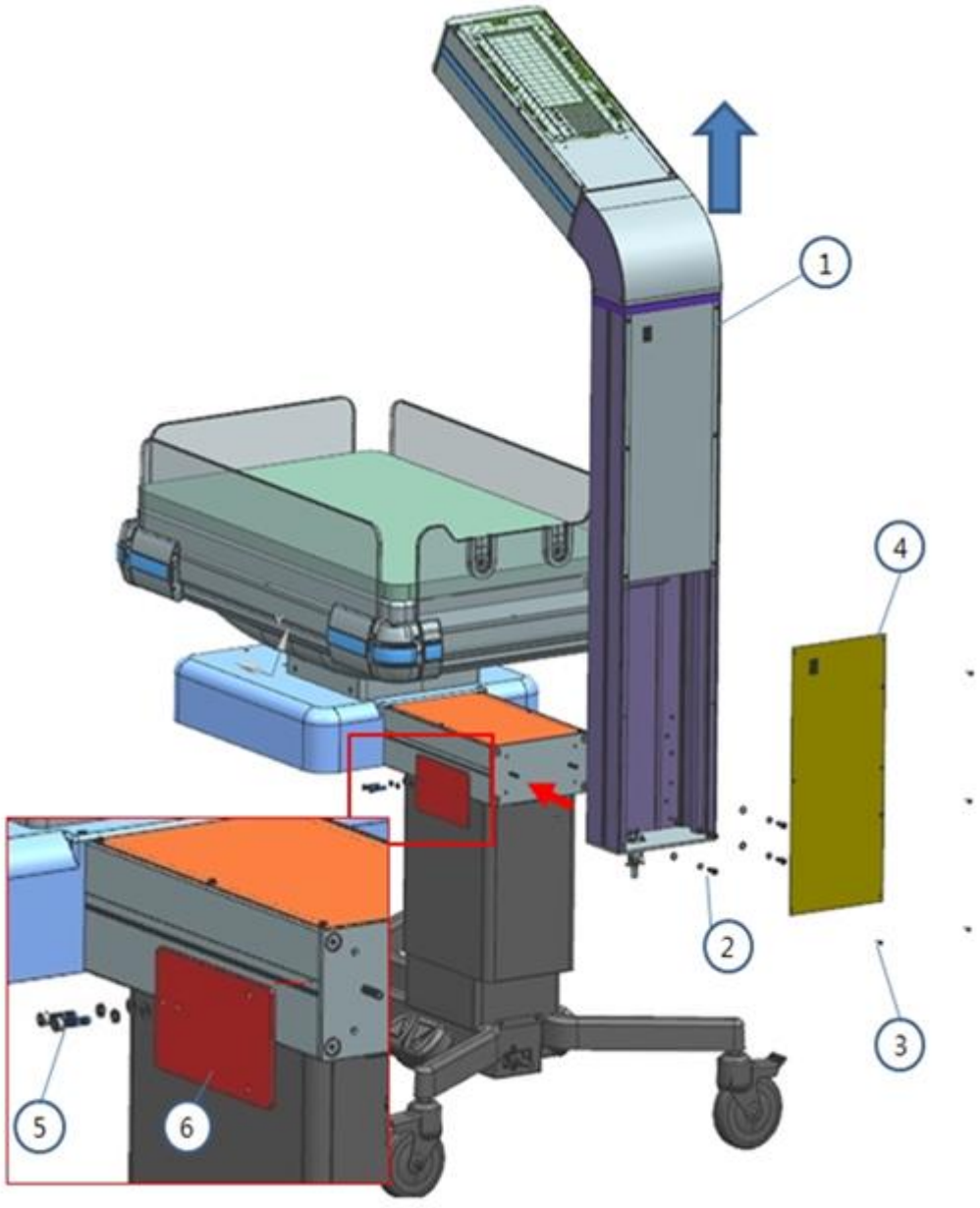


Figure2-2: Repositioning the column (2)

1. Push up the column and align with the fixing hole as indicated in the figure with red arrow
2. Fix with four M6x15 bolts (number ② in figure) which removed above procedure. Hold column tightly until bolting finished to prevent fall down.
3. Replace the back cover (number ④ in figure) and fix with six M4X8 (number ③ in figure) which removed above procedure.
4. Detach the fixing bracket from device by loosening the M6x25 9number ⑤ in figure).

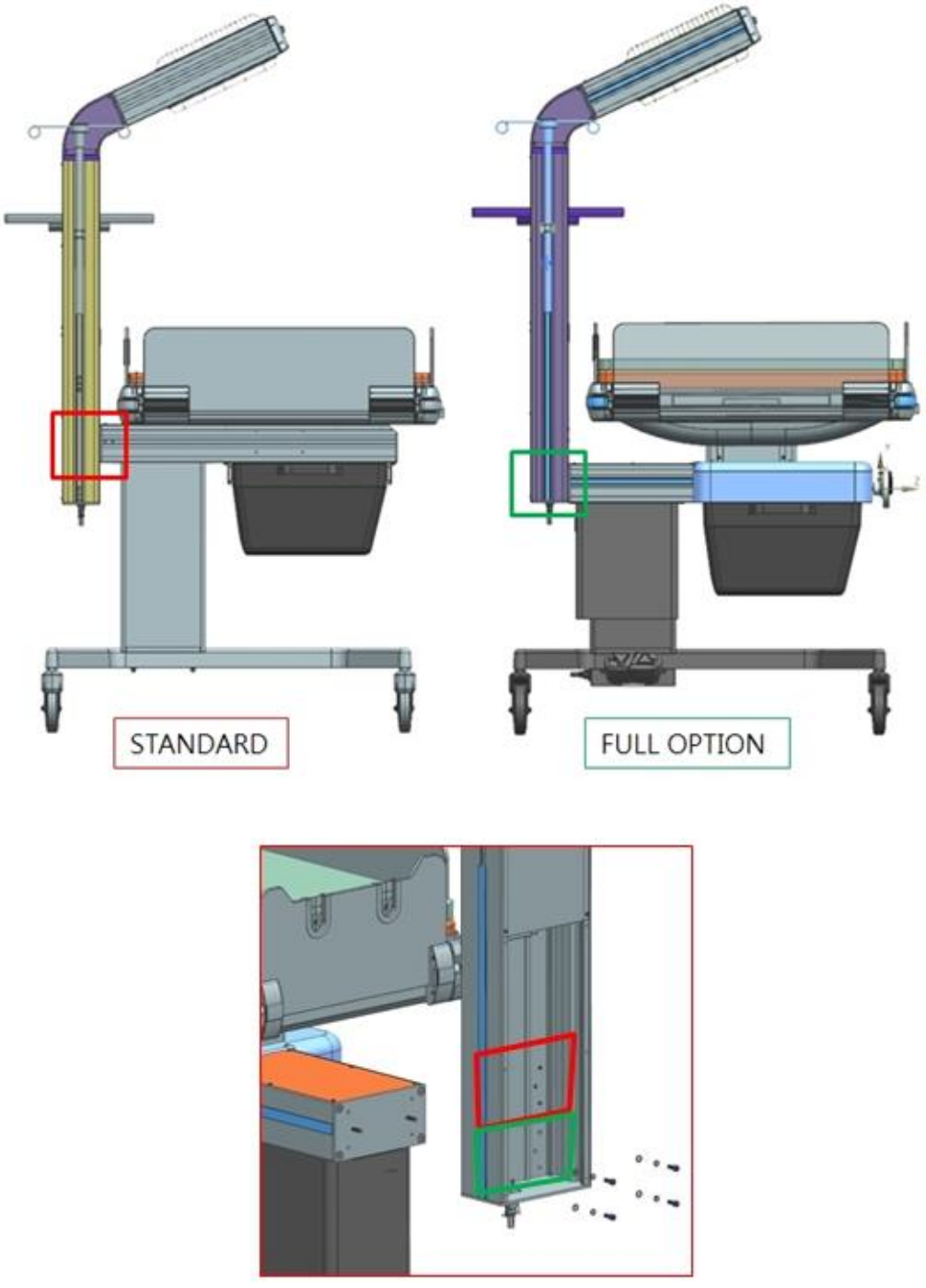


Figure2-3: Repositioning the column (3)

The assembling position is different for standard configuration and full option configuration. Be sure to fixing on the right position depending on the options.

2.2.2 Installing the IV pole to column (Option)

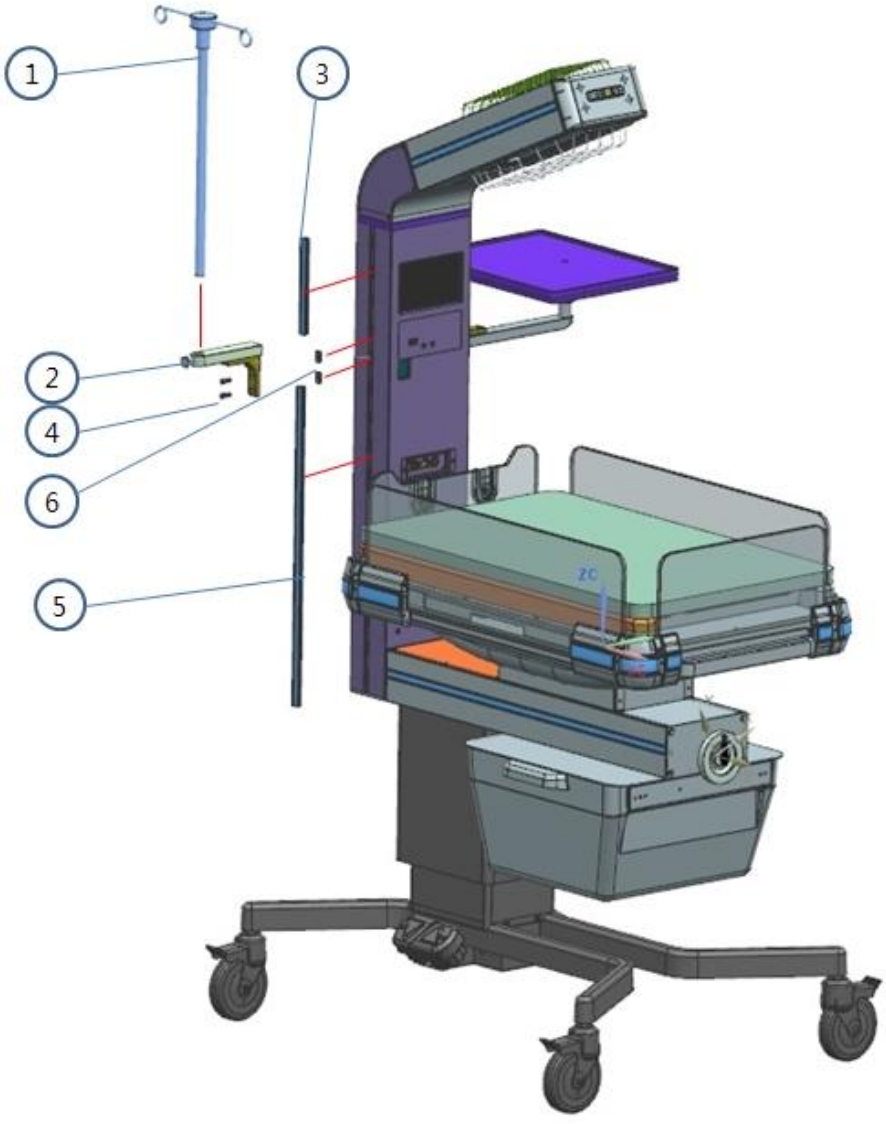


Figure2-4 : Installing IV pole

1. Put the lower damper (number ⑤ in figure) to the lower part of column rail.
2. Slip-in the two joint nuts (number ⑥ in figure) to the column rail above the lower damper.
3. Put the upper damper (number ③ in figure) to the upper part of column rail.
4. Fix the IV frame to column with two M6X15 (number ④ in figure) using enclosed hexagon 5 mm wrench.
5. Put the IV pole (number ① in figure) to IV frame and fix it with turning screw located in the frame.

2.2.3 Installing the plate for auxiliary equipment to column (Option)

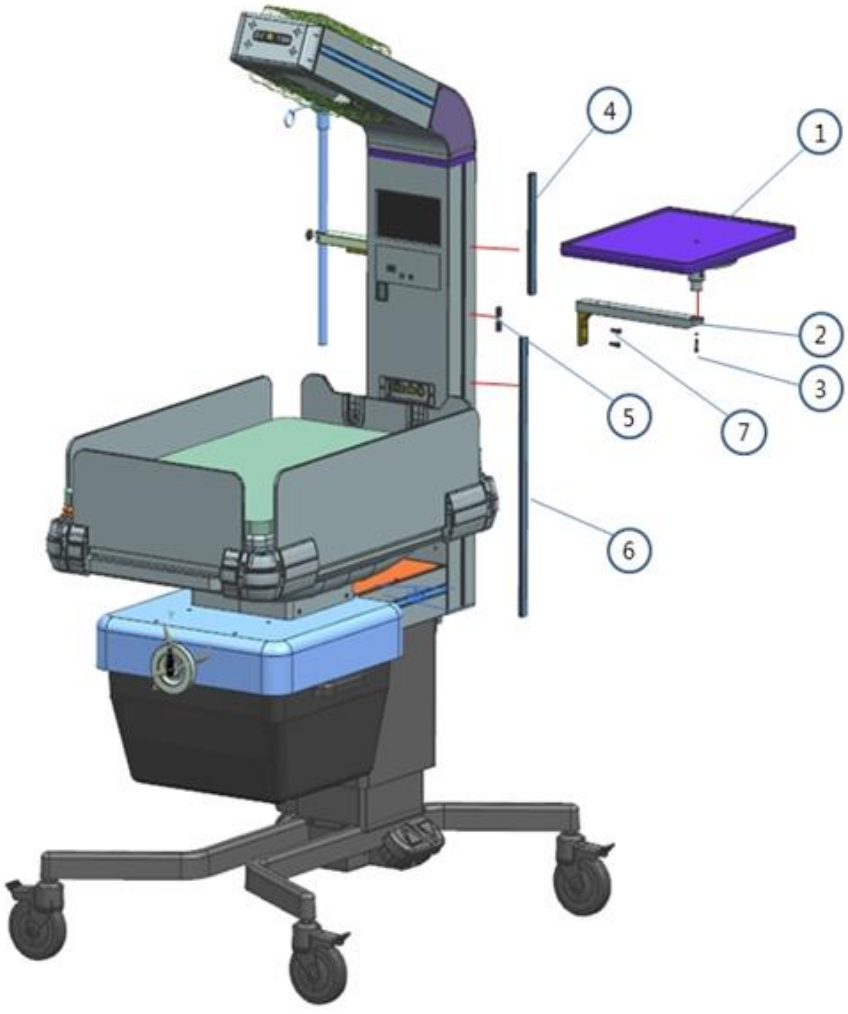


Figure2-5 : Installing plate for auxiliary equipment to column

1. Put the lower damper (number ⑥ in figure) to the lower part of column rail.
2. Slip-in the two joint nuts (number ⑤ in figure) to the column rail above the lower damper.
3. Put the upper damper (number ④ in figure) to the upper part of column rail.
4. Fix the plate frame (number ② in figure) to column with two M6X15 (number 7 in figure) using enclosed hexagon 5 mm wrench.
5. Fix the plate (number ① in figure) to plate flame with M5X15 hexagon head bolt using enclosed hexagon 4 mm wrench.

2.3 Separating barriers

Pull the barrier upward.

Decline the barrier backward and detach upper locking pin.

Pull the barrier upward again and detach lower locking pin.

Figure2-6 : Separating barriers

WARNING

- Do always for both ends together.
- Regularly inspect the latches and closing devices of barriers to prevent the infant falling out.
- Keep the barrier latched always when possible.

2.4 Bed tilting mechanism

The bed can tilted for 15°±2° to backward or forward

Figure 2-7: Tilting handle

⚠ **CAUTION**

- Do not press a bed with over pressure.
- Do not turn the tilting handle with excessive force.

⚠ **WARNING**

- Tilting of the mattress from its horizontal position relative to the infant warmer heater can affect the performance of the infant warmer.
- The accessories such as phototherapy or heated mattresses, or sunlight can cause an increase in infant temperature to dangerous levels.

2.5 Skin temperature sensor

- Before adhere the sensor to infant, hold the metallic part of sensor end with fingers and check the temperature display relevant to body temperature.
- Attach the S1 sensor to the abdomen and S2 sensor (option) to the foot or ear lobe of infant using adhesive tape.
- The temperature measurement automatically started when power on the device if the sensor is connected.
- Sensor is reusable. After use clean and store according to the instructions described in section 4 of this manual.

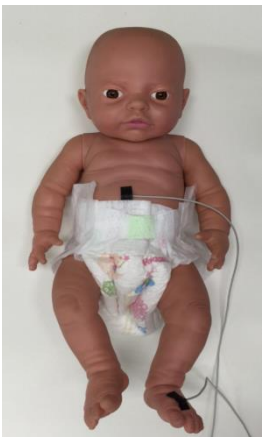


Figure 2-8
Skin temperature sensor

⚠ WARNING

- Never try to move the device while the infant placed in the device.
- The skin temperature sensor should be contacted to bare skin of infant for correct measurement. Otherwise the temperature can increase to dangerous levels. Frequently check whether the sensor contacted correctly to infant's skin and overheat.
- Do not pull the wire of sensor. Remove the sensor by detach the adhesive tape.
- Independent monitoring of the temperature of the infant by the operator is essential. Monitor the temperature of infant regularly with auxiliary thermometer.
- The infant warmer cannot differentiate between an increase in core temperature with a cold skin (fever) and a low core and skin temperature (hypothermia). Monitor the temperature of infant regularly with auxiliary thermometer.
- The rectal temperatures are not appropriate for controlling the heater output of the infant warmer.

2.6 Prepare to use

1. Connect the power cord to the power inlet connector of BT-550. In the basic configuration, the power inlet connector is located under the column. In the full option configuration, it is located behind the stand assay. Clip the power cord to prevent detached unintentionally.

Figure 2-9: Power cord

2. Connect all cables and sensors to the relevant connectors. Be sure to connect the cables and sensors to the right connectors.

3. Turn on the power. At booting screen in left photo of Figure 2-10, you can see the software version.

4. After booting sequence finished, the main screen will be displayed. Check whether all the relevant information are displayed

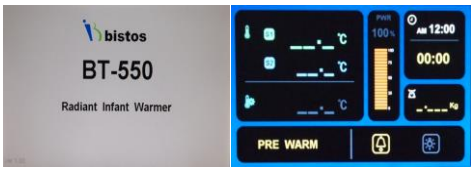


Figure 2-10: Product logo and initial screen

5. When the power on, BT-550 start to operate in 'pre warm' mode with 100% heater output (28 ㎽/㎠±20%) for five minutes. After then the heater output decrease to 60% for 10 minutes and further decrease to 25%.

⚠ WARNING

- Securely latch the power cord to prevent the power cord unintentionally detached from power inlet connector.
- Do not pull or push when connecting or disconnecting connector from or to main body in force. Check the shape, position and direction of connector.

2.7 Operation

(0) Power On

When the power switch turned on, initial logo screen displayed.

(1) Measuring the skin temperature of infant

The BT-550 start to measure the skin temperature of infant as the power switched on. When the skin temperature sensor does not connected to the connector in baby mode, sensor disable message displayed and audible alarm activated.

(2) Mode selection

Baby Mode – Heater output controlled automatically by measured skin temperature

- Select Baby Mode by pressing [MODE] button.
- Set the desired temperature by pressing [INCREASE] or [DECREASE] button. The heater output controlled according to the measured skin temperature of S1 skin temperature sensor.
- 'Baby Check' message will displayed and alarm activated after 12 minutes if the heater output stay 100 % and the output will be decreased to 25 % after 3 minutes when no button operation detected.

Manual Mode – Heater output controlled manually

- Select Manual Mode by pressing [MODE] button.
- Set the desired heater output by pressing [INCREASE] or [DECREASE] button.
- 'Baby Check' message will displayed and alarm activated if the device stay in Manual Mode more than 12 minutes and the power will be decreased to 25 % after 3 minutes when no button operation detected.

⚠ WARNING

- Infant warmer may increase the patient's insensible water loss. Keep the water balance of patient properly.
- Do not place any objects in the infant warmer to prevent the objects getting hot. The objects can disturb the transfer of heat to patient.
- Heater, lamp and adjacent areas are very hot. Do not touch these parts with bare hand.
- Infant warmer does not adjust for patient temperature in Pre-warm Mode. The mode shall be changed to Manual Mode or Baby mode immediately when the patient is placed on the device.
- The skin temperature of infant can be affected by environment such as strong air flow, direct sunlight. It is always recommended to use infant warmer in Baby Mode as possible.
- Use the infant warmer in the place where the air flow is slower than 0.3 m/s.

(3) Weighing scale(Option)

Weighing scale is option. The infant warmer measures the weight of infant automatically when the weighing plate is connected to the infant warmer. Press [ZERO] button to set the scale to zero.

(4) SpO_2 and pulse rate (Option)

The SpO_2 option is disabled when delivered. The enable/disable of SpO_2 option can be changed in Service Mode. Press the following buttons in sequence to enter Service Mode: [UP] → [DOWN] → [UP] → [DOWN] → [SETUP] → [APGAR] → [APGAR RESET]. Change the SpO_2 Option from DIS to EN. Select [EXIT] using [UP] or [DOWN] button and press [SETUP] button.

The SpO_2 function only activated when the SpO_2 module connected to BT-550. The measurement is started when the sensor is attached to infant's index finger or other part (such as toe, ear lobe etc.). Use site appropriate according to each sensor's individual direction for use.

(5) APGAR Timer

Press [APGAR] button to start the APGAR timer. Indicating sound will be heard on 1 minute, 5 minutes and 10 minutes. Press [APGAR] button to mute the timer. To reset the timer, press [APGAR RESET] button.

(6) Examination lamp

You can control the brightness of examination lamp. Press the [LAMP] button to change the lamp brightness from OFF to low, mid and high. Press the [LAMP] button again to OFF the lamp.

(7) Setup

Below is the initial factory setting of parameters;

Parameters	Default value
Control temperature in Baby Mode	36 ℃
Heater output in Manual Mode	50 %
Temperature unit	℃
Weight Unit	Kg
Alarm mute period	5 minutes
Alarm sound level	Max
Pulse rate beep volume	3 steps
SpO_2 algorithm mode	Normal sensitivity
SpO_2 alarm delay	0 second
Average time	2-4 seconds
SpO_2 low limit	85
Pulse rate high limit	200
Pulse rate low limit	100
Scale calibration value	Disabled

In Setup Mode following parameters can be changed.

Category	Parameter	Description	Selection
System	Time	To set the current time	AM/PM, Hour and minutes
	Temp. Unit	To select the temperature unit	℃(Celsius)/ ˚F(Fahrenheit)
	Weight Unit	To select the weight unit	kg(kilogram)/lb(pound)
	Default set	All parameters are reset to factory setting	
Alarm	Mute period	Alarm paused time	2/5/10/15 minutes
	PR beep volume	Pulse rate volume sound	0 ~ 5 steps
	SpO_2 alarm delay	SpO_2 alarm delay time setup	0/5/10/15 seconds
	Alarm test	To check alarm work correctly. The audio and visual alarm can be generated by ON the alarm test in Setup mode. The operator should be test the alarm system normality of audible and visible status before operating.	
SpO_2	Algorithm mode	SpO_2 measuring algorithm selection	Normal sensitivity, Maximum sensitivity, APOD(Adaptive Probe Off Detection)
	Normal sensitivity	This selection provides the best combination of sensitivity and probe-off detection performance and is recommended for the majority of patients	
	Maximum sensitivity	This selection should be reserved for the sickest patients, where obtaining a reading is most difficult. Maximum sensitivity is designed to interpret and display data for even the weakest of signals, and is recommended during procedures and when clinician and patient contact is continuous.	
	APOD® (Adaptive Probe Off Detection)	This mode is the least sensitive in picking up a reading on patients with low perfusion but has the best detection for probe-off conditions. This mode is useful for patients that are at particular risk of sensor becoming detached (pediatric, combative, etc.)	
	FastSat®	Enable rapid tracking of arterial oxygen saturation changes	ON/OFF When the average time set to 2-4 or 4-6, the FastSat® is automatically activated
	Average	Set the time to average	2-4/4-6/8/10/12/14/16 seconds
	SpO_2 Low alarm limit	SpO_2 low alarm limit. Alarm activated when measured value are lower than this limit. The range of 85 to 95 can be selectable.	
	PR alarm limit H, L	Pulse rate low and high alarm limit. Alarm activated when measured value are lower or higher than this limit. High limit can be set to 50 -240 and low setting value should be more than 10 higher from low limit setting. Low limit can be set to 40-230 and high setting value should be less than 10 lower from high limit setting.	

(8) Power Off

Turn the power off after using the device. When the device expected do not used for a while, then unplug the power cord from socket outlet.

2.8 SpO_2 Monitor(option)

MASIMO This symbol means that the Masimo product inside.

BT-550 uses the Masimo SpO2 oximetry to monitor the oxygen saturation in the blood. You can find the detailed Masimo product information below.

Patent information for Masimo product can be found at www.masimo.com/patents.htm.

"Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more the patents relating to this device"

⚠ WARNING

- SpO_2 monitor of BT-550 must be operated by qualified personnel only.
- Do not use the MS board pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- A pulse oximeter should NOT be used as an apnea monitor.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
- A pulse oximeter should be considered an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's condition.
- If an alarm condition (other than exceptions listed herein) occurs while the alarm silence period is set to off, the only alarm indications will be visual displays and symbols related to the alarm condition.
- The MS board pulse oximeter is to be operated by qualifier personnel only. These manual, accessory directions for use, all precautionary information, and specifications should be read before use.
- Do not remove the monitor cover except to replace the battery. An operator may only perform maintenance procedures specifically described in this manual. Refer servicing to Masimo in repair of this equipment.
- Measure the oximeter's leakage current whenever an external device is connected to the serial port. Leakage current must not exceed 100 microamperes.
- Connect the oximeter only to a three-wire, grounded, hospital-grade receptacle. The three-conducting plug must be inserted into a properly wired three-wire receptacle is not available, a qualified electrician must install one in accordance

with the governing electrical code.

- Do not under any circumstances remove the grounding conductor from the power plug.
- Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.
- If there is any doubt about the integrity of the protective earth conductor arrangement, operate the oximeter on internal battery power until AC power supply protective conductor is fully functional.
- To ensure patient electrical isolation, connect only to other equipment with electrically isolated circuits.
- Do not connect to an electrical outlet controlled by a wall switch or dimmer.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the monitor or external power supply in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient cable; use only the handle on the monitor.
- Carboxyhemoglobin may erroneously increase readings. The level of increase in approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.
- Do not use the MS board pulse oximeter or Masimo oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The MS board pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- Consult IEC 60601-1 for system interconnection guidance. The specific requirements for system interconnection are dependent upon the device connected to the MS board pulse oximeter and the relative locations of each device from the patients, and the relative location of the connected device to the medically used room containing the MS board pulse oximeter. In all circumstance the MS board pulse oximeter must be connected to a grounded AC power supply. The MS board pulse oximeter is referred to as an IEC 60601 F device in the summary of situation table contained in IEC 60601-1.

⚠ **CAUTION**

- Do not autoclave or gas sterilize this oximeter.
- Do not soak or immerse the monitor in any liquid.
- Use the cleaning solution sparingly. Excessive solution can flow into the monitor

and cause damage to internal components.

- Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the panel.

- Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the oximeter. These substances attach the device's materials and device failure can result.

- Check alarm limits each time the MS board pulse oximeter is used to ensure that they are appropriate for the patient being monitored.

- If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs by alternate means and the check the MS board pulse oximeter for proper functioning.

- Inaccurate measurements may be caused by
  - Incorrect sensor application or use
  - Significant levels of dysfunctional hemoglobin. (e.g., carboxyhemoglobin or methemoglobin)
  - Intravascular dyes such as indocyanine green or methylene blue.
  - Interfering Substances: Dyes, Nail polish or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
  - Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG based arrhythmia analysis.
  - Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material)
  - Excessive patient movement
  - SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter cannot measure elevated levels of COHb or MetHb. Increase in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.
    - For increased COHb: COHb levels above normal tend to increase the level of SpO_2. The level of increase is approximately equal to the amount of COHb that is present. High levels of COHb may occur with a seemingly normal SpO_2. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
    - For increased MetHb: the SpO_2 may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO_2 may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Venous congestion may cause under reading of actual arterial oxygen saturation. Therefore, assure proper venous outflow from monitored site. Sensor should not be below heart level (e.g. sensor on hand of a patient in a

bed with arm dangling to the floor).
- Venous pulsation may cause erroneous low readings (e.g. tricuspid value regurgitation).
- Patient suffers from abnormal pulse rhythm.
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the oximeter pulse rate display. Verify patient's pulse rate against the ECG heart rate.
- Use only Masimo approved accessories.
- Motion artifact man lead to inaccurate measurements.
- Elevated levels of Total Bilirubin may lead to inaccurate SpO2 measurements.
- With very low perfusion at the monitored site, the readings may read lower than core arterial oxygen saturation.
- Do not expose the Pulse CO-Oximeter to excessive moisture such as direct exposure to rain. Excessive moisture can cause the Pulse CO-Oximeter to perform inaccurately or fail.
- Do not immerse the sensor or patient cable in water or, solvents, or cleaning solutions (The sensors and connectors are not waterproof).
- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line.

- The MS board can be used during defibrillation, but the readings may be inaccurate for a short time.

- Loss of pulse signal can occur in any of the following situation
  - The sensor is too tight
  - There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight.
  - A blood pressure cuff is inflated on the same extremity as the one with a SpO2 sensor attached
  - The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia.
  - There is arterial occlusion proximal to the sensor.
  - The patient is in cardiac arrest or is in shock.

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor is connected to the pulse oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in two ways: 1) as a percent value for arterial oxygen saturation (SpO_2), and, 2) as a pulse rate (PR).

- Operating Principles

The BT-550 MS board pulse oximeter is based on three principles:

1. Oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry).

2. The volume of arterial blood in tissue and the light absorbed by the blood changes during the pulse (plethysmography).

3. Arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse.

The pulse oximeter of BT-550 as well as traditional pulse oximetry determines SpO_2 by passing red and infrared light into a capillary bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as the light sources, a photodiode serves as the photodetector.

Traditional pulse oximetry assumes that all pulsations in the light absorbance signal are caused by oscillations in the arterial blood volume. This assumes that the blood flow in the region of the sensor passes entirely through the capillary bed rather than through any arterio-venous shunts. The traditional pulse oximeter calculates the ratio of pulsatile absorbance (AC) to the mean absorbance(DC) at each of two wavelengths, 660 nm and 905 nm:

S(660) = AC(660) / DC(660)

S(905) = AC(905) / DC(905)

The oximeter then calculates the ratio of these two arterial pulse-added absorbance signals:

R = S(660) / S(905)

This value of R is used to find the saturation SpO_2 in a look-up table built into the oximeter's software. The values in the look-up table are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

The BT-550 MS board pulse oximeter assumes that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is the major components of noise during the pulse. BT-550 MS board decomposes S(660) and S(905) into an arterial signal plus a noise component and calculates the ratio of the arterial signals without the noise:

S(660) = S1 + N1

S(905) = S2 + N2

R = S1 / S2

Again, R is the ratio of two arterial pulse-added absorbance signals and its value is used to find the saturation SpO_2 in an empirically derived equation into the oximeter's software. The values in the empirically derived equation are based upon human blood studies against a laboratory co-oximeter on healthy adult volunteers in induced hypoxia studies.

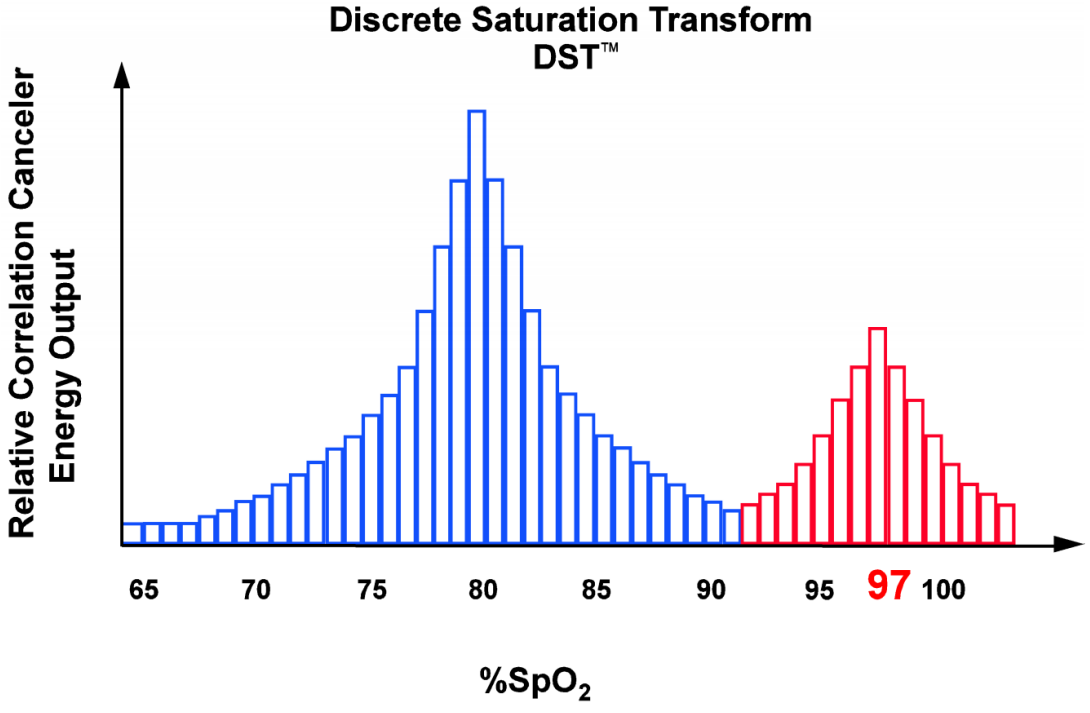
The above equations are combined and a noise reference (N') is determined:

N' = S(660) – S(905) x R

If there is no noise N' = 0: then S(660) = S(905) x R which is the same relationship for the traditional pulse oximeter.

The equation for the noise reference is based on the value of R, the value being sought to determine the SpO_2. The MS board software sweeps through possible values of R that corresponds to SpO_2 values

between 1% and 100% and generates an N' value for each of these R-values. The S(660) and S(905) signals are processed with each possible N' noise reference through an adaptive correlation canceler (ACC) which yields an output power for each possible value of R (i.e., each possible SpO_2 from 1% to 100%). The result is a Discrete Saturation Transform (DST™) plot of relative output power versus possible SpO_2 value as shown in the following figure where R corresponds to SpO_2 = 97%:



The DST plot has two peaks: the peak corresponding to the higher saturation is selected as the SpO_2 value. This entire sequence is repeated once every two seconds on the most recent four seconds of raw data. The MS board SpO_2 therefore corresponds to a running average of arterial hemoglobin saturation that is updated every two seconds.

- Grounding

Connect the oximeter only to a three-wire, grounded, hospital-grade receptacle. The three-conductor plug must be inserted into a properly wired three-wire receptacle; if a three-wire receptacle is not available, a qualified electrician must install one in accordance with the governing electrical code.

⚠ WARNING

- Do not under any circumstances remove the grounding conductor from the power plug.
- Do not use extension cords or adapters of any type. The power cord and plug must be intact and undamaged.

If there is any doubt about the integrity of the protective earth conductor arrangement, operate the oximeter on internal battery power until the AC power supply protective conductor is fully functional.

- Patient Isolation

To ensure patient electrical isolation, connect only to other equipment with electronically isolated circuits.

Note: Do not connect to an electrical outlet controlled by a wall switch or dimmer.

- Cabling entanglement/strangulation

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

⚠ **WARNING**

- Do not place the monitor or external power supply in any position that might cause it to fall on the patient. Do not lift the monitor by the power supply cord or patient cable; use only the handle on the monitor.

- RS-232 & Alarms

RS-232 System Interconnection. Consult IEC-601-1-1 for system interconnection guidance. The specific requirements for system interconnection are dependent upon the device connected to the MS board pulse oximeter and the relative locations of each device from the patient, and the relative location of the connected device to the medically used room containing the MS board pulse oximeter. In all circumstance the MS board pulse oximeter must be connected to a grounded AC power supply. The MS board pulse oximeter is referred to as an IEC 60601/F device in the summary of situations table contained in IEC 60601-1-1.

Check alarm limits each time the MS board pulse oximeter is used to ensure that they are appropriate for the patient being monitored.

3 Placing infant and moving BT-550

3.1 Placing infant

(1) Pre-warm infant warmer.

(2) Place the infant in the center of mattress.

(3) Attach the skin temperature sensor to the appropriate part such as abdomen with adhesive tape.

(4) Select the operating mode and set the desired temperature or heater output according to the selected mode.

⚠ WARNING

- Pre-warm the infant before placing infant in the infant warmer under the direction of qualified medical personnel who are familiar with currently known risks and benefits of infant warmer use.
- Do not leave an infant unattended under the infant warmer.

3.2 Move the BT-550

3.2.1 Precautions

(1) Check whether an infant placed in the infant warmer mattress.

(2) Disconnect all cables from stand and remove unused accessories.

(3) For the height adjustable stand, adjust the height to lowest position.

(4) Place the power cord on the device to protect.

⚠ WARNING

- Never move the infant warmer while an infant is placed.
- Push or pull to the direction along the longitudinal of stand to prevent overbalancing.
- The infant warmer should be carried by two persons.

3.2.2 Stand caster lock

At least two casters should be locked before using. To lock the caster, depress the caster lock. To unlock the caster, raise above the caster lock.

Caster unlocked

Caster locked

Figure 2-11: Caster locks

⚠ **WARNING**

- Always keep the caster locked for safety. When the infant warmer placed on the inclined floor, do not leave the infant warmer unattended.

4 Maintenance and cleaning

4.1 Service policy

The repair of infant warmer should be performed qualified service personnel. Contact to Customer Service Department of Bistos when the device fault or malfunctioning.

4.2 Maintenance

It is recommended to have a safety inspection every year regularly for the safe use of BT-550. Refer to the service manual for the inspection items and method.

NOTE: The heater is recommended for replacement every year and a half.

⚠ WARNING

- Do not remove the covers of BT-550 yourself to avoid damage to the infant warmer and unexpected electrical shock. Only qualified Bistos service engineer must repair or replace components.

4.3 Cleaning

Follow the instruction prior to clean the infant warmer.

- Turn off the BT-550 and detach the power cord.
- Detach all accessories from BT-550.
- Cool down the BT-550 for about 30 minutes.
- Use a clean gauze pad or lint-free cloth, lightly moistened with a water or mild detergent, to wipe the surface of BT-550.

⚠ WARNING

- Do not use the conductive or flammable cleaning agent to avoid electric shock, fire or explosion.
- Do not use spray type cleaning agent.
- Do not scrub the display with rough or sharp objects.
- Do not use steam to clean the infant warmer. Excessive steam can damage the infant warmer.
- Avoid using alcohol and strong detergent to bassinet made of acrylic.
- Ensure no part of the warmer or accessories are immersed in any cleaning agents.

4.3.1 Skin sensor

- Clean the sensors with alcohol, or detergent or soap solution.

- Apply the cleaning solution with a clean cloth or sponge, and dry all surfaces after cleaning with a clean soft cloth or paper towel.

⚠ CAUTION:

- Do not immerse, boil, autoclaves or gas sterilize the sensor.
- Avoid soaking in alcohols, strong detergents. Or highly alkaline solutions.
- Ensure the skin sensor is only removed from the controller by grasping the plug at the front panel. Ensure excessive strain is not placed on the sensor lead either during use, cleaning or inspection

4.3.2 SpO_2 sensor

- Clean the sensor by wiping it with a 70% isopropyl alcohol pad or mild detergent.

- Dry the sensor and cable with a clean cloth or dry gauze pad.

⚠ CAUTION:

- Do not immerse the connector of YI cable in any liquid solution.
- Do not sterilize by irradiation, steam, autoclave, Gluteraldehyde (Cidex) or ethylene oxide.
- Carefully read 2.8 SpO2 Monitor(option) for proper use, cleaning or inspection

4.3.3 Mattress

- Clean the mattress with an approved and correctly diluted disinfectant-detergent solution, ensuring the manufacturer's directions for use of the cleaning agent are followed.

- Apply the cleaning solution with a clean cloth or sponge, and dry all surfaces after cleaning with a clean soft cloth or paper towel.

⚠ CAUTION:

Do not autoclaves or gas sterilize the mattress.

5 Trouble shooting

5.1 General

⚠ **WARNING**

- Do not attempt to open the covers, disassemble or modify the infant warmer except the qualified person. It may cause safety hazard. Only the qualified Bistos service engineer must repair or replace the infant warmer or components.

Please check before contact to Customer Service Department of Bistos for following cases

The infant warmer does not turned on	Check the power cord securely connected to power consent
Measured values are not displayed	Check the sensor cable or extension cable correctly connected to appropriate connector. Check the sensor properly operating after connecting the sensor.
Measured values are too high or low	Check the sensor correctly attached to patient. For the weight, check the heavy objects are placed while zero set or measuring.

5.2 Understanding alarm

The following alarms are displayed on the conditions of

Alarm message	Alarm conditions
Power Fail	Power cord was not connected properly or power does not supplied
Sensor Disable	Skin temperature sensor was not connected or measured temperature is too low
S1 (S2) Temp Low	Measured skin temperature is too low
S1 (S2) Temp High	Measured skin temperature is too high
Baby Check	Stay in the Manual Mode more than 12 minutes Heater output remains 100 % in Baby Mode more than 12 minutes
Head Rotation	The head on infant warmer rotated more than 20°
Masimo check Alarm	Refer to the table on page 18

6 Manufacturer's declaration on EMC

BT-550 needs special precautions regarding EMC (Electromagnetic compatibility) and needs to be used according to the EMC information provided in this user manual. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect the BT-550 and should be kept at least 1 m away from the equipment.

6.1 Electromagnetic emissions

The BT-550 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-550 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The essential performance of BT-550 is radiating far infrared onto the skin of a patient from a distance. So there is no intentional or controlled RF emission for it's intended performance. Therefore, its RF emissions are very low and are not likely cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The BT-550 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

6.2 Recommended separation distances between portable and mobile RF communications equipment and the BT-550

The BT-550 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-550 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-550 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

6.3 Electromagnetic immunity

The BT-550 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-550 should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 ㎸Contact ±2㎸, ±4㎸, ±8㎸, ±15㎸ Air	±8 ㎸Contact ±2㎸, ±4㎸, ±8㎸, ±15㎸ Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	230 V~ 50 ㎐ Power supply line, ±2 ㎸ AC, 100 ㎑ PRR	230 V~ 50 ㎐ Power supply line, ±2 ㎸ AC, 100 ㎑ PRR	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	230 V~ 50 ㎐ Power supply line, ±0.5㎸,±1㎸ L1 to L2	230 V~ 50 ㎐ Power supply line, ±0.5㎸,±1㎸ L1 to L2	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100V~ 50 ㎐, 240 V~ 50 ㎐ Power supply line 0 % UT for 0.5 cycle 0% UT for 1 cycle 50 ㎐ : 70 % UT for 25 cycles 60 ㎐ : 70 % UT for 30 cycles 50 ㎐ : 0 % UT for 250 cycles 60 ㎐ : 0 % UT for 300 cycles	100V~ 50 ㎐, 240 V~ 50 ㎐ Power supply line 0 % UT for 0.5 cycle 0% UT for 1 cycle 50 ㎐ : 70 % UT for 25 cycles 60 ㎐ : 70 % UT for 30 cycles 50 ㎐ : 0 % UT for 250 cycles 60 ㎐ : 0 % UT for 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BT-550 image intensifier requires continued operation during power mains interruptions, it is recommended that the BT-550 image intensifier be powered from an uninterruptible power supply.
Power frequency (50 Hz and 60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

The BT-550 is intended for use in the electromagnetic environment specified below.
The customer or the user of the BT-550 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	230 V~ 50 ㎐ Power supply line 3 Vrms, 150㎑ -80㎒ 6 Vrms in ISM Bands between 0.15㎒ and 80 ㎒	230 V~ 50 ㎐ Power supply line 3 Vrms, 150㎑ -80㎒ 6 Vrms in ISM Bands between 0.15㎒ and 80 ㎒	
Radiated RF IEC 61000-4-3	3 V/m, 10 V/m 80 ㎒ to 2.7 G㎐ 80%, 1 ㎑ AM RF Wireless Comm. (Refer to test report clause 1.15)	3 V/m, 10 V/m 80 ㎒ to 2.7 G㎐ 80%, 1 ㎑ AM RF Wireless Comm. (Refer to test report clause 1.15)	

NOTE 1) At 80 MHz and 800 MHz, 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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BT-550 is used exceeds the applicable RF compliance level above, the BT-550 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BT-550.

[b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than **3 V/m.**

7. Technical specifications

Functional Characteristics			
Temperature		Infrared Heater	
Operation Mode (Each of tolerance range is ± 20%)	-Prewarm (100% @28 ㎽/㎠) -Baby mode (100% @ 28 ㎽/㎠) -Manual (100% @ 8 ㎽/㎠)	Manual Control Range	0 ~ 100%, 20levels
Skin Display Range	26 ~ 42°C ±0.3°C	Output Power	600W
Skin Control Range	34 ~ 38°C (in Baby Mode)		
Display		**APGAR**	
Type	7" TFT Color LCD	Setting Range	0sec ~ 59min 59sec
Alarm (Visual & Sound)	6 Events Alarms	Indicating Beep	1, 5, 10min
Examination Lamp		**Function**	
LED	40W(10W x 4ea)	Microprocessor Controlled	
Brightness Control	3levels	Rotation of Head	90° (Left, Light both Directions)
Illumination	> 7,000lx	Tripod Water Level	
Power		**PC Interface**	
Input	AC 100/240, 50/60Hz	RS232C	
Consumption	750VA		
Standard Configuration (Fixed height stand)			
Skin Temperature Sensor	2ea	Mattress	1ea
		Quick guide	1ea
Power Cord	1ea	Operation manual	1ea
Options	**Weight limit or Angle**	**Options**	**Weight limit or Angle**
Lifting Stand		IV Pole	Approx. 5 kg
IV Plate	Approx. 11 kg	Weighing Scale	0 ~ 10.0 kg, ±50g
Basket(Drawer)	Approx. 10 kg	Masimo SpO2	
Basket Partition		Extension for SpO2	
Tilting Bed	±15°, accuracy ± 2°		
Physical Characteristics			
Dimension		Weight	
Standard	1,027(W)x690(D)x1,890(H)mm	Standard	83 Kg
Fixed stand	725(H) mm	Full option	98 kg
Lifting stand	615 ~ 815(H)mm		
Mattress	495(W) x 810(D) x 27(H)mm	with Safe Working Load	Approx. 124kg
Packing	1,150(W)X750(D)x1,550(H)mm	Packing	126Kg(Full Option)
Operation environment		**Storage environment**	
Temperature	18 ~ 30°C (64.4 ~ 86°F)	Temperature	–10 ~ 60°C (14 ~ 140°F)
Humidity	0 ~ 95% non-condensing	Humidity	0 ~ 95% non-condensing
Air pressure	70~106 kPa	Air pressure	70~106 kPa
Standard			
IEC60601-1, IEC60601-1-2 IEC60601-2-21, ISO 80601-2-61			

The following materials are used	
Mattress	Elastomer

Masimo Oximeter		
Range	Saturation (% SpO_2) Pulse Rate (bpm) Perfusion	1% - 100 % 25 – 240 bpm 0.02% - 20%
Accuracy	Saturation (% SpO_2) – During no motion conditions Neonate	 70% - 100%, ± 3 % 0% - 69%, unspecified
	Saturation (% SpO_2) – During motion conditions Neonate	 70% - 100%, ± 3 % 0% - 69%, unspecified
	Pulse Rate (bpm) – During no motion conditions	25 to 240, ± 3 bpm
	Pulse Rate (bpm) – During motion conditions	25 to 240, ± 5 bpm
Resolution	Saturation (% SpO_2) Pulse Rate (bpm)	1% 1

NOTE: Below contents were cited by IFU of Masimo sensor

Arms accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- Arms of the reference measurements in a controlled study.

SpO2 accuracy was determined by testing on healthy adult volunteers with light to dark skin in the range of 70% - 100 % SpO2 against al laboratory co-oximeter. Accuracy specifications are statistically distributed, and only about two-thirds of the measurements fall within the 1 Std. Dev. specification.

Low Perfusion Performance	> 0.02% Pulse Amplitude and % Transmission > 5%	Saturation (%SpO2) ± 2 % Pulse Rate ± 3 bpm
Interfering Substances	Carboxyhemoglobin may erroneously increase readings. The level of increase in approximately equal to the amount of carboxyhemoglobin present. Dyes or any substances containing dyes that change usual arterial pigmentation may cause erroneous readings.	
Power	Voltage Input Range Max. AC power consumption Rechargeable battery	90 – 240 VAC, 47 – 63 Hz 20 VA Up to 7 hours battery life
Fuses	0.75A, Time Delay, 250 V	
Isolation	Chassis Leakage current Ground resistance	Less than 100 μAmp Less than 1.0 Ω
Environment	Operating temperature Storage temperature Relative humidity Operating altitude	41˚F to +104˚F(5℃ to + 40℃) -40˚F to +158˚F(-40℃ to + 70℃) 5% to 95% non-condensing 500 mbar to 1060 mbar pressure -1,000ft to 18,000ft(-304m to 5,486m)
Circuitry	Microprocessor controlled Automatic self-test of oximeter when power on Automatic setting of default parameters Automatic alarm messages Trend data output of SpO2, pulse rate	
Auto indicators	Adjustable volume audible pulse: OFF and 33% to 100% in 4 steps Adjustable volume audible alarm tone: levels and 33% to 300% in 4 steps Alarm silence (120 seconds); all mute (continuous silence) Smart tone ON/OFF: excessive motion and low perfusion conditions pulse tones Pulse rate out-of-limits alarm SpO2 level out-of-limits alarm Sensor conditions alarms	

	System failure and battery low alarms	
Physical characteristics	Dimensions	8.2” x 6.0” x 3.0” (20.8cm x 15.2cm x 7.6cm)
	Weight	2.1 lbs, 32 oz (0.928 kg)
Modes	Averaging mode	2,4,8,10,12,14 and 16 seconds
	Sensitivity	Normal, APOD, and MAX

Product Warranty

Product Name	Infant Warmer
Model Name	BT-550
Serial No.	
Warranty Period	2 Years
Date of Purchase	
Customer	Hospital: Address: Name: Telephone:
Sales Agency	
Manufacture	Bistos Co., Ltd.

※ Thank you for purchasing BT-550.
※ This product is manufactured and passed through strict quality control and inspection.
※ Compensation standard concerning repair, replacement, refund of the product complies with "**Framework Act on Consumers**" noticed by Fair Trade Commission of Republic of Korea.

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