Infant Phototherapy Equipment

BT-450

Operation Manual

Please keep this user's guide for future reference.

P/N: 450-ENG-OPM-EXP-R01

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Intended use/Indications for use

The infant phototherapy equipment, BT-450 is indicated for use to treatment of infants diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes. The devices can be used in a hospital or at home.
The device is designed to use for patient population described in the infant, who is age up to 3 months and weight less than 10kg.

Product Description

Jaundice refers to the yellow appearance of the skin that occurs with the deposition of bilirubin in the dermal and subcutaneous tissue. Bilirubin is the orange-yellow pigment of bile, formed principally by the breakdown of hemoglobin in red blood cells at the end of their normal lifespan.
Normally in the body, bilirubin is processed through the liver, where it is conjugated to glucuronic acid by the enzyme in the liver. This conjugated form of bilirubin is then excreted into the bile and removed from the body via the gut. When this excretion process is low following birth, does not work efficiently, or is overwhelmed by the amount of endogenously produced bilirubin, the amount of bilirubin in the body increases, resulting in hyperbilirubinemia and jaundice.

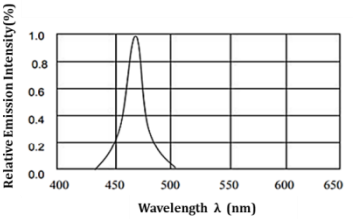


Figure 1. Relative light intensity according to the wavelength of the LED component. This graph is from the datasheet.

In newborns, the lifespan of red blood cells is shorter than that of adults, which makes a lot of bilirubin, the function of an enzyme to conjugate the bilirubin is poor, and the function to excrete bilirubin out of the body is also weak.
Phototherapy refers to the use of light to convert unconjugated bilirubin molecules into water-soluble isomers that can be excreted in bile or urine without the need for conjugation. Bilirubin absorbs light most strongly in the blue region of the spectrum near 460 nm, a region in which penetration of tissue by light increases markedly with increasing wavelength. Only wavelengths that penetrate tissue and are absorbed by bilirubin have a phototherapeutic effect. Lamps with output predominantly in the 460-to-490-nm blue region of the spectrum are probably the most effective for treating hyperbilirubinemia.
The infant phototherapy equipment, BT-450 pad consists of LEDs that emits light of peak wavelength 455 to 465 nm. The microcontroller generates the PWM, and it is rectified to direct current through a resistor and a capacitor. When the rectified PWM is output through the LED driver, the LED can be stably turned on. The intensity of light can be adjusted by changing the duty cycle of PWM, and BT-450 has two types of intensity, high and low.

⚠ **WARNING**	Eye Protection: Do not look directly into the LED. During the treatment, always use a patch or equipment to protect a baby's eyes. Periodically, check the hospital or treatment protocol and makes sure that the baby's eyes are protected from contamination. Patients near the light should use protective pads or equipment to protect their eyes.

Contraindications

It should not be used in cases of congenital porphyria, a family history of porphyria, and treatment with photosensitive drugs or medicines.

1. Safety information

Before using the infant phototherapy equipment, read this entire manual and be fully understood, and follow instructions and safety information to prevent injury.

Symbols and safety sign used:

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

WARNING	Can incur serious injury or death.
CAUTION	Can incur minor injury or product/property damage

The following symbols and safety signs are placed on the product, label, packing, and this manual to stand for the information about:

Symbol	Standard/Symbol Reference no.	Description
	ISO 7010 — Graphical symbols — Safety colours and safety signs — Registered safety signs / W001	Used to display safety information for warnings. Before using the BT-450, please be fully understand the information provided with the device.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.4.4	Used to display safety information for caution. Before using the BT-450, please be fully understand the information provided with the device.
IP21 IP22 IP23	IEC 60529 Degrees of protection provided by enclosures	These indicate the protection level against the ingress of solid objects and liquid. IPX1 is protection against falling water drops vertically. IPX2 is protection against some falling water drops vertically when the enclosure tilted up to 15°. IPX3 is protection against spraying water at any angle up to 60° from the vertical shall. IP2X is protection against solid foreign objects like a finger.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.4.3	Refer to the operation manual. Read the manual before placing the device.
	ISO 7010 — Graphical symbols — Safety colours and safety signs — Registered safety signs / M002	Refer to the operation manual. Read the manual before placing the device.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5032	This symbol means alternating current.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5031	This symbol means a DC power adapter.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied –	This symbol indicates the manufacturer.

	Part 1: General requirements / 5.1.1	
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.3	This symbol indicates the date of manufacture.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.7	This symbol indicates the serial number of the device.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.6	This symbol indicates a reference number.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5172	This symbol means the power adapter is a Class II device.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5333	This symbol indicates the BF applied part. This applies to the Pad.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.4	This symbol indicates to keep the device dry.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.1	This symbol indicates the medical device that can be broken or damaged if not handled carefully.
	ISO 7000 — Graphical symbols for use on equipment -- Registered symbols / 0623	This symbol indicates to keep upright
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.2	This symbol indicates to keep the device away from sunlight.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.7	This symbol indicates the temperature limitation for transport and storage.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.8	This symbol indicates the humidity limitation for transport and storage.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.9	This symbol indicates the range of atmospheric pressure to which the medical device can be safely exposed for transport and storage.
	Universal Recycling symbol	This symbol indicates the packing material is recyclable.
	IEC TR 60878, Graphical symbols for electrical equipment in medical practice	This symbol indicates that always protect the infant's eyes with eye patches or equivalent.

Symbols on the adapter

Symbol	Standard/ Symbol Reference no.	Description of symbol
	IEC 60417 — Graphical Symbols for Use on Equipment / 5172	This symbol indicates that the power adapter is a class II device.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5957	This symbol indicates that the power adapter is for indoor use only.
	UL Mark (200-195S 10M/8/98)	This symbol indicates compliance with both Canadian and U.S. component requirements. (Recognized Component Mark for Canada and the United States)

WARNING

- Check every 2–4 hours the patient's condition including body temperature and skin against hyperthermia, pressure ulcers, water loss, hygiene, etc.
- To minimize the heat between the pad and the patient, the patient should not be wrapped in a thick blanket or wrapped too tightly.
- The patient's body temperature may rise if the patient and pads are wrapped in a material that does not allow heat to escape, such as a thick blanket or clothes. When the temperature warning is on, check the patient's body temperature.
- Not for use with patients greater than 10 kg.
- Do not use the device while bathing the patient.
- Do not use the device near water.
- Do not use the device without a disposable cover.
- Do not use the device with other thermotherapy devices that may affect the patient's body temperature such as incubators, heaters, mattresses, heating blankets, etc.
- During phototherapy, the patient's skin and core body temperature should be monitored.
- Do not use the device with ECG (EKG) device.
- Do not use the device in the presence of flammable materials.
- Class I equipment: There is a risk of electric shock, so this equipment should be connected to a power supply with protective earth.
- If the power rating is inappropriate or the device is connected to an outlet that is not grounded, there is a risk of electric shock or fire. If in doubt about the grounding condition, have an electrician inspect it.
- BT-450 should be used under the direction of appropriately trained personnel and qualified medical personnel who are familiar with the currently known risks and benefits of neonatal jaundice therapy.
- If the normal operation of this device with other devices nearby is not confirmed, the BT-450 cannot be used adjacent to or with other devices.
- Do not touch or manipulate BT-450 with wet hands, as it may cause electric shock.
- If the device falls into water, do not touch any electrical appliances and immediately disconnect the power from the power outlet.
- Do not place the power cable in a place where people or objects frequently move. There is a risk of electric shock.
- Use the BT-450 for neonatal jaundice treatment only as the intended use described in this manual.
- Keep the device out of direct sunlight.
- BT-450 and accessories are not heat resistant. Avoid contact with radiators, open flames, or heated surfaces.
- Supervision is required when using the device near children or pets. Keep all parts out of reach when not in use.

- Eye protection: Do not look directly into the LED. During treatment, always protect your baby's eyes with an eye patch or protective equipment. Periodically, check the hospital or treatment protocol and makes sure that the baby's eyes are protected from contamination. Patients near the light should use protective pads or equipment to protect their eyes.
- Sensitive people may develop headaches, nausea, or mild dizziness if left in the irradiated area for too long. Wearing yellow lens glasses can reduce the potential impact.
- Bilirubin Photo isomers may have toxic effects.
- Water balance: Water balance may be disturbed for some patients.
- Photosensitive Drugs: Irradiation may reduce the effectiveness of light-sensitive drugs. Do not store the medication near light irradiation.
- Flammable gas: Do not use the device near combustible gases. (eg oxygen, nitrogen dioxide, or other anesthetics)
- Power off: When cleaning the light source, always turn off the power and remove the power cable.
- Even an adult may be affected by staying in the light for a long time.
- Do not use flammable solution directly on the LED lamp. The LED lamp may be damaged or its function may deteriorate. For cleaning or maintenance, follow the instructions described in section 7 of this manual.
- Use of other accessories not provided by Bistos Co., Ltd. may degrade the safety and performance of the device, so be sure to use the designated accessories.
- Using a reflective film can cause an increase in body temperature when the film affects a type of phototherapy radiation.
- Blue light might interfere with the clinical management of a patient with cyanosis.
- Infants with increased direct reactions or cholestatic jaundice after receiving phototherapy may develop the bronze-baby syndrome.
- Do not use any damaged parts including the power adapter.
- Before using the device, visually check each part for cracks, folds, tears, discoloration, or deterioration. If damage to the device is observed, discontinue until the part is replaced.
- Do not use the BT-450 for neonatal jaundice treatment near or in combination with other equipment. If you want to use adjacent to or overlapping with devices, you must confirm the normal operation or BT-450.
- Portable RF communication equipment (including peripheral devices such as antenna cables and external antennas) should not be used closer than 30cm (12 inches) to any part of the BT-450, including cables specified by the manufacturer. Otherwise, the performance of this device may be degraded. Wireless home network devices, mobile phones, wireless phones, and wireless communications equipment such as base stations and radios can affect the device and should be used at a distance of 1 m or more.
- This device requires special precautions regarding EMC and must be serviced according to the EMC information provided in this manual.
- Excessive electromagnetic interference may cause the device to generate excessively high or low light levels temporarily. Use the device in an appropriate environment stated in this manual.
- Components other than those approved for use with this device may increase or decrease immunity.
- Do not open the pad cable where there the power is connected. There is a risk of electric shock.
- Do not disassemble the device. The battery can be replaced by disassembling the device by an authorized service person and must be replaced with a battery of the same model and specification.
- Incorrect battery replacement may cause high temperature, fire, or explosion.
- If the device is not used for a long time, the battery must be removed and stored. Charge the battery and store it at room temperature with low humidity.
- Use only the AC/DC power adapter supplied or designated by Bistos. Use of adapters other than those provided or specified by the manufacturer may increase electromagnetic emissions or reduce the electromagnetic immunity of the device, resulting in improper operation.

- Do not place the device where it is difficult to disconnect the adapter.
- Be careful not to let dust or especially metallic objects get into the device.
- Keep away from electric heaters.
- Do not place in a humid or hot place.
- Do not use the device where humidity, temperature, and atmospheric pressure are beyond those specified in this manual.
- Do not place in a hazardous location that leaks chemicals or explosive gases.

⚠ **CAUTION**

- BT-450 is non-transit-operable equipment that can be used at home.
- Lay operators (non-experts, people who are not good at operating the machine) can also operate.
- The patient's condition should be monitored during phototherapy.
- Do not place drugs or liquids around the light source that may be deteriorated by the light source.
- While BT-450 is in operation, wear protective equipment to protect the patient's eyes, and frequently check whether it is properly worn.
- Keep all components dry after cleaning and disinfecting.
- When charging is complete, immediately disconnect the power adapter from the device.
- The battery charging stage displayed on the LCD may differ from the actual battery capacity. Use a fully charged device whenever possible.
- If a low battery status is displayed, charge the battery immediately.
- If you are not using the device for a long time, make sure the battery is fully charged before keeping the device.
- If you use a device that has not been used for a long time, check whether it operates safely before use.
- BT-450 can only be repaired or replaced by qualified personnel.
- Do not use the device outdoors, where aerosol (spray) products are being used, or where oxygen is administered.
- When disposing of BT-450, please follow all laws regarding recycling.
- When disposing of packaging materials, comply with local waste disposal laws and regulations. Keep the packaging material out of reach of children.
- Dispose of or recycle replaced batteries properly according to local regulations.
- Always use accessories provided by Bistos.
- Unpack carefully to avoid damaging the device. Inspect the packaging before unpacking. In case of damage, immediately contact Bistos. Unpack correctly, carefully remove the unit and components from the box and check the list. Make sure there is no damage to the device, and do not use it if it is damaged.
- Excessive pressure on the pad may damage it.
- Use the cover provided only, otherwise, treatment may not be effective due to decreased light output.
- There should be no material (ex. Blanket, clothes, etc.) between the covered pad and the patient. Covered pads should always be on bare skin.
- Patients should always wear diapers. This is especially important for male patients because prolonged exposure to light on the male genitals can be harmful.
- Treatment using the device shall be as directed by the doctor.
- Do not let the device come into contact with liquids.
- Do not throw or shake the device.
- If the device is crushed or damaged, such as a hole, stop using it.
- When charging the device, connect the AC adapter to the control box and charge it until the battery charging stage indicator shows full.

2. Product configuration

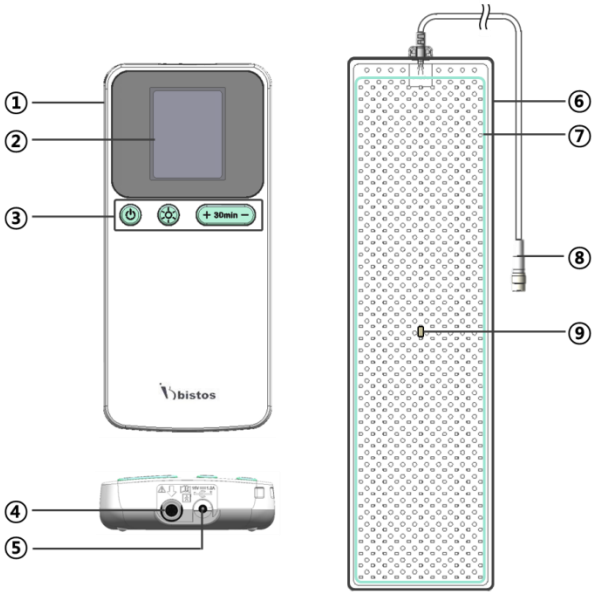
When unpacking, make sure you have all the following items. The eyeshield patch and cover are disposable and the pad is consumable. The standard components are as follows.

Name	User Manual	Power Adapter	Control Box
Shape			
Quantity	1	1	1
Name	Pad	Cover	Eyeshield Patch
Shape			
Quantity	1	1(disposable)	1(disposable)

CAUTION

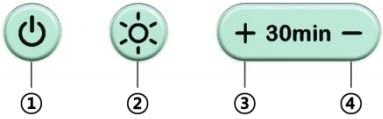
- Use only Bistos accessories.
- Check the consumables for wear or damage before use and replace them if necessary. Do not use them if there are signs of damage or defects.
- The eyeshield patch and cover are disposable, multiple uses are prohibited.
- To maintain optimum performance, it is recommended to replace consumables periodically.

2.1 Description of each part



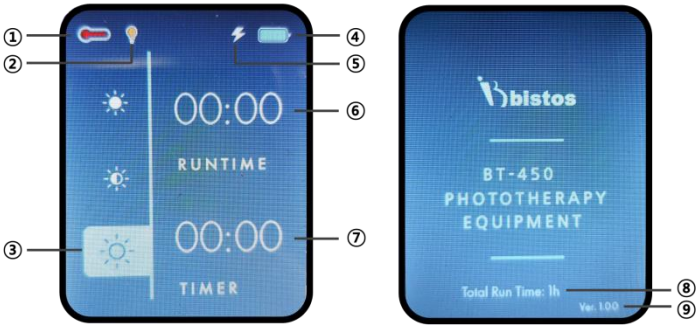
No.	Name	Description
①	Control Box	Has a button to control the device and an LCD display shows the current operation status.
②	LCD display	Shows the current operation status. (Adapter and Battery status, running and remaining time, light intensity, etc.)
③	Operating Button	Power ON/OFF, Light intensity, and operating time can be set.
④	Pad connection terminal	Terminal to connect the pad.
⑤	Power adapter terminal	Terminal to plug in the power adapter for charging.
⑥	Pad	Has a built-in LED module and temperature sensor.
⑦	Light emitting area	Light emitting area from the built-in LED.
⑧	Pad connection part	Part to connect with control box
⑨	Temperature Sensor	Measures temperature in the pad to protect the patient from the heat of the LED.

2.2 Button Description



No	Name	Description
①	Power Button	For power ON/OFF
②	Light Intensity control Button	Sets the light intensity to one of High, Low, and OFF.
③	30-minute increase Button	Increase the scheduled operating time by 30-minutes in timer mode.
④	30-minute decrease Button	Decrease the scheduled operating time by 30-minutes in timer mode.

2.3 LCD Description



No	Name	Description
①	High temperature icon	If the contact part temperature of the pad is high, the pad is automatically turned off before the temperature exceeds 40 °C. The high temperature icon appears on the display.
②	Pad connection icon	If the communication between the control box and the pad is not normal, the pad connection icon appears on the display.
③	Light intensity	Display the current set light intensity (High, Low, OFF).
④	Battery icon	Display the current battery level.
⑤	Charging icon	The charging icon appears when the adaptor charges the device.
⑥	Operating Time	Display the elapsed time from the pad was on.
⑦	Remaining Time	Display the remaining time set in the timer mode.
⑧	Total Usage Time	Display the total usage time from the pad was on for the first time.
⑨	Firmware version	Display the currently downloaded firmware version.

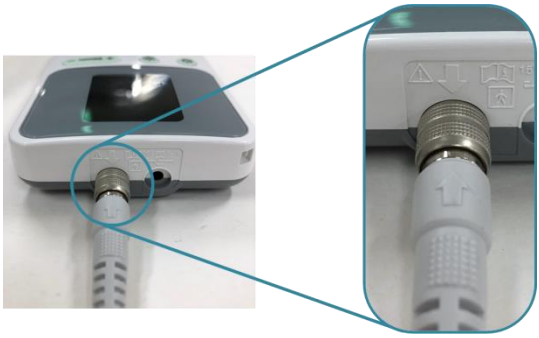
WARNING

- If the high temperature icon appears, turn off the control box and check the patient's body temperature.
- If the low battery information signal is on, connect the adapter to the device.

3. How to use

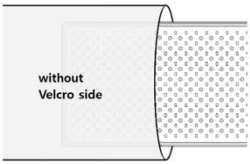
3.1 Preparation before use

① Check the arrow symbols on the pad connector and the control box and then combine them.



NOTE

When disconnecting
: Pull the metal part toward the pad to disengage it.



② Put the pad in the disposable cover. Put the without Velcro side of the cover and the LED side of the pad facing the same side.

NOTE

If the cover gets dirty during use, discard the cover and use a new one. If there is any foreign substance on the pad, it must be cleaned according to “Section 7 Cleaning and maintenance.” before use.

③ Before starting the phototherapy treatment, always shield the baby’s eyes.
Use the certified product (e.g. eye mask/shield) for blue light protection from phototherapy.

WARNING Eye protection: Do not look directly at the LED. During treatment, the baby’s eyes should always be protected with an eye shield or other eye protection device.
Make sure that the baby’s eyes are protected from contamination regularly. Patients near the light should use protective pads or equipment to protect their eyes.

3.2 Patient placement

① Ensure the pad is already wrapped with the disposable cover. As shown in the picture on the left, place the patient into the light emitting area of the pad. When placing the patient on Light pad, be sure the patient’s back and temperature sensor location are aligned.

② Wrap the patient with a pad, fix it with Velcro.

WARNING

- To minimize the heat between the pad and the patient, the patient should not be wrapped in a thick blanket or wrapped too tightly.
- The patient's body temperature may rise if the patient and pads are wrapped in a material that does not allow heat to escape, such as a thick blanket or clothes.
- Do not use the device without a disposable cover.
- Do not use the device with other thermotherapy devices that may affect the patient's body temperature such as incubators, heaters, mattresses, heating blankets, etc.

3.3 Product Operation

3.3.1 Operation mode

Mode	Description
Normal Mode	The pad is on when the timer indicates 0 then the device operates in the normal mode.
Timer Mode	The pad is on when the timer indicates higher than 0minutes; the device operates in Timer Mode. In timer mode, the pad operates as long as the set time. When the set time reaches 0 minutes, the pad turns off. And the maximum setting time is 24hours. The pad automatically turns off after 24hours.

3.3.2 How to operate

(1) Power ON/OFF

1) Press the power button (⏻) for more than 1 second to turn the power ON or OFF.

2) When booting, the total usage time and F/W version are displayed at the bottom of the LCD display.

< Boot screen >

< Basic screen >

(2) Mode setting

1) Normal mode

① Use the 30 minutes decrease button(+ 30min −) to set the Timer 0 minutes.

② Set the light intensity to High or Low by using the light intensity control button(☼).

③ In the normal mode, the power is not automatically turned off, so the user must manually turn off the power.

2) Timer mode

① Use the 30 minutes increase or decrease button(+ 30min −) to set the desired Timer time.

② The timer can be set at a maximum of 24 hours.

③ Set the light intensity to High or Low by using the light intensity control button( ).

(3) Pad output setting

1) When the power is turned on, the status of the pad is OFF.
2) Press the light intensity control button to determine the pad output.
3) Pad output can be set as one of OFF, High, and Low.
(High : 60±10 μW/cm²/nm, Low : 30±10 μW/cm²/nm)
4) When the device power is turned off while the pad output is set to High or Low, this pad output set status is recorded. So when the power is turned on again and presses the intensity control button, the pad output indicates the previous set status.
5) However, when the device power is turned off with the pad output is set to off, the pad output status will indicate High when the light intensity control button is pressed after the device is turned on again.

< Off >

< High >

< Low >

(4) LCD Auto-Off

When there is no button input for 10minutes during use, the LCD turns off but the device is working normally. The LCD is turned on by briefly pressing one of the four buttons.

NOTE

- The charging level indication displayed on the LCD may differ from the actual battery capacity. Make sure that the device is fully charged before use.
- Charge the battery immediately when the low battery warning flashes.
- If the device has not been used for a long time, make sure the battery is fully charged before use.
- Measure the patient's bilirubin level regularly.

4. Alarm

4.1 Alarm condition

(1) High temperature
If the contact part temperature of the pad is high, the pad is automatically turned off before the temperature exceeds 40 °C. The high temperature icon ( ) appears on the LCD display, and the beep alarm sounds until the user turns off the control box.

(2) Low battery
When the battery becomes low, the low battery icon ( ) appears on the display, the beep alarm will sound for 10 seconds, and the control box and the pad will automatically turn off.

(3) Pad connection

If the communication between the control box and the pad is irregular, the pad connection icon ( ) appears on the LCD display. The beep alarm will sound once and the pad turns off automatically. The icon disappears when the control box and the pad are properly reconnected.

4.2 Alarm characteristics

(1) High temperature

- Alarm priority: Low priority
- Audible alarm: Beep-beep
- Alarm icon: The high temperature icon( ) is displayed and blinked until the user turns off the control box.

(2) Low battery

- Alarm priority: Information signal
- Audible alarm: Beep
- Alarm icon: The battery icon( ) is displayed and blinked.

(3) Pad connection

- Alarm priority: Information signal
- Audible alarm: Beep
- Alarm icon: The pad connection icon( ) is displayed.

⚠ **WARNING**	• If the high temperature alarm is on, check the patient's body temperature. • If the patient's body temperature is too high, the pad should be separated from the patient. • When the high temperature alarm sounds, turn off the control box. Use it again after the pad has cooled down sufficiently. • When the temperature information signal sounds, remove the thick blanket or clothes surrounding the pad. • When using the phototherapy equipment, periodically measure the patient's temperature and check it.

5. Precautions for Pad

(1) Before use, measure the output power of the LED using a measuring device according to section 7.1 Brightness check.
(2) Protect the infant's eyes with a protective eye shield designed for use of phototherapy.
(3) The cover is disposable, and multiple uses are prohibited. Replace the cover every 24 hours, between patients, or if soiled, whichever occurs first.

⚠ **WARNING**	Eye protection: Do not look directly at the LED. During treatment, the baby's eyes should always be protected with an eye shield or other eye protection device. Make sure that the baby's eyes are protected from contamination regularly. Patients near the light should use protective pads or equipment to protect their eyes.

(4) Make sure the patient does not get off the pad during treatment. The light intensity decreases when the patient is away from the light source.

⚠ **CAUTION**	There should be no other material (blanket, clothing, etc.) between the covered pad and the patient. Covered pads should always be on a patient's bare skin.

6. Essential Performance(EP)

The infant phototherapy equipment, BT-450 irradiates the blue lights of the following conditions to treat jaundice.

- low Intensity: 30 ± 10 μW/cm^2/nm
- high intensity: 60 ± 10 μW/cm^2/nm

7. Cleaning and maintenance

7.1 Brightness check

Before use, it is recommended to measure the light intensity of the pad using a calibrated measuring device. The light intensity of the pad must be measured with the pad disposable cover on, and the receptor part of the measuring device is directed toward the light emitting area of the pad.

If the intensity is not verified to 60±10 μW/cm²/nm when it is high, and 30±10 μW/cm²/nm when it is low, Pad might need a replacement. Otherwise, it is normally recommended to replace the pad after 3 years of use, based on operating the pad 24 hours a day.

⚠ **WARNING**	Do not open the pad arbitrarily or attempt to change the LEDs. Only qualified personnel should perform service. LEDs that are changed without the manufacturer's permission can influence the safety and effectiveness of phototherapy.

NOTE
The LEDs of the pad are not subject to repair, and if necessary, the entire pad including the LEDS should be replaced. Contact Bistos Service Center.

7.2 Cleaning

(1) Wash

- Before cleaning, turn off the device and disconnect the pad connector.
- Remove residues on the surface of the control box and pad with a soft brush or soft clean-cloth wet with a proper amount of clear water.

(2) Disinfection

- Before disinfection, turn off the device and disconnect the pad connector.
- Clean the surface of the control box and pad with a soft brush or soft clean-cloth wet with a proper amount of 70 ~ 90 % alcohol (Ethanol alcohol or isopropyl alcohol).
- Always follow the hospital's hygiene regulations when handling devices contaminated with bodily fluids or other substances.

⚠ **WARNING**	Disconnect the AC power cable before cleaning. Turn off the device and disconnect the pad connector before cleaning.

⚠ **CAUTION**	Clean the pads before use on a new patient.

8. Troubleshooting

Problem	Solution
The battery cannot be charged.	• Check if the power adapter is properly connected. • If the charging problem persists, replace the power adapter with a new one. • If the charging problem persists, the battery needs to be replaced. Contact Bistos Service Center.
The power does not turn on.	• Check the battery charging status. • Inspect the power button and the outside of the control box for foreign substances.
The control box gets wet.	• Remove the plug of the power adapter from the socket. • Turn off the power of the control box. • Wipe the body with a dry cloth and store it in a warm dry place for at least 12 hours.
LED does not light up.	• Check if the pad is properly connected to the control box. • If parts of the LED module do not light on, the pad needs to be replaced.
The pad connection icon still appears.	• Unplug the pad connector and reconnect it to the control box. • If the pad connection icon still appears, the pad needs to be replaced. Contact Bistos Service Center.

※ If the problem is not solved or have additional questions, contact Bistos Service Center.

9. Manufacturer's declaration on EMC

The Infant Phototherapy Equipment 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 Infant Phototherapy Equipment and should be kept at least 1 m away from the equipment. And it does not suitable for use in an MRI environment.

9.1 Electromagnetic emissions

BT-450 is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Infant Phototherapy Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Infant Phototherapy Equipment is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC61000-3-2	Class A	
Voltage fulctuations /flicker emissionsIEC61000-3-3	Complies	

WARNING

- The Infant Phototherapy Equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Infant Phototherapy Equipment should be observed to verify normal operation in the configuration in which it will be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of adapter other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

9.2 Recommended separation distances between portable and mobile RF communications equipment and the Infant Phototherapy Equipment

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

Rated maximum output power of transmitter [W]	Separation distance according to the frequency of transmitter [m]	
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 2.7 GHz $d = 2.0\sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

For transmitters 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.

NOTE2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

9.3 Electromagnetic immunity

The Infant Phototherapy Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the Infant Phototherapy Equipment should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, relative humidity of at least 30% is recommended.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	The mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	The 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 IEC61000-4-11	0% U_T (100% dip in U_T) for 0.5/1 cycles[a)] 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 23/30 cycles[a)] (for 0.5sec) 0 % U_T (100% dip in U_T) for 250/300 cycles (for 5 sec)	0% U_T (100% dip in U_T) for 0.5/1 cycles[a] 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 23/30 cycles[a] (for 0.5sec) 0 % U_T (100% dip in U_T) for 250/300 cycles[a] (for 5 sec)	The mains power quality should be that of a typical commercial or hospital environment. If the user of the Infant Phototherapy Equipment requires continued operation during power mains interruptions, it is recommended that the Infant Phototherapy Equipment is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	30 A/m, 50 or 60 Hz	30 A/m, 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.
[a] For example 10/12 means 10 cycles at 50Hz or 12 cycles at 60Hz

Immunity test	Test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz Outside ISM bands[a)] 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands 80% AM at 1kHz	3 Vrms 150 kHz to 80 MHz Outside ISM bands[c] 6 Vrms 150 kHz to 80 MHz in ISM [c] and amateur radio bands 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Infant Phototherapy Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ IEC 60601-1-2 : 2007 $d = 1.2\sqrt{P}$ 80 MHz ~ 800 MHz $d = 2.3\sqrt{P}$ 800 MHz ~ 2.7 MHz IEC 60601-1-2:2014 $d = 2.0\sqrt{P}$ 800 MHz ~ 2.7 MHz where P is the maximum output power rating of the transmitter (W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80%, 1 kHz AM	10 V/m 80 MHz to 2.7 GHz 80%, 1 kHz AM	

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 Infant Phototherapy Equipment is used exceeds the applicable RF compliance level above, the Infant Phototherapy Equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Infant Phototherapy Equipment.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.
[c] The ISM(industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

WARNING

- Excessive ambient EM (Electromagnetic) DISTURBANCES can cause the pressure of the unit to be temporarily excessively high or low. Please use in environments below the above test standards.

10. Product Specifications

Function			
Category		Infant Phototherapy Equipment for Neonatal Jaundice Treatment	
Light source	Light intensity	With the disposable cover on the pad, High : 60±10 μW/cm²/nm Low : 30±10 μW/cm²/nm	
	Effective light emitting area	412 mm x 102.7 mm	
Display		Format	2.4" TFT Color LCD
		Light intensity Level	Picture
		Operating time	Hours display (hour: minute)
		Battery charging	3 steps
Function		Mode	- Normal Mode - Timer Mode
		Pad temperature measurement	

Auditory information		
	condition	Volume
Alarm	High temperature	43 ± 1 dBA
Information signal	Low battery	43 ± 1 dBA
	Pad connection	43 ± 1 dBA

Power		
Power adapter	For electrical safety, a power adapter complying with IEC 60601-1 must be used.	
	Manufacturer : Dongguan Shilong Fuhua Electronic Co., Ltd. Model : UES18LCP4-150120SPA	Input : (100 to 240) V~, 50/60 Hz, 500 mA Output : 15 Vdc, 1.2 A
	11.1 V Li-ion Polymer 4000 mAh	
	Operation time: 10 hours	
	Charging time: 4 hours	
	Maximum charge/discharge cycle: 300 times (based on initial charge capacity 80%)	

Standard configuration	
User Manual	1EA
Control box	1EA
Pad	1EA
Power adapter	1EA
Disposable cover	1EA
Eye Shield Patch	1EA

Environmental conditions	
Operation	
Operating temperature	15 °C to 30 °C (59 °F to 86 °F)
Operating humidity (R.H.)	5 % to 85 % non-condensing
Atmospheric pressure	70 kPa to 106 kPa
Storage and Transport	
Storage temperature	-20 °C to 60 °C (-4 °F to 140 °F)
Storage humidity (R.H.)	0 % to 95 % non-condensing
Atmospheric pressure	70 kPa to 106 kPa

Dimension and weight	
Size	
Control box	84 mm x 184 mm x 27 mm
Pad	123 mm x 459 mm x 12 mm
Weight	
Control box	360 g
Pad	510 g

IP rating	
Control box	IP 21
Pad	IP 23
Power adapter	IP 22

Product Warranty

Product name	Infant Phototherapy Equipment
Model	BT-450
Product name	
Manufacturing Certification	
Serial number	
Date of manufacture	
Packing unit	1 pc
Warranty period	・Control box and adapter: 1.5years from the manufacturing date. ・Battery: 6 months from the manufacturing date (excluding batteries consumed over time) ・Pad: 8 months from the manufacturing date. ・The manufacturing date is based on the date indicated on the BT-450 control box label.
Purchase date	
Customer Information	・Name : ・Address : ・Contact :
Seller	
Manufacturer	Bistos co., Ltd.

※ Thank you for purchasing the Infant Phototherapy Equipment.
※ This product has passed strict quality control and inspection.
※ The compensation standard for repair, exchange, and refund of this product is subject to the Fair Trade Commission's "Consumer Basic Law."

Service Contact

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