

Phototherapy

BT-400



- 100,000 hours operating time
- High intensity with efficient treatment
- 2.4" TFT color LCD display
- Operating and total using time display
- 2 levels adjustable intensity
- Timer function

Specifications : BT-400 Phototherapy

Functional Characteristics			
Light Source		Function	
Type	Blue LED (8ea)	Uniform Distribution Intensity	
Wavelength	Peak Between 450 ~ 475nm	Intensity (at 40cm)	Low : 25 ~ 35 μ W/cm ² /nm
Variation in Intensity	\pm 10% (over 6hrs)		High : 35 ~ 55 μ W/cm ² /nm
Effective Surface Area	40 x 20cm	Timer	30min ~ 999hrs/30min
LED Life Time	100,000hrs	Operating & Total Using Time Display	
Display			
LCD	2.4" TFT Color LCD		
Power			
Voltage	Input : AC 100 ~ 240V (50/60Hz)	Consumption	70VA
Standard Configuration			
Power Cord	1ea	Operation manual	1ea
Eye Shielder	2ea		
Options			
Cart		Shade	
Warranty			
Main Unit	2years		
Physical Characteristics			
Dimension		Weight	
Main Unit	340(W) x 210(D) x 75(H)mm	Main Unit	3.6Kg
Main Unit Packing	580(W) x 305(D) x 250(H)mm	Main Unit Packing	5.1Kg
Cart	326(W) x 276(D) x 96(H)mm	Cart	8.4Kg
Cart Packing	560(W) x 450(D) x 180(H)mm	Cart Packing	9.5Kg
Environmental Conditions			
Operating Temperature	10 ~ 40°C (50 ~ 104°F)	Storage Temperature	-20 ~ 60°C (-4 ~ 140°F)
Operating Humidity	5 ~ 85% non-condensing	Storage Humidity	0 ~ 95% non-condensing
Certificates			
Certificates	KFDA, CE, FDA	Standard	IEC60601-1, IEC60601-1-2 IEC60601-2-50

• Easy to Use

- Flexible Arm and Neck
- Swivel Head
- 2.4" TFT color LCD display



Allow a main unit to move vertically to provide a proper treatment



Treatment timer & adjustable intensity

• Various Installation with Cramp

- Cart
- I/V Pole
- Incubator
- Others



Main Unit with Cart

Main Unit



Main Unit with I/V Pole

Cart (option)



Main Unit with Incubator

* All specifications can be different by country and are subject to change without notice.



Total Health care for everyone

Product

- | Fetal Monitor
- | Fetal Doppler
- | Patient Monitor
- | Vascular Doppler
- | Head lamp
- | Phototherapy
- | Infant Incubator

Fetal Monitor

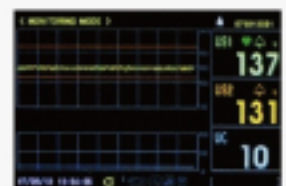


BT-350 LCD Monitor / LED Monitor

- ◆ 7" TFT color LCD / Large size LED
- ◆ Desktop & Wall mount
- ◆ Display mode variation
 - Graph mode, Number mode, Trend mode
- ◆ Multi language support : 12 Languages
- ◆ Trend : 450 hours (3 hours/patient)
- ◆ Diagnosis function



BT-350E



BT-350L

BT-300 LED Monitor

- ◆ Clear display & Sound
- ◆ Compact & Light (Extreme mobility)
- ◆ Easy to use each function
- ◆ High sensitivity ultrasound probe
- ◆ Carrying bag



Carrying bag



Acoustic stimulator



Specifications		BT-300	BT-350E	BT-350L
FHR	US Frequency		1 MHz	
	FHR Range		30 ~ 240bpm	
FM			Auto-detection & Print	
UC			Range : 0 ~99	
Printer	Type		Thermal Array Type	
	Speed		1,2,3cm/min, high	
	Auto Print (min)		Off, 10,20,30,40,50,60	
Function			FHR II Offset	
Power			Auto FM Print	
Warranty			AC 100 ~ 240V (50 ~ 60Hz)	
Display		LED	LED	7" color LCD
Diagnosis		-	-	0
Others	Multi-language	-	-	0
	Trend(Data Save)	-	-	450hours
Central monitoring system			BCM-350 (RS-232C / Bluetooth)	
Option			Rechargeable battery, Acoustic stimulator	

Fetal Doppler



BT-200S



BT-200L / 200T



BT-200C

BT-200 Sound / Mono / Color

- ◆ FHR LCD / OLED display
- ◆ High quality sound
- ◆ High sensitivity probe (2,3MHz)
- ◆ Hand-held style
- ◆ Low battery indicator
- ◆ Waterproof Probe



Black

White

Blue



BT-220S



BT-220L



BT-220C

BT-220 Sound / Mono / Color

- ◆ 2.4" Color LCD display
- ◆ Acoustic stimulator
- ◆ Air Temp. & Humidity
- ◆ Body fat analysis
- ◆ Mother HR function
- ◆ Rechargeable battery (optional)
- ◆ Variable choice of color
- ◆ Waterproof Probe



BT-250 Desktop Doppler

- ◆ 3.2" Color LCD display
- ◆ Data Save : 4 Hours
- ◆ Multi languages support
- ◆ Built-in rechargeable battery
- ◆ High quality sound
- ◆ High sensitivity(2MHz)
- ◆ Compact & Light
- ◆ Waterproof probe

Specifications	BT-200S	BT-200L	BT-200C	BT-200T	BT-220S	BT-220L	BT-220C	BT-250
US Frequency	2 MHz		3 MHz		2 MHz			
FHR Range	-	50~240		-	30~240			
Display	-	Mono	Color	Mono	-	Mono	2.4" TFT	3.2" TFT
Battery Time (hours)	6						4	5
Power	1.5V AA battery							100~240V
Trend	-	-	-	-	-	-	○	○
Acoustic Stimulator	-	-	-	-	○	○	○	-
Body Fat Analysis	-	-	-	-	-	-	○	-
Mother HR	-	-	-	-	-	-	○	-
Air Temp. & Humidity	-	-	-	-	-	-	○	-
Rechargeable Battery	Option							○

Patient Monitor



BT-750 Multi-parameter Patient Monitor

- ◆ 10.4" Color LCD display
- ◆ ECG(2ch), SpO₂, NIBP, Temp.(2ch), IBP, RESP.
- ◆ PVC and ST level display Pacemaker detection
- ◆ Detection of 12 kinds of arrhythmia
- ◆ Trend : 72 hours
- ◆ Central monitoring system (LAN)



BT-700 Vital Sign Monitor

- ◆ 3.2" LCD display
- ◆ SpO₂, NIBP, Temp.
- ◆ Trend : 4 hours
- ◆ Compact and light
- ◆ Easy F/W upgrade (USB)
- ◆ Apply nurse call state
- ◆ SpO₂ – (700S)
NIBP – (700N)
SpO₂+NIBP – (700)
Temperature – (optional)

Specifications		BT-700	BT-750
Display		3.2" color LCD	10.4" color LCD
Battery Operating Time		3 hours	3 hours
SpO ₂	Measuring Range	0 ~ 100%	0 ~ 100%
	Pulse Rate	70 ~ 100% ±3 20~250 bpm ±3	70 ~ 100% ±3% 20 ~ 300 bpm ±2%
NIBP	Measuring Mode	Auto, Manual, STAT	Auto, Manual, STAT
	Auto Mode(min)	1,2,3,4,5,10,15,30 45,60,90,120,240	1,3,5,10,30,60,90,120, 240
	Adult Systolic	30 ~ 250mmHg	50 ~ 255mmHg
	Adult Diastolic	20 ~ 210mmHg	30 ~ 220mmHg
	Adult Mean	20 ~ 235mmHg	40 ~ 235mmHg
	Neonate Systolic	20 ~ 120mmHg	30 ~ 130mmHg
	Neonate Diastolic	10 ~ 100mmHg	20 ~ 100mmHg
ECG	Neonate Mean	10 ~ 110mmHg	25 ~ 120mmHg
	Lead	-	3/5 leads
	HR Range	-	20 ~ 300 ±3%
Resp	Sweep Speed	-	12.5, 25, 50 mm/s
	Method	-	Transthoracic impedance
	Range	-	0 ~ 150 breaths/min
Temp	Sweep Speed	-	6.25, 12.5, 25 min/s
	Range	-	30 ~ 45°C ±0.1°
Options			
Temp		30 ~ 45°C ±0.1°	-
Printer		-	2", 50mm/s
IBP		-	2 channels
EtCO ₂		-	0

BT-200 Vascular Doppler



- ◆ Compact and light
- ◆ High-Sensitive Doppler Probe
- ◆ 4 Ranges of probes
- ◆ Easy to use
- ◆ Low power consumption
- ◆ Long time continuous use (6 hours)

Specifications	BT-200V
US Frequency	4, 5, 8 MHz
HR Range	50 ~ 240 bpm
Power	1.5V AA Type Battery
Battery Using Time	6 hours

BT-410 LED Head Lamp



Full set



Astral lamp



Loupe

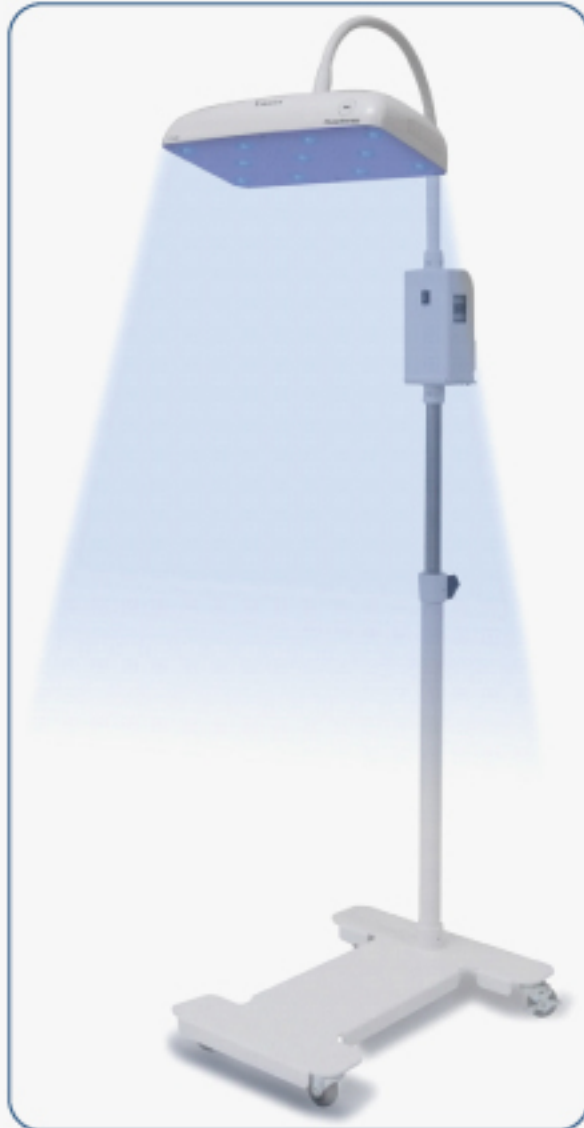


- ◆ Light & comfortable
- ◆ Low battery display
- ◆ Quick battery recharge
- ◆ Ultra bright LED
- ◆ Easy to adjust Head band
- ◆ More than 50,000 hours LED life
- ◆ loupe (Optional)
- ◆ Astral Lamp (Optional)

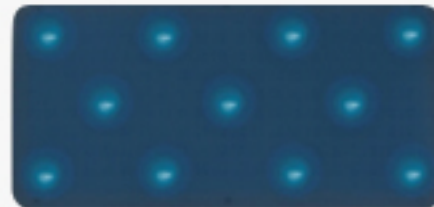
Specifications	BT-410
Illumination	30,000 lux / 50,000 lux (with astral lamp)
Color temperature	6,000 Kelvin
Battery Module	Output : 3.7V Operating time : 4 hours Service life : 800 cycle Capacity : 2,200 mA
Charger	Type : Li-ion (built-in protected circuit module) Input : AC 100 ~ 240v, 50 / 60 Hz Output : DC 4.2V / 750 mA Charging time : 4 hours Battery pack(1cell), Charger, Manual
Standard Accessory	
Optional Accessory	Astral lamp, Loupe (3x), additional battery

Phototherapy

BT-400 Phototherapy



- ◆ Lamp : Blue LED
- ◆ High Intensity of Radiation
- ◆ Long life time (about 20,000 hours)
- ◆ Compact design
- ◆ Flexible geese neck
- ◆ Wide effective area
- ◆ Time counter
- ◆ Easy to Use



Power 11 LED



Time Counter & Clamp



Cart (optional)

Specifications	BT-400
Light Source	Intensity : 55 ~ 130 $\mu\text{W}/\text{cm}^2/\text{nm}$ Variation in intensity over 6 hours : < 10% Life time : about 20,000 hours Effective area : 40 x 20 cm Wave Length : Peak between 450~475 nm
Power	Input : AC 100 ~ 240V (50/60Hz) Consumption : about 80VA
Heat Output	Over 6 hours : < 10°C
Time counter	Operating time, Total operating time
Audible Noise	< 60dB
Dimension	Main unit : 7.5cm(H) x 34cm(L) x 21cm(D) Cart : 120cm(H) x 43cm(L) x 52cm(D)
Warranty	2 years
Optional Accessory	Cart, Eye shielder

BT-500 Infant Incubator



Full set

- ◆ Stable Air / Skin temperature control
- ◆ Accurate humidity control
- ◆ Comfortable & soft tilting structure
- ◆ 7" Color LCD Display
- ◆ Powerful Lifting cart (optional)
- ◆ SpO2 / O2 Monitoring (optional)



Control unit



SpO2 & Camera



Humidifying module



X-ray tray

Specifications	BT-500	
General	Display : 7" color TFT LCD Double wall hood Weight : 55 kg (exclude stand) Mattress tilt : 12° Air velocity : below 10cm/s (at 10cm above the center of ,mattress)	
Dimension	Main body : 102cm(W) x 61cm(D) x 76cm(H) Mattress : 73cm(W) x 39cm(D) x 27cm(H)	
Air temperature	Normal mode : 23.0°C ~ 37.0°C ±0.3°C (Override mode : 37.1°C ~ 39.0°C ±0.3°C)	
Skin temperature	Normal mode : 35.0°C ~ 37.5°C ±0.3°C (Override mode : 37.6°C ~ 39.0°C ±0.3°C)	
Humidity	Setting range : 40 ~95% (display : 15~99% ±5% RH) Hybrid control : Ultrasonic & Steam humidity	
Option		
Fixed stand	-Dimension : 100cm(W) x 81cm(D) x 80cm(H)	-Weight : 36 kg
Lifting stand	-Dimension : 100cm(W) x 81cm(D) x 62 ~ 82cm(H)	-Weight : 40.5 kg
Weighing scale	Measurement : 0~10Kg ±50g	
SpO2 & CCD Camera	SpO2 Range : 1%~100% ±2 digit (MASIMO module) CCD resolution : 510 x 492 pixel	
O2 Module	Measurement range : 18% ~ 100% ±5%	
TV plate	-Dimension : 40cm x 32cm	-Weight limit : 11kg
Shelf	-Dimension : 33cm x 20cm	-Weight limit : 3kg



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BT-400

Neonatal Phototherapy unit

Operation Manual



BT-400

Keep this manual for future reference

P/N: 400-ENG-OPM-EUR-R12

Proprietary Material

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Section 1

Safety Information

1.1 Instructions for the Safe Operation and Use of BT-400



- BT-400 should be used only appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known risks and benefits of infant phototherapy equipment use.
- Do not attempt to service the BT-400. Only qualified service personnel by Bistos Co., Ltd. should attempt any needed internal servicing.
- The BT-400 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.
- Only the AC cord supplied with the BT-400 is approved for use with the Unit.
- Monitoring the patient's status while receiving phototherapy.
- Due to photo effects, drugs and infusion liquids shall not be stored in the radiation area.
- Do not touch the equipment with wet hand. There is a risk of electrical shock.
- Do not leave the power cable in the place where people or cargo passes through frequently. There is a possibility that product or person trips on a cable.
- While BT-400 is operating, use the eye shield or blindfold to protect eye when the light for the treatment illuminates other patients. And please check frequently that it has been worn properly.
- When the equipment is about to exceed the useful life, it must be treated in accordance with relevant local laws and regulations or the hospital's rules and regulations.
- Please unpack carefully to prevent damage. Before unpacking, carefully inspect the package. If any damage, please immediately contact the Bistos. Unpack in the correct way, carefully remove the monitor and accessories from the box and check with the packing list. Check if there is any mechanical damage. When the device is damaged, do not use it.


1.2 General Safety Information


Before administering phototherapy, read all section of this manual carefully. Observe all precautions to ensure the safety of the patient and those near the instrument.


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 BT-400. When used in conjunction with the following words, the symbols indicate:


 Warning	Be informed that it may cause serious injury or death to the patient, property damage, and material losses
 Caution	Be informed that it may cause no harm in life but lead to injury
NOTE	Background information provided to clarify a particular step or procedure.


 Warning!	CLASS I ME EQUIPMENT - To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
---	--

 Warning!	BT-400 should not be used adjacent to or stack with other devices, unless verification of normal operation is completed.
---	--

 Warning!	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 effect medical electrical equipment.
---	---

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

 Warning!	Eye protection: Do not look directly into the LEDs. During treatment, always protect the baby's eye with patches or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection. Patients adjacent to the light may also need to be protected with eye patches or equivalent.
---	---

 Warning!	Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area. Wearing glasses with yellow lenses can alleviate potential effects.
---	--

**Warning!**

Photoisomers: Bilirubin Photoisomers may cause toxic effects.

**Warning!**

Water balance: Some patients' water balance may be disturbed.

**Warning!**

The unit can be tumbled at surface inclined more than 10 degrees.

**Warning!**

Photosensitive Drugs: The light generated can degrade photosensitive medications. Do not place or store any drugs near or in the illuminated area.

**Warning!**

Combustion gases: Do not use the light in the presence of gases that support combustion (for example, oxygen, nitrous oxide, or other anesthetic agents).

**Warning!**

Disconnect electrical power: Always switch off the power and disconnect the power cord when cleaning the light.

**Warning!**

Even though she/he is an adult, the operator may experience some effects if she/he stays longer in the area irradiated by phototherapy

**Warning!**

Do not use flammable solution directly to the LED lamps. It may cause of degradation or damage on the LED lamps. For cleaning or maintenance, please follow the instruction described in Section 6 of this manual.

**Warning!**

Incorrect use of the LED, or the use of parts and accessories that are not manufactured or supplied by Bistos Co., Ltd can damage the light, and may cause injury to the patient and/or user.

**Warning!**

When attaching light to any floor stand, other than Bistos Roll Stand, confirm weight capacity of stand.

**Warning!**

Use of reflective foils may cause hazardous body temperatures when the type of phototherapy influences radiation.

**Warning!**





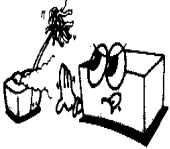





Blue light can hinder clinical observations by masking skin color changes, such as cyanosis.

**Warning!**



















Infants who receive phototherapy and have an elevated direct-reacting or conjugated bilirubin level (cholestatic jaundice) may develop the bronze-baby syndrome.

1.3 General precaution on environment






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

	<p>Avoid placing in an area exposed to moisture. Do not touch the equipment with wet hand.</p>		<p>Avoid exposure to direct sunlight</p>
	<p>Avoid placing in an area where there is a high variation of temperature. Operating temperature ranges from 10°C to 40°C. Operating humidity ranges from 5% to 85%.</p>		<p>Avoid in the vicinity of Electric heater</p>
	<p>Avoid placing in an area where there is an excessive humidity rise or ventilation problem.</p>		<p>Avoid placing in an area where there is an excessive shock or vibration.</p>
	<p>Avoid placing in an area where chemicals are stored or where there is in danger of gas leakage.</p>		<p>Avoid dust and especially metal material into the equipment.</p>
	<p>Do not disjoint or disassemble the equipment. BISTOS Co., Ltd. does not take responsibility of it.</p>		<p>Power off when the equipment is not fully installed. Otherwise, the equipment could be damaged.</p>

1.4 Meaning of Symbols

Symbol	Meaning
	The wrong operating and controlling the device might be cause an undesirable consequence.
	Refer to operation manual. Read manual before placing the device.
	Always protect the Infant's eyes with eye patches or equivalent. - IEC 60878
	This symbol indicates that BT-400 can overbalance when in any transport position on a plane inclined at an angle of 10° from the horizontal plane.
	Never step on surface of device.
	This symbol indicates the manufacture.
	This symbol indicates manufacturer's serial Number of device.
	This symbol indicates the production date
	This symbol indicates the Authorized Representative in European Community of manufacturer.
	This symbol indicates to keep the device dry.
	This symbol indicates the correct upright position of package.
	This symbol indicates the device is fragile.
	This symbol indicates that the device contains an object which is capable of being recycled.
	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 maximum number of identical packages which may be stacked on one another.
	This symbol indicates the maximum stacking load permitted on the transport package.
	The product is in conformity with European Medical Directive 93/42/EEC. This has been verified by a notified body.

1.5 Button symbols

Symbol	Meaning
	Power ON/OFF
	Add an hour setting time in Timer mode
	Remove a half-hour setting time in Timer mode
	Stop the device and keep power ON
	LED Control(ON, Intensity control, Pause)

Section 2

Product Description

BT-400 **Phototherapy Unit** consists of two parts – Phototherapy light source (Main Body) and the Roll stand.

2.1 Intended Use

BT-400 Phototherapy light is intended for treatment of neonatal hyperbilirubinemia. The light can be used for infants in a bassinet, incubator, open bed, or radiant warmer. The equipment is useful for an infant who is up to the age of three months and a weight less than 10 kg.

Note

Before use, read this entire manual carefully. There are safety considerations that should be read and understood before use

2.2 Physical Characteristics

BT-400 Phototherapy Unit is a floor-standing, mobile phototherapy light that delivers a narrow band of high-intensity blue light via blue light emitting diodes(LEDs) to provide treatment for neonatal hyperbilirubinemia.

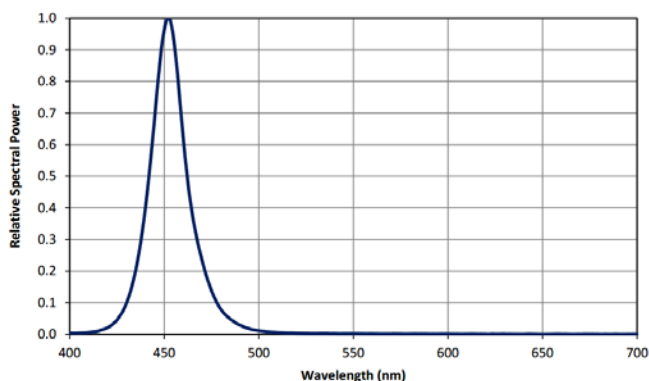
2.3 Operating Principle

- Light Source(Main Body)

The light consists of a lightweight plastic light enclosure and power assembly. When used with the Roll Stand, the light can be adjusted both horizontally and vertically on the roll stand assembly.

The Phototherapy light can be used independently from the Roll Stand. In this case, joint assembly can be used to fix the light source.

Blue LEDs emit light in the range of 400 – 550 nm (peak wavelength 450 – 475 nm).



This range corresponds to the spectral absorption of light by bilirubin, and is thus considered to be the most effective for the degradation of bilirubin.

Blue LEDs do not emit significant energy in the ultraviolet (UV) range of spectrum, so there is no concern about UV exposure to infant.

In addition, Blue LEDs do not emit significant energy in the infrared (IR) range of spectrum, so there is no concern about IR exposure and excessive warming of the infant.

When using phototherapy, protective eyeshades must be used to protect the infant's eyes from excessive light exposure.

**Warning!**

Eye protection: Do not look directly into the LEDs. During treatment, always protect the baby's eye with patches or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection. Patients adjacent to the light may also need to be protected with eye patches or equivalent.

LEDs have minimal light output degradation over their lifetime with proper use. The light is expected to operate as specified approximately 100,000 hours.

2.4 Contraindication

Phototherapy is contraindicated in infants with congenital porphyria or a family history of porphyria and those treated with photosensitizing drugs or agents.

2.5 Configuration



Main unit: Main Body+Control part Roll Stand(Optional) Disposable eye shield patch

2.6 Appearance of BT-400

The BT-400 phototherapy system includes the components shown in the following figure.

2.6.1 Description of Each Part of BT-400

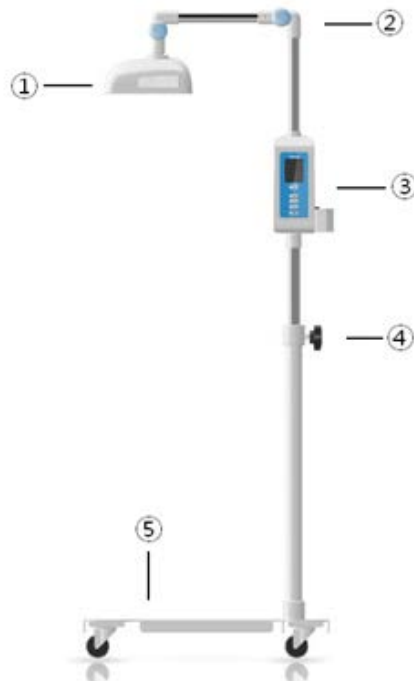


Fig1. Main Unit and Roll Stand

- ① Light Source: The light can be adjusted both horizontally and vertically on the roll stand assembly to desiring angle.
To remove the light from the roll stand, loosen the knob and lift the light source assembly up and away from the roll stand.
- ② Adjustable Neck
- ③ Control Box (Power Assembly): It contains power switch, key button and LCD displays. Especially, LCD window shows operating hours, status and information.
- ④ Height Adjustment Knob: The knob allows you to adjust the height of the light source.
First loosen the knob, then adjust the height of the light, and finally tighten the knob to lock the height.
- ⑤ Roll Stand (Optional)

⚠ Caution!

When you use roll stand, please fix it by using the locking device that is attached to casters. Otherwise, personal injury or equipment damage could occur.

2.6.2 Description of Display and Control part of BT-400



Fig1. Display and control part




- ① LCD: Display the status information.
- ② Power button: Power ON/OFF.
- ③ Operating button : Time Setting and intensity of LED lights Control

Section 3

Installation and Connection

3.1 Installation

The System consists of two products shipped in two separate boxes. One box contains the light source assembly and the other box contains the Roll Stand. Refer to assembly instructions enclosed in the Roll Stand.

	<p>1. Check the components</p>
	<p>2. To combine the main unit and roll stand, screw the 5mm M5 hexagonal bolt clockwise using 2.5 mm wrench</p>
	<p>Note: Be sure to check the mounting normal direction. Main body is possible to adjust the height and rotate by using hinge structure. Please be used with fixed position to the correct direction.</p>

To install the BT-400 in desired place, you should lock the two casters on the stand. To lock a caster, lower the stopper on the caster to the locking position. To unlock a caster, raise the stopper.

⚠ Caution!

You should lock the casters on the roll stand. If you lose the balance of the equipment, personal injury or equipment damage could occur.

3.2 Power Connection

The following figure shows the power assembly.



The device is required an AC power source of 100V to 240V and 50/60 Hz as an input power source.

- 1) While tilting the clip for fixing cables to the side, plug in the power cord into the inlet of the device.
- 2) Fasten the clip again to prevent the breakaway of power cord.

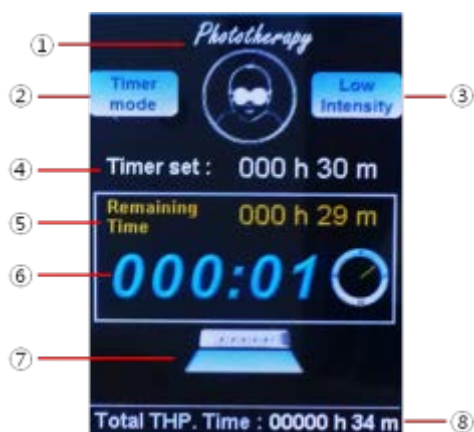
 **Warning!**

Disconnect electrical power: Always switch off the power and disconnect the power cord when cleaning the light.
Only the AC cord supplied with the BT-400 is approved for use with the unit.
Do not connect the power cord with wet hands.

Section 4 Operation

4.1 Operating Method for Control part

4.1.1 Display



No.	Item
①	Phototherapy Baby Icon
②	Mode Information
③	Operating Information
④	Setting Time
⑤	Remaining Time
⑥	Operating Time
⑦	Operating Status
⑧	LED Driving Time

4.1.2 Icons


Item	Icon	Meaning
Mode information		Continuous mode
		Timer mode
Operating Information		LED OFF
		LED High intensity (maximum)
		LED Low intensity (minimum)
		LED pause
Operating Status		LED OFF and pause
		LED maximum intensity
		LED minimum intensity

4.1.3 Operating Mode

Mode	Meaning
Continuous Mode	LED status is ongoing until the user stops the device.
Timer Mode	LED operating is stopped automatically after setting time.

4.1.4 Operating Method

(1) Power ON /OFF

- 1) Turn on or off the power by pressing  button.





<Booting screen>



<Initial screen after booting>

(2). Mode setting

1) Timer mode

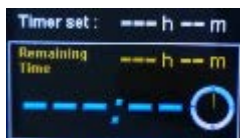
- ① Set the operating time by pressing  or  button.
- ② LED is stopped automatically after setting time.



<Timer mode screen>

2) Continuous mode

- ①  buttons can be used to enter the Continuous mode.



<Continuous mode screen>

(3) LED Control

1) LED ON

- ① In LED OFF or pause status, LED can be on high intensity by pressing **Intensity** button.



2) Intensity Control

- ① In LED ON(maximum intensity), LED intensity can be changed to low by pressing **Intensity** button.



3) Pause

- ① In LED ON(low intensity), LED and Timer can be paused by pressing **Intensity** button.



4) Stop

- ① Off the LED and initialize the operating and setting time by pressing **Reset** button.
- ② Timer mode is automatically switched to Continue mode.



(4). LED Operating Time Initialization

- 1) Press **Reset** and **Power** buttons at the same time when the device is OFF.
- 2) Then, LED operating time is initialized with turning the device ON.

4.2 Operating Method for Light Source

1. Check Intensity: Before use, check the intensity of the light using a spectrophotometer. The light provides the range of intensity from $25 \mu\text{W}/\text{cm}^2/\text{nm}$ to $55 \mu\text{W}/\text{cm}^2/\text{nm}$ at 40cm(16 inches) distance from the baby.
2. Prepare infant: Infant may lie in an open crib, a bassinet, an infant incubator, or under an infant radiant warmer.



Warning!

The infant's body temperature may be increased a bit when BT-400 is used in combination with the warming therapy devices such as the infant incubator, infant transport incubators an infant radiant warmer or devices supplying heat via blankets, pads or mattress.

Please note that the use of the baby controlled mode of these warming therapy devices is recommended when BT-400 is used in combination with one of these devices, otherwise the set air temperature or the heater output of these warming devices has to be reduced according to the body temperature measurements.

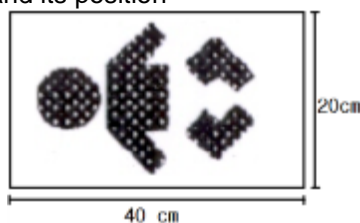
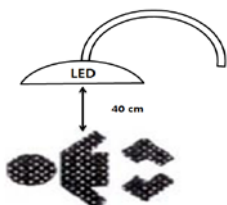
3. Shield infant's eye with protective eye shields designed for use during phototherapy.



Warning!

Eye protection: Do not look directly into the LEDs. During treatment, always protect the baby's eye with patches or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection. Patients adjacent to the light may also need to be protected with eye patches or equivalent.

4. Position light over infant. Position the face of the light source no closer to the infant than 40 cm(16 inches). If the light source is far from effective surface, radiation intensity lowers.
5. Check the size of the effective surface and its position



< Effective Surface Area >

6. Switch on the power by using the power switch at the control part.
7. Monitoring the patient during treatment.

**Warning!**

Regular monitoring during treatment is recommended. Use the following guidelines:

- Measure the patient's bilirubin level periodically during treatment.
- Turn off the light when checking the baby's condition and visualizing skin color.
- Verify that baby's eyes are protected and free of infection.
- Closely monitoring the infant's status including temperature, water balance while receiving phototherapy, and signs suggestive of early bilirubin encephalopathy such as changes in sleeping pattern, deteriorating feeding pattern, or inability to be consoled while crying.
- Do not let the patient depart from the effective surface area of the light. Changing the infant's posture every 2 to 3 hours may maximize the area exposed to light.

8. When finished, switch the power off and remove light from the therapy area.

4.3 Essential performance

- Blue LEDs emit light in the range of 400nm ~ 550nm (peak between 450 – 475nm) for neonatal jaundice treatment
- Irradiance level 25 ~ 55 $\mu\text{W}/\text{cm}^2$ at 40 cm (16 inches) distance from light source

Section 5

Troubleshooting



Warning!

Disconnect power cord before opening the light for repair.



Warning!

Do not attempt to service the BT-400. Only qualified service personnel by Bistos Co., Ltd. should attempt any needed internal servicing refer to service manual 400-ENG-SVM-EUR-XX.

Problem	Possible Cause	Action
The unit does not turn on.	No power	Ensure that the power cord is plugged in correctly.
	Defective MAIN PCB	Have a qualified technician check the components and replace as necessary.
	Defective power supply	Have a qualified technician check the PCB and replace as necessary.
Some LEDs are not lit.	One LED may have burned out causing 4 LEDs to go off.	<ul style="list-style-type: none"> - Check the connection first. - Choose the defective LEDs. And then replace the relevant LEDs. - Have a qualified technician check the LED PCB and replace as necessary.
The light source enclosure is heated more than 50°C.	The current is adjusted too high. Constant current circuit is broken.	Have a qualified technician check the LED and Main PCB and replace as necessary.

※ *It is recommended that the intensity of the light should be checked after partly or whole changing LED.*

Section 6

Maintenance and Cleaning

6.1 Checking the Light Intensity

It is recommended that the intensity of the light should be checked every 10,000 hours use by the qualified technician. Also, we recommend that you should change LED lamps after using 100,000 hours.

Have a qualified technician test the intensity level and readjust the intensity potentiometers to achieve the desired output, if required.



Warning!

Only qualified personnel should perform service and repair, and then the light should be readjusted.



Caution!

All LEDs must be changed at the same time. And LEDs recommended by Bistos Co., Ltd. shall be used, and use of other LEDs can influence safety and effectiveness of the phototherapy

6.2 Cleaning and Disinfection



Warning!

Disconnect light from AC powercord before cleaning.

Cleaning: Remove dust from the exterior of the light with a soft brush or soft cloth dampened with water. Turn off and unplug the unit before cleaning.

Clean the remaining debris with a mild solution of detergent and water, a noncaustic commercial cleaner, or hospital disinfectant.

Disinfection: Always observe the hygiene regulations of the hospital when handling devices which are contaminated with bodily fluids or other.

If necessary, use the disinfected products based on

- Ethylic alcohol 70% or isopropyl alcohol 70%
- Sodium hypochlorite 500 ppm



Caution!

Observe the following precautions;

- Do not spray liquids directly onto the light, or allow them to seep into the interior.
- Do not use caustic or abrasive cleaners.
- Do not clean with alcohol, acetone, or other solvents.

Never immerse the light or its components parts.

Important : Some chemical substances contained in cleaning and disinfecting products can affect the device. Exposition to these substances may cause damages on material, which are not always visible. Therefore, it is unadvisable to use cleaning and disinfecting products whose chemical composition contains.

(eg. Phenols, Formyl, Glutaraldehyde, Chlorhexidine, Strong organic acids, etc.)

6.3 Disposal of the BT-400

When disposing of the BT-400, adhere to all applicable laws regarding recycling. If you are not able to dispose the BT-400 or you need a help for disposing the BT-400, please contact us. In case there are no appropriate ways to dispose, we will pick up the BT-400 for you.

Section 7 Specifications

Functional Characteristics			
Light Source		Function	
Type	Blue LED (8ea)	Uniform Distribution Intensity	
Wavelength	Peak Between 450 ~ 475nm	Intensity (at 40cm)	Low : 25 ~ 35 μ W/cm ²
Variation in Intensity	\pm 10% (over 6hrs within effective surface area)		High : 35 ~ 55 μ W/cm ²
Effective Surface Area	40 x 20cm	Timer	30min ~ 999hrs/30min
LED Life Time	100,000hrs	Operating & Total Using Time Display	
Display		Heat output at 40cm over 6hrs	
LCD	2.4" TFT Color LCD	< 10 °C warmer than ambient	
Noise at 40cm < 30 dB			
Power			
Voltage	Input : AC 100 ~ 240V (50/60Hz)	Consumption	70VA
Standard Configuration			
Main unit	1ea	Eye shielder	2ea
Power Cord	1ea	Operation manual	1ea
Options			
Cart		Shade	
Warranty			
Main Unit	2years		
Physical Characteristics			
Dimension		Weight	
Assembled	525.5(W) x 430(D) x1770(H)mm	Assembled	12.0Kg
Main Unit	541.6(W) x 370(D) x 568.9(H)mm	Main Unit	3.3Kg
Main Unit Packing	575(W) x 300(D) x 245(H)mm	Main Unit Packing	5.1Kg
Cart	525.5(W) x 430(D) x 1150(H.MAX.)mm	Cart	8.5Kg
Cart Packing	545(W) x 435(D) x 150(H)mm	Cart Packing	9.8Kg
Environmental Conditions			
Operation		Transport & Storage	
Temperature	10 ~ 40°C (50 ~ 104°F)	Temperature	-20 ~ 60°C (-4 ~ 140°F)
Humidity	5 ~ 85%, non-condensing	Humidity	0 ~ 95% non-condensing
Pressure	80 ~ 106 kPa	Pressure	70 ~ 106 kPa

Certificates			
Certificates	KFDA, CE	Standard	IEC60601-1, IEC60601-1-2 IEC60601-2-50

Section 8

Manufacturer's Declaration on EMC

The BT-400 is intended for use in the electromagnetic environment specified below. The customer or the user of the BT-400 should assure that it is used in such an environment.


8.1 Disposal of the BT-400

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BT-400 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The BT-400 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 purposes, provided the following warning is heeded:
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	<p>Warning: This BT-400 is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the BT-400 or shielding the location.</p>

8.2 Electromagnetic immunity

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV Contact ±2, ±4, ±8, ±15 kV air	±8 kV Contact ±2, ±4, ±8, ±15 kV 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	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50 Hz and 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dip < 5 % U_T (> 95 % dip in U_T) for 0.5 and 1 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 and 30 cycles Voltage Interruption <5 % U_T (> 95 % dip in U_T) for 250 and 300 cycles at 50Hz, 60Hz respectively	Voltage Dip < 5 % U_T (> 95 % dip in U_T) for 0.5 and 1 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 and 30 cycles Voltage Interruption <5 % U_T (> 95 % dip in U_T) for 250 and 300 cycles at 50Hz, 60Hz respectively	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BT-400 image intensifier requires continued operation during power mains interruptions, it is recommended that the BT-400 image intensifier be powered from an uninterruptible power supply.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

8.3 Electromagnetic immunity

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz</p>	<p>3 Vrms</p>	<p>Portable mobile RF communications equipment should be used no closer to any part of the BT-410, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1,2\sqrt{P}$
<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	$d = 1,2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2,3\sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ <p>where P is the maximum output power rating of the transmitter in watts (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 :</p> 
<p>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.</p>			
<p>^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-410 is used exceeds the applicable RF compliance level above, the BT-410 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-410.</p> <p>^b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.</p>			

8.4 Recommended separation distances between portable and mobile RF communications equipment and the BT-400

The BT-400 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BT-400 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BT-400 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 metres (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.

Product Guarantee

Product Name	Neonatal phototherapy unit
Model Name	BT-400
Approval No.	
Approval Date	
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-400.
- ※ 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.

Reference:

1. American Academy of Pediatrics, Subcommittee on Hyperbilirubinemia. *Clinical Practice Guideline Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation* [Published correction appears in Pediatrics. 2004; 114(4):1138]. Pediatrics. 2004;114(1):297-316
2. American Academy of Pediatrics, The committee on fetus and newborn. *Technical Report_ Phototherapy to Prevent Severe Neonatal Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation*. Copyright © 2011 by the American Academy of Pediatrics. ISSN Numbers: Print, 0031-4005; Online, 1098-4275

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