



# BT-400

Neonatal Phototherapy unit

Operation Manual



**BT-400**

**Keep this manual for future reference**

*P/N: 400-ENG-OPM-EUR-R13*

## 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.

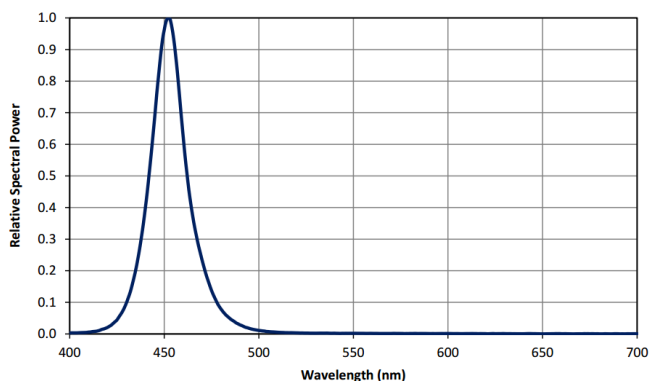
### 2.3 Operating Principle

- 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, the 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 the spectrum, so there is no concern about UV exposure to the infant.

In addition, Blue LEDs do not emit significant energy in the infrared (IR) range of the 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.

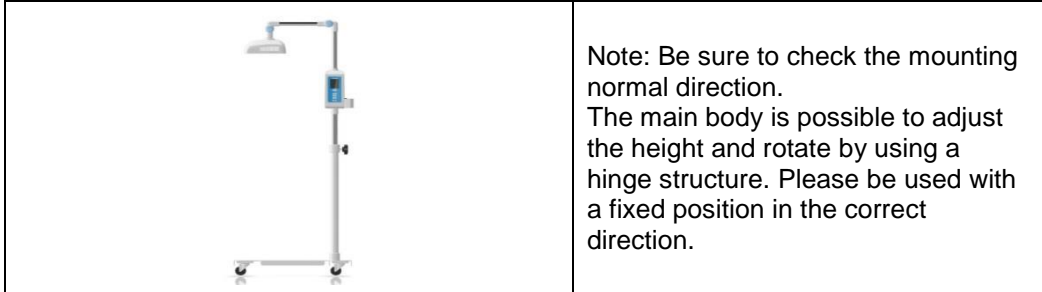
## 2.4 Contraindication

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



To install the BT-400 in the 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 the power cord into the inlet of the device.
- 2) Fasten the clip again to prevent the breakaway of the 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)
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

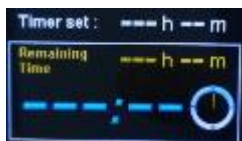
- ① Set the operating time by pressing  or  button.
- ② LED is stopped automatically after setting time.



<Timer mode screen>

##### 2) Continuous mode

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



<Continuous mode screen>

## 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: The 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 mattresses.

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.

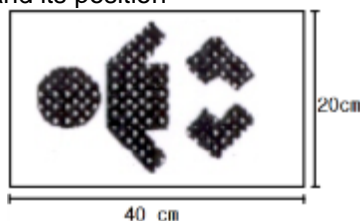
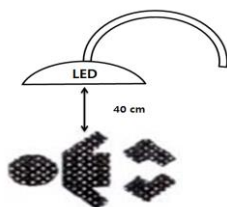
3. Shield infant's eye with protective eye shields designed for use during phototherapy.



### **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 the 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 the 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.

## Section 7 Specifications

<b>Functional Characteristics</b>			
Light Source		Function	
Type	Blue LED (8ea)	Uniform Distribution Intensity	
Wavelength	Peak Between 450 ~ 475nm	Intensity (at 40cm)	Low : 25 ~ 35 $\mu$ W/cm <sup>2</sup>
Variation in Intensity	$\pm$ 10% (over 6hrs within effective surface area)		High : 35 ~ 55 $\mu$ W/cm <sup>2</sup>
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			
<b>Power</b>			
Voltage	Input : AC 100 ~ 240V (50/60Hz)	Consumption	70VA
<b>Standard Configuration</b>			
Main unit	1ea	Eye shielder	2ea
Power Cord	1ea	Operation manual	1ea
<b>Options</b>			
Cart		Shade	
<b>Warranty</b>			
Main Unit	2years		
<b>Physical Characteristics</b>			
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
<b>Environmental Conditions</b>			
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