

# Brilliance Bottom Phototherapy



***User Manual***

**Brilliance Bottom Phototherapy**

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## USER MANUAL

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### *Declaration of Language Translation:*

*Brilliance Phototherapy unit comes to you as a package, complete with Labels, User Manual and related documents, all of which are in English. The product targets the customers who are proficient in the language and can read the instructions and understand the product better. This user manual will be supplied in the local language on request to EU customers.*



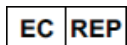
## Phoenix Medical Systems (P) Ltd

DP42, Sidco Industrial Estate, Thirumudivakkam, Chennai 600044, INDIA.

Ph +91 44 2478 1705 / 2227, Toll Free No: 1 800 425 3503

Email : India - sales@pmsind.com, International - exports@pmsind.com, service@pmsind.com

European Authorized representative:



Obelis s.a

Bd. General Wahis 53, 1030 Brussels, Belgium Phone: +32.2.732.59.54

Fax No.:

+32.2.732.60.03

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## I. User Responsibility

This user manual is intended to provide important information for the proper assembly, operation, and maintenance of the Brilliance bottom device (“Brilliance Bottom”). Failure to follow these instructions may result in:

- Decreased efficiency of operation
- Ineffective treatment
- Detrimental effects on the health of the patient, the user or other persons
- Deterioration of the equipment

*Please note:*

- The user is responsible for checking the device for broken bulbs and other worn, broken, or missing parts on a regular basis and arranging for maintenance and repair.
- The product must be checked periodically up to the expected service life of eight years.
- A defective product should not be used.
- Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately.
- Neither this product nor any of its parts should be repaired in any manner other than in accordance with written instructions provided by PHOENIX.
- The product must not be altered without the prior written approval of the PHOENIX Quality Assurance Department.



*CAUTION: Should product repair or part replacement become necessary, please call or make a written request for service to the nearest PHOENIX Regional Service Centre. Only PHOENIX trained personnel should carry out the service, maintenance or repair of this product.*

The owner of this product shall have the sole responsibility for any malfunction resulting from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than PHOENIX.



*Federal (USA) law restricts this device to sale or use by or upon the order of a licensed healthcare practitioner. Its use is restricted to healthcare facilities and persons with specific training and experience in the use of the device.*

## II. Definitions and Symbols



**Caution:** A caution is to draw attention to a procedure which, if not done correctly, can lead to equipment damage.



**Warning:** A warning calls attention to hazardous or dangerous situations inherent to the cleaning, operation and maintenance of the equipment which may result in personal injury or death of the operator or Patient.



Protect infant's eye from injury caused by intense light.



Refer to instruction manual / booklet or Follow instructions for use



Reset the therapy timer



Alternating current



Fuse rating



New waste disposal procedure for safe disposal of the device at the end of its life



Model number of the device



Details of the manufacturer of the device



This symbol denotes the “European Conformity Mark”

**IPX3**

Protected from spraying water at angle up to 60° on either side of the vertical

### III. Operating Precautions



**All users are strongly advised to read this manual and understand its contents before operating the equipment.**

*The following precautions must be taken at all times:*

- Cover infant's eyes and genitals. The infant's eyes must be covered whenever the phototherapy light is in use. Brilliance uses high intensity lights, and eye coverage is critical to protect against possible retinal damage. Medical experts also recommend that the infant's genitals be covered during phototherapy treatment.
- Monitor infant's bilirubin level. Proper tests should be conducted to measure the bilirubin level in the infant's blood. The user is advised to monitor the infant's bilirubin level regularly during treatment, at least every 24 hours.
- Monitor infant's temperature. Exposure to phototherapy can cause severe hyperthermia. The infant's temperature should be monitored every 30 minutes
- Monitor water balance. Prolonged exposure to phototherapy causes dehydration. Check the infant's water balance frequently.
- Monitor skin reddening. Porphyrins are the by-products of the photochemical breakdown of the bilirubin molecule. In some cases, exposure of porphyrins to phototherapy may result in a localized reddening of the infant's skin. These photoisomers of bilirubin may cause toxic effects. Therefore, check for skin reddening frequently. The colour of the infant's skin is not a direct measure of the bilirubin content in the blood of the infant. Proper clinical tests should be conducted to monitor the bilirubin level in the infant's blood
- Do not place any blankets or covers over the infant. Covering the infant with blankets or other insulating objects reduces the effectiveness of the phototherapy treatment and poses a possible risk of overheating of the infant due to heat accumulation.
- Do not place unit in direct path of heat. When using the phototherapy unit with a radiant warmer, make sure the unit is not directly in the path of the radiant heat rays since this will block heat to the infant, and may damage the phototherapy device.
- Protect adjacent patients. Patients near to those being treated by Brilliance should be protected from the phototherapy light. Such protective measures include eye and genital covering, or a protective shield.
- Avoid looking directly at the lights on the Phototherapy unit. Prolonged exposure to this light may harm the unprotected eyes of the operator and/or caregiver, such as parent. For safety, avoid looking directly at the light and inform all caregivers the same.
- Do not store drugs near the path of phototherapy light. Do not store drugs, infusion liquids, flammable solutions or combustible gases within the treatment area.

- Use caution with supplemental heat therapies. Use of Brilliance with warming devices such as a heat lamp, warmer or heating mattress must be monitored and adjusted so that there is no danger to the infant from increased body temperature.
- When using other thermotherapy devices like radiant warmers with the phototherapy unit, the user is advised to operate them in the baby controlled mode. Otherwise the set temperature of the thermotherapy device has to be changed according to body temperature measurements.
- Be careful when moving the Brilliance unit. Before moving the Brilliance unit, be sure to check that the position and length of the attached power cord is ready and long enough to reach. While moving the Brilliance unit, continue to monitor the position and length of the power cord to avoid toppling the device, causing injury, entangling the power cord in the casters (wheels), and/or pulling the plug out of the wall.
- Do not use reflective materials. The use of reflective materials may unsafely increase the infant's body temperature.
- Protect drugs from light. Light can adversely affect drugs and other infusion liquids. When using intravenous delivery systems during phototherapy, take suitable measures to protect the drugs and liquids.
- Keep the device and treatment area clean. Do not place items on or near the Brilliance unit or treatment area. Do not store infusion liquids, flammable solutions or combustible gases on or around Brilliance.
- Use only mild detergents for cleaning. Abrasive and strong solvents may damage Brilliance. See Section 6 (Cleaning Procedure) for more information.
- Do not use in presence of flammable materials. Do not use Brilliance in the presence of flammable materials, including anesthetics or gases that can support combustion. An explosion hazard exists under these conditions.
- Don't allow the excess fluid retain on the bed surfaces. Any fluid ingress into the light unit can cause to electrical shock.
- Check the absorbing material at regular interval to avoid over showing of the absorbing material and hence dripping.
- Don't place any material below the baby. The phototherapy efficiency will affect if any opaque/cloth material is kept between the baby and Acrylicbed.
- Inspect regularly. Regularly inspect the bed side panel hinge mechanism and the bed side locking mechanism for proper operation and hence ensure infant safety.
- Compliance with other devices. Additional devices that should be used in combination with Brilliance must conform to IEC 60601-1
- No service and or maintenance should be done during use with infant. Equipment should be serviced by Phoenix authorized service personnel only.
- **WARNING:** To avoid risk of electric shock, this equipment must be connected to supply mains with protective earth only.

## IV. Manufacturer's Declaration: Electromagnetic Emissions

This phototherapy unit is intended for use in the electromagnetic environment specified below. The user of the equipment should ensure that it is used in such an environment.

<b>Emissions test</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment - Requirements</b>
RF emissions CISPR II	Group 1	This phototherapy unit uses RF energy only internally. Therefore, its RF emissions levels are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	This phototherapy unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purpose.
Harmonic emissions	Class A	This phototherapy unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purpose
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	
<b>Immunity test</b>	<b>Compliance Level</b>	<b>Electromagnetic Environment - Requirements</b>
Electrostatic Discharge (ESD) IEC 61000-4-2	Contact discharge $\pm 6$ kV Air discharge $\pm 8$ kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Radiated RF IEC 61000-4-3	80 Mhz to 2,5 Ghz 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the unit.
Electrical fast Transient/burst IEC 61000-4-4	$\pm 2$ Kv	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1$ kV Differential mode $\pm 2$ kV Common mode	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	0.15 to 80 Mhz 3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the unit.
Power frequency Magnetic field IEC 61000-4-8	3 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 IEC 61000-4-11	0% short interruption for 5Sec 40% dips for 5 cycles 70% dips for 25 cycles 0% of AC mains voltage for 0.5 cycles.	Mains power quality should be that of a typical commercial or hospital environment.



# 1. General Information

## Introduction

This manual provides the technical specifications and a description of the Brilliance Bottom device, as well as operating instructions and precautions to be followed while using the device.

Brilliance Bottom Phototherapy unit should be used only by properly trained personnel and under the direction of qualified medical personnel who are familiar with the known risks and benefits of this device. It is strongly recommended that all personnel operating and caring for this device read and understand this manual before they start using the equipment.

## Hyperbilirubinemia in Newborns

Neonatal Hyperbilirubinemia results from the increased production and limited elimination of bilirubin during the first few days of a baby's life. This affects nearly 70% to 80% of pre-term babies during the first week of life. Babies with Hyperbilirubinemia need close monitoring so that the potential risk of bilirubin-induced brain damage can be reduced.

## Phototherapy

Phototherapy significantly reduces the bilirubin level content and has been found to be effective in treating Hyperbilirubinemia. This decline is dependent upon the dosage of irradiance and area of skin exposed. Exposure to phototherapy at particular wavelengths (or colors of light) results in the conversion of unconjugated bilirubin into water-soluble photoproducts.

These photoproducts are water-soluble and non-toxic and are excreted in the intestine and urine. The most effective lights for phototherapy are those with a high-energy output near the maximum absorption peak of bilirubin. Special blue light with a peak output of 425 to 475 nm are the most efficient, and yet do not emit harmful ultraviolet (UV) rays.

## Intended Use

Brilliance is an affordable world-class phototherapy device to treat newborns with mild to severe jaundice.

High-intensity blue LEDs to enable effective treatment, provide long lamp life, and minimize maintenance. Bottom unit consists of transparent acrylic infant bed with lockable side panels and lockable castors for mobility.

## 2. Technical Information

### Specifications

Table 2.1 Performance Specifications

Performance feature	Specification
Illumination source	Blue LEDs, 12 Nos
Peak spectral irradiance	> 30 $\mu\text{W}/\text{cm}^2/\text{nm}$ at infant bed
Peak wavelength	451 nm
Emission spectrum	430-490 nm (maximum bounds of FWHM range)
Effective surface area	500 mm x 250 mm
Irradiance ratio	$\geq 0.4$ (minimum/maximum irradiance)

Table 2.2 Physical Specifications

Performance & Physical	Specification
Bassinet dimensions	Height x Width x Depth: 78 cm x 52 cm x 15 cm
Bassinet height from floor	94 cm
Total unit mass	<24 kg
Casters	4" Castors, Lockable
Bassinet tilting	Up to 12°
Time totalizers	Non-resettable Total therapy time (up to 99999.9 Hours) Resettable Patient therapy time - Optional
Safe working load	$\leq 10\text{Kg}$ on the infant bed

Table 2.3 Electrical Supply Specifications

Electrical supply	Specification
Voltage	110v-230vAC ~
Frequency	50/60Hz, single phase
Power consumption	20W (Max)
Expected life of the LED	30000 Hours

Table 2.4 Electrical Classifications

Feature	Classification
Type of protection against electrical shock	Class 1
Degree of protection against electrical shock	Type B
Mode of operation	Continuous
Protection against ingress of liquids	IPX3

Coating: Epoxy powder coated for scratch resistance and rust protection.

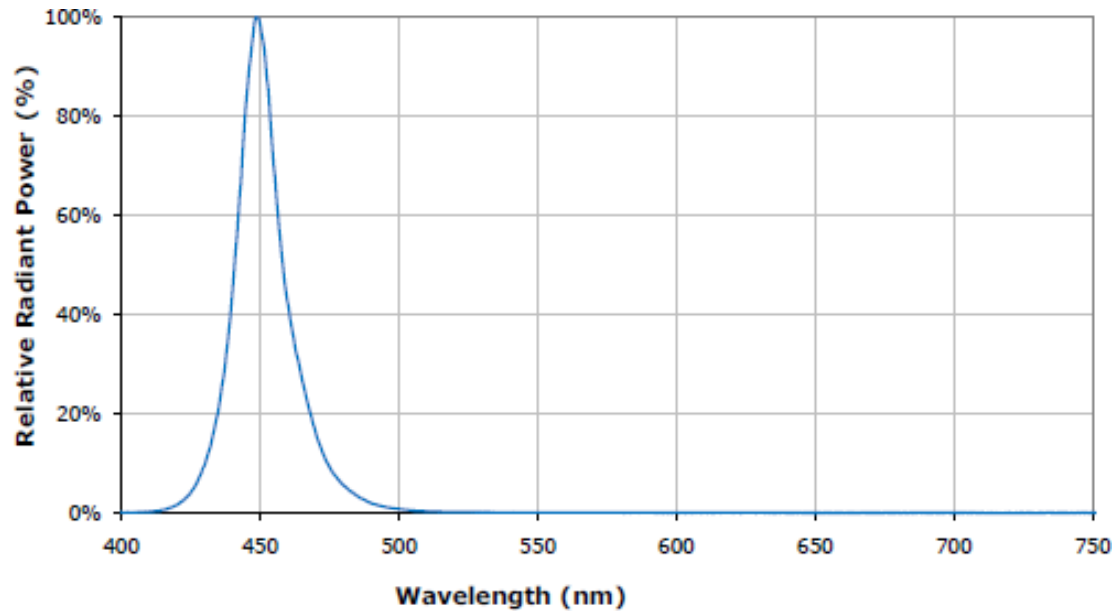
Table 2.5 Environmental Specifications during Operation\* and Transport/Storage\*\*

Environmental feature	Specification*	Specification**
Ambient temperature	10°C to 35°C	0°C to 50°C
Relative humidity	0% to 90% noncondensing	0% to 90% noncondensing
Atmospheric pressure	70 kPa to 106 kPa	50 kPa to 106 kPa

Table 2.6 Conformity with standards

IEC 60601-1, IEC 60601-1-2, IEC 60601-2-50

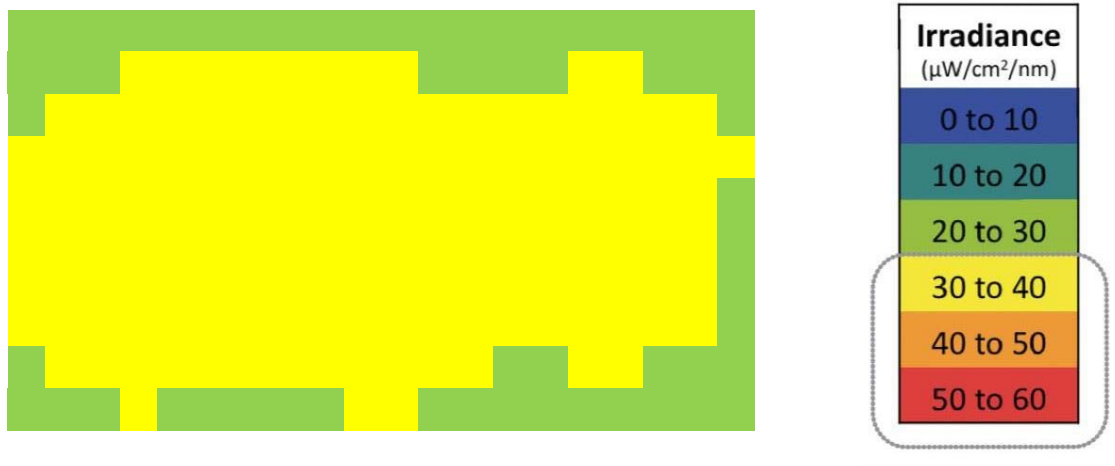
## Relative Spectral Power Distribution of Blue LED



## Irradiance Map

The American Academy of Pediatrics (AAP) recommends an irradiance of  $\geq 30$   $\mu\text{W}/\text{cm}^2/\text{nm}$  over maximum body surface area for effective phototherapy. Figure 2.1 shows the irradiance map of Brilliance Bottom, which meets the recommended AAP standards.

*Figure 2.1 Irradiance Map of Brilliance Bottom*



### 3. Installation Procedure

*Note: Only Phoenix personnel should perform the following steps for installation.*

#### General

The Brilliance unit is shipped partially disassembled and must be assembled before use. The following tools are required to assemble the equipment.

- Phillips screwdriver
- 5 mm Allen (or hex) key

#### Unpacking

Brilliance Bottom unit comes packed in a corrugated cardboard box. When removing the equipment from the box, take care not to scratch or otherwise damage unprotected surfaces.

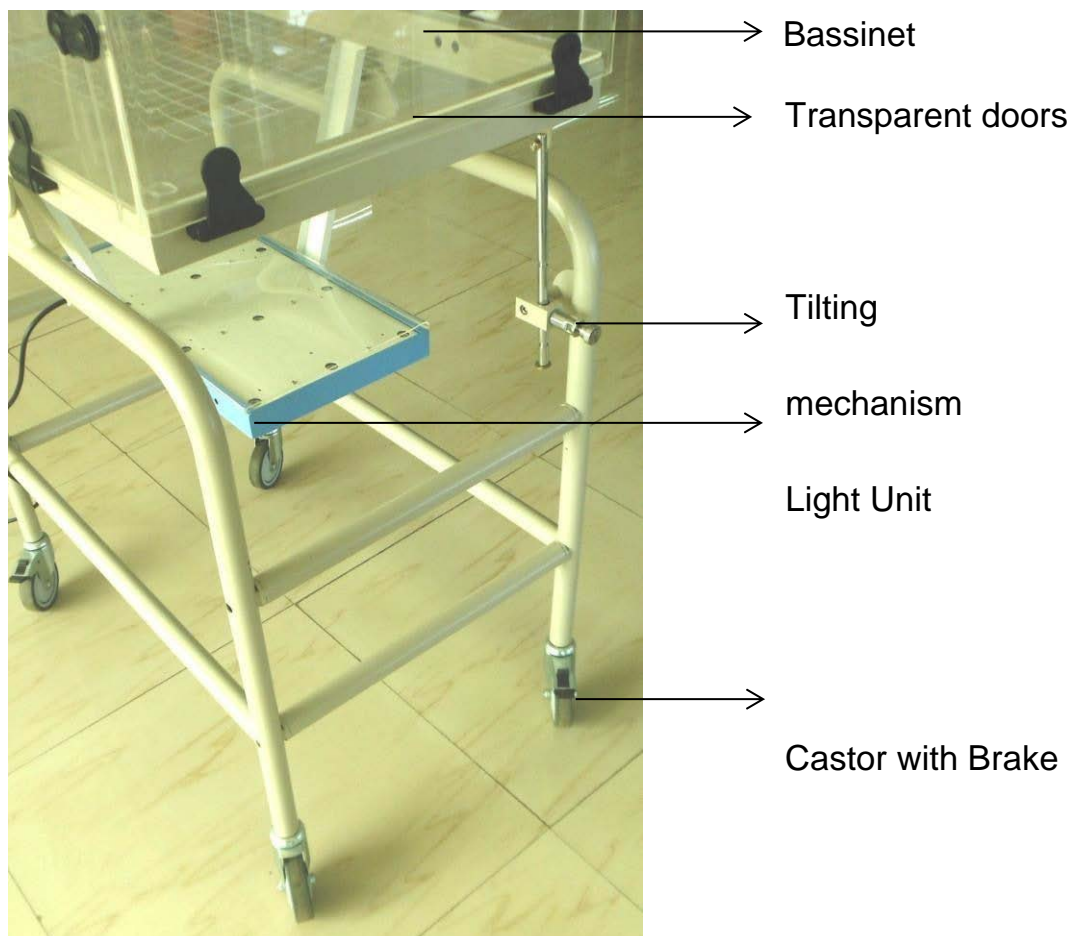
*Before starting installation, remove all packing material.*

Each Brilliance Bottom unit package is shipped with the following components:

1. Infant bed
2. Transparent Acrylic bottom sheet
3. Transparent Side doors with Latches
4. U frame with lockable casters
5. Dummy poles
6. Light unit
7. Power cord
8. User manual
9. Bag of accessories, including and tilting mechanism

## Parts Identification

- The Bassinet consist of Acrylic side panels, Acrylic transparent sheet (used as infant bed) and tilting mechanism
- The Light unit contains LED, Power supply and an ON/OFF Switch for the Equipment.
- 'U' shape Structure with castor for mount the Bassinet and Light Unit.



## Assembly Steps



→ Bassinet Transparent Acrylic bed

→ Light unit support 1

→ Tilting Slider Rod

→ Light unit support 2

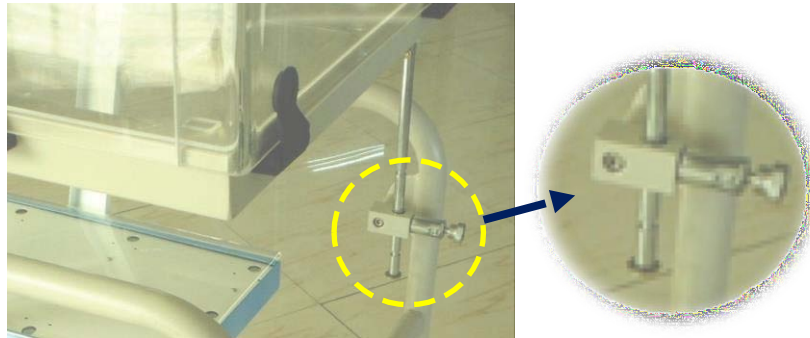
→ Dummy poles

- Assemble four dummy poles to the bottom of the “U” Frame
- Fix the bassinet (infant bed) top of the “U” frame
- Fix the two light unit supports at bottom middle of the “Bassinet”
- Fix the light unit on the light unit supports
- Fix the tilting rod between the bed and “U” frame
- Fix the tilting mechanism in its place
- Fix the four transparent acrylic doors in its place
- Place the transparent acrylic sheet on the bassinet
- Lock the acrylic side doors and check the function of locks.
- Switch ON the device and check whether the indicator is ON and blue LED glowing.
- Check the irradiance of the device

***Bottom unit assembly is complete!***

### Tilting of the Bottom Phototherapy Unit

- Unscrew the tilting mechanism Knob by pull it.
- Adjust the Tilting slider at require level.
- Tilt the bassinet and secure the bassinet position and release the knob to tighten the position.



**CAUTION:** Do not tilt the bassinet while transporting and secure all the panels must be locked properly to avoid infant falling from bassinet.

### USING THE BOTTOM PHOTOTHERAPY

- Place infants over the Acrylic bed (Transparent sheet).
- Switch on the Light Unit using the ON/OFF switch provided on the light unit.
- Switch OFF the unit while not in use and unplug the power cord from the wall outlet.

### ***THE FOLLOWING ARE IMPORTANT WHEN USING PHOTOTHERAPY.***

- For effective Therapy do not keep the baby draped as for as possible.
- Keep the undersurface of the baby free of any cloth or any opaque/ transparent material.
- Keep sufficient absorbing material (Gauze with Cotton) on the edges of the bed, so that any fluid will not dripping down to the light unit.
- Wear diaper for baby if possible to avoid fluid / urine falling on the floor or on the light unit
- Cover patient's eyes and genitals whenever the device is in use.
- Don't place more than 10kg on acrylic bed. More weight leads to sheet damage and infant injury.

**WARNING:** *Always lock the side door of patient bed while in use. If not locked properly, infant may fall from the bed and leads to injury to the infant.*

## 4. Operation

### Pre-Operation Check List

*Before operating the Brilliance unit, be sure to perform the following checks:*

1. Light unit:
  - a. Check the overall appearance of the phototherapy unit. There should be no damage.
  - b. Ensure that the unit head is firmly fixed to the supporting plates.
  - c. Ensure that power cord is firmly connected to the Brilliance device.
2. Base frames:
  - a. Check that all casters are in firm contact with the floor and that the phototherapy unit is stable and moves freely.
  - b. Check that the casters' screws are fixed tightly and that wheels rotate freely.
3. Bassinet:
  - a. Ensure that the side doors of bassinet are firmly fixed and locked.
  - b. Ensure the tilting knob is positioned properly and the bassinet in horizontal position.
  - c. ***Always check the transparent acrylic infant bed. If found any crack or damages, don't use it and replace with new one.***
  - d. Check that the casters are fixed tightly and that wheels rotate freely and check the brake are properly functioned.
  - e. Ensure that power cord is firmly connected to the Brilliance bottom unit.
  - f. Examine the power cord for any damage. Call Phoenix to replace the power cord if damage is evident.

### General Operating Guideline



1. Cover patient's eyes and genitals whenever the device is in use. Make sure there is adequate eye protection for any patients nearby, and that all the other operating precautions listed in Section IV (Operating Precautions) have been addressed.
2. Plug the Brilliance unit's power cord into the wall outlet and press the power switch located on the light of the unit.
3. Press and hold the reset button on the light unit for few seconds  
to reset patient therapy time to zero. (Optional)
4. Place the infant on the acrylic sheets and cover the eyes and genitals firmly.
5. Lock casters properly.
6. Position the Brilliance bed surface parallel to the ground fall while therapy. And tighten the side panels properly to avoid the infant



## 5. Cleaning Procedure

Clean the phototherapy unit after each patient or at least once a week as follows:

- Clean the exterior of the unit using a mild detergent solution.
- Use a damp cloth or sponge or disinfectants as recommended.
- Gently wipe the undersurface of the light head with a clean dry cloth.
- Do not allow liquids to seep into the electrical housing.

The following recommended cleaning solutions are safe to

use. Table 6.1 Recommended Cleaning Solutions

Generic Formulation	Maximum Concentration
Hydrogen Peroxide	6%
Sodium hypochlorite compound	0.5% aqueous solution
Quaternary ammonium	0.2%
Idophors	50mg/liter
Glutaraldehyde	2%

**WARNING:** Do not use water or any other liquid to clean electrical or electronic parts. Do not allow water to spill or spray into the unit head.



**WARNING:** Do not use alcohol or any other flammable solvents for cleaning the equipment.

**HOT SURFACE:** In order to avoid injury or burn, turn off Brilliance unit's power and allow the unit head to cool before cleaning.

**CAUTION:** Use the cleaning solution sparingly on a cloth when cleaning the phototherapy unit. Excessive solution causes damage to the internal components. Never allow liquids to seep into the head unit.

**CAUTION:** Use of cleaning/disinfecting solutions containing chemicals that are not listed above (i.e., alcohol, acetone, etc.) or chemicals in greater concentrations than those listed above may damage the Brilliance unit.

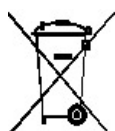
## 6. Troubleshooting

#	Problem	Parts to be checked	Checks	Measures
1	Blue LED lights are not glowing	Power cord	Check whether power cord is plugged improperly	If not, plug it properly
			Check power cord for damage	If damaged, change the power cord with proper rating or contact PHOENIX
		Main power switch	Check if main power is switched ON	Switch main power ON
		Fuse	Check for blown fuse	Switch OFF the main supply & Replace correct rated fuse
2	LCD display not functioning	Main power switch	Whether Blue LED are glowing	If not, switch main power ON
		Blue LED	Whether blue LED lights are glowing	If yes, contact PHOENIX
3	AC indicator not glowing	Main power switch	Check if main power is switched ON	If not switch main power ON
		Blue LED	Whether blue LED lights are glowing	If yes, contact PHOENIX
4	Bed cannot be tilted	Tilting mechanism	Check if the pull and rotate knob; it can be loosened and tightened easily	If not contact PHOENIX
			Pull and rotate may be damaged	Replace the knob or contact PHOENIX
5	The device cannot be moved	Castors	Check if the castors are in locked position	Unlock the castors and move
			Clean the castors	If jammed or worn out, contact PHOENIX for replacing the castors

## 7. Disposal

- Disposal of all components of this equipment is possible in environmentally Safe way in compliance with statutory state laws for disposal of solid wastes.
- All metal parts can be recycled through re-melting processes.
- All non-metallic parts like nylon, rubber and wire sheaths can be recycled in accordance with statutory local state laws.
- The glass fiber, resin filled polymerized plastic (FRP) is disposable as solid waste conforming to state laws on solid waste disposal standards. The material is fully polymerized and does not emit any hazardous gases.
- All electrical wiring and cable sheathing are to be segregated under professional supervision and diverted to the approved recycling agencies for complying with the concerned state laws for plastic disposal and metal disposal separately.
- The wood used to make the shipping crates and the cardboard coverings are biodegradable.
- The plastic sheets wrapped around the equipment and the polystyrene packing provided is not recyclable. They must be disposed of in accordance with prevailing environmental laws.
- All users are advised to check with prevailing environmental safety hazard regulations for safety compliance.

### Disposal Procedure for EU countries:



When the user wishes to discard this product, it must be sent to appropriate facilities for recovery and recycling.



By not discarding this product along with other household-type waste, the volume of waste sent to incinerators or landfills will be reduced and natural resources will be conserved.

## 8. Warranty

Brilliance Bottom phototherapy unit is warranted against manufacturing defects or defective workmanship for one year from the date of purchase.

All consumables and disposable products are guaranteed to be free from defects at the time of dispatch only.

Calibrations are not included in the one year warranty.

During the warranty period any defective parts other than those listed above will be replaced at no charge to the customer. There will be no labour charge for replacing the parts within the state where the first purchase was made.

This warranty is not applicable if

- Damage to the unit is caused as a result of mishandling or improper use.
- The customer fails to maintain the unit in a proper manner.
- The customer uses any parts, accessories or fittings not recommended by PHOENIX.
- Sale or service is performed by a non-authorized agency.

PHOENIX is not liable for incidental or consequential damages including loss of use, property damage or personal injury resulting from breach of warranty.

## 9. Contact Details

### REPAIRS AND MAINTENANCE

*When calling the PHOENIX service team, please provide the following information:*

1. Your name and telephone number
2. Name of your hospital
3. Serial number of the Brilliance Bottom Unit (refer to batch sticker)
4. The part or feature of the equipment not working
5. A brief description of the problem and support needed from PHOENIX
6. The name and telephone number of the person to contact after service is completed

### **Phoenix Medical Systems (P) Ltd**

DP42, Sidco Industrial Estate, Thirumudivakkam, Chennai 600044, INDIA.

Ph +91 44 2478 1705 / 2227, Toll Free No: 1 800 425 3503

Email : India - sales@pmsind.com, International - exports@pmsind.com, service@pmsind.com

Web: www.phoenixmedicalsyste.ms.com