

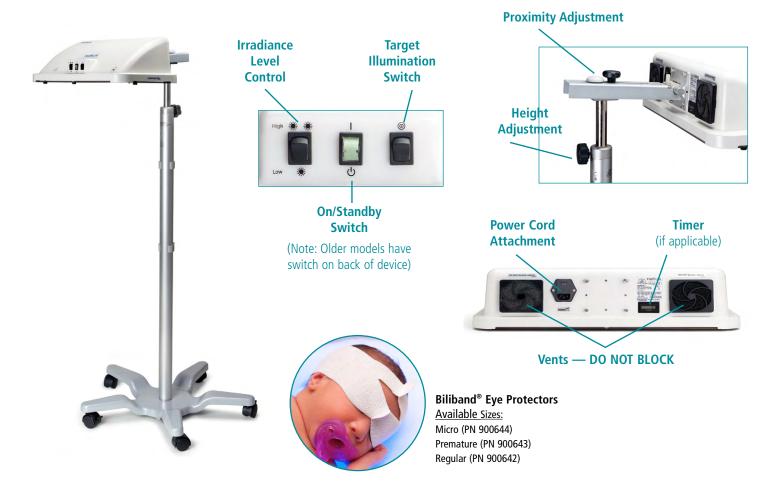


QUICK GUIDE

The neoBLUE LED Phototherapy System 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 in the hospital setting.

OPERATING INSTRUCTIONS

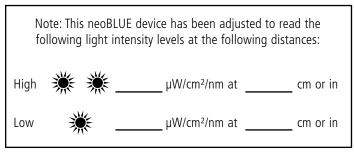
- 1. Check intensity of the light using a radiometer per your institution's procedures (see "Measuring Intensity" below).
- 2. Prepare infant. Infant may lie in an open crib, a bassinet, an incubator, or under a radiant warmer.
- 3. Shield infant's eyes with protective eye shields designed for use during phototherapy.
- 4. Position light over infant.
- 5. Switch on power.
- 6. Press the target illumination switch to center the light over the infant. Tilt or position the light enclosure as desired.
- 7. **Select High or Low** intensity setting, as appropriate for the patient.
- 8. Monitor the patient during treatment.
- 9. When finished, switch power to stand-by and remove light from the therapy area.



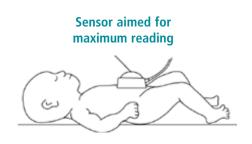
MEASURING INTENSITY

The light output was factory calibrated with the neoBLUE Radiometer to provide an initial intensity of $35 \pm 3.5 \,\mu\text{W/cm}^2/\text{nm}$ at the high setting and $15 \pm 2 \,\mu\text{W/cm}^2/\text{nm}$ at the low setting at a distance of 12 inches (30.5 cm) from the light enclosure to the baby. This measurement is taken at the central area of the effective surface area for phototherapy. The intensity of the light is inversely related to the distance from the light source to the baby. The light output can be adjusted by a biomedical engineer using the two potentiometers (located at the side of the light enclosure) to accommodate different distances.

If serviced or adjusted, record your intensity settings below:







neoBLUE Radiometer

Use with an incubator

The neoBLUE system can be positioned over an incubator with the roll stand or placed directly on top of incubators with flat tops. Removing the enclosure from the roll stand should be done with the help of a biomedical technician.



The neoBLUE system with roll stand shown with the NatalCare LX and Drape (P/N 013138).



Use with a radiant warmer

The neoBLUE system is correctly positioned to the side of a radiant warmer, not directly under the heat source.



The neoBLUE light enclosure can be tilted by grasping the device on either side and torqueing to the desired angle.





Use with a bassinet

The neoBLUE system positioned over a bassinet.



The neoBLUE light drape (P/N 001241) can be used to reduce draft and light spillage.



Do not block vents located on the underside of the enclosure when using drapes. (Note: Older models do not have these vents)



SAFFTY INFORMATION

WARNING! Select only infants for whom phototherapy has been prescribed

WARNING! The intensity level and duration of treatment should be prescribed by the physician for each patient.

WARNING! Intensive phototherapy (>30 µW/cm²/nm) may not be appropriate for all infants (i.e. preterm infants ≤1000g).¹

 Δ WARNING! Eye Protection: Do not look directly into the LEDs. During treatment, always protect the baby's eyes with eye shields or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection.

WARNING! Regular monitoring during treatment is recommended.

WARNING! Operator Safety: Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area. Using the neoBLUE system in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects. The neoBLUE light drapes may be used and are available through Natus Medical Incorporated (P/N 001241). Guard Dog Bones glasses are recommended and are available through Natus Medical Incorporated (P/N 900627) or online at www.safetyglassesusa.com.

 Δ WARNING! Placement Directly on Incubator: The light enclosure can be placed on flat surfaces only. Confirm rubber feet are fully seated on top of the incubator to prevent slippage. When placing light enclosure directly on incubator, care must be taken to ensure a safe operating environment. Secure power cord to minimize risk of tripping.

△ WARNING! Placement Directly on Incubator: The use of skin-controlled mode (patient servo) of the incubator or radiant warmer is recommended unless manual mode (air servo) specifically prescribed.

WARNING! Use with Radiant Warmer: Do not place neoBLUE light directly under heat source.

CAUTION: Federal Law (U.S.) restricts this device to sale or use by or on the order of a physician (or properly licensed practitioner).

For a complete list of warnings/cautions and additional information, please refer to the neoBLUE user manual. For service information, please refer to your service manual or contact Natus Medical Technical Service, or your authorized service representative.

¹ Maisels MJ, Watchko JF, Bhutani VK, Stevenson DK. An approach to the management of hyperbilirubinemia in the preterm infant less than 35 weeks of gestation. Journal of Perinatology (2012) 32, 660-664.



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