neoBLUE® LED Phototherapy System

User Manual

natus®

P/N 027159 Rev C
Revision Date 2021-07

Rx ONLY

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

Natus Medical Incorporated.
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville, Ontario L6H 5S1
Canada
natus.com

EC REP Natus Manufacturing
Limited IDA Business Park
Gort, Co. Galway, Ireland

CE 2797

Telephone:	+1-650-802-0400
Fax:	+1-650-802-0401
Customer Service:	+1-800-303-0306
Customer Service Fax:	+1-650-802-6620
E-mail:	customer_service@natus.com
Technical Service:	+1-888-496-2887
E-mail:	technical_service@natus.com

International Support - Please contact your local Distributor. Distributor locations can be found at www.natus.com

Table of Contents

1 PRODUCT DESCRIPTION

The neoBLUE® Phototherapy System consists of two products – the neoBLUE LED Phototherapy light source (light) and the neoBLUE LED Phototherapy roll stand.

Before assembling the neoBLUE light and administering phototherapy, read all sections of this manual carefully. There are safety considerations that should be read and understood before use.

Intended Use/Indications for Use

The neoBLUE LED Phototherapy System is indicated for the treatment of hyperbilirubinemia for neonates and infants in a hospital environment, and administered by trained, professional medical staff, on the order of a licensed medical practitioner. The light can be used with a bassinet, incubator, open bed, or radiant warmer.

Contraindications

Congenital porphyria or a family history of porphyria is an absolute contraindication to the use of phototherapy, as is the concomitant use of drugs or agents that are photosensitizers.[1]

Clinical Benefit

The clinical benefit to the patient is the degradation of bilirubin for the treatment of hyperbilirubinemia.

Intended Patient Population

The terms “infant” and “baby” are used throughout this manual and both include the patient population of neonates and infants.

When treating term and near-term neonates with intensive phototherapy for treatment guidance, please refer to the AAP Guidelines (American Academy of Pediatrics Clinical Practice Guideline – Management of Hyperbilirubinemia in the Newborn Patient 35 or More Weeks of Gestation).

When treating preterm neonates with intensive phototherapy, please seek guidance from physician on duration of the treatment as well as appropriate patient monitoring.

Physical Characteristics

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.

Light Source

The light consists of a lightweight plastic light enclosure. When used with the neoBLUE roll stand, the light can be tilted and adjusted both horizontally and vertically on the roll stand assembly. The light enclosure can be tilted to approximately 40° up from horizontal (the resting position). The light enclosure height can be adjusted vertically along the roll stand post, as well as horizontally out from the roll stand post (proximity adjustment) to aid in positioning the light. To help position the light over the infant, a red target light can be briefly illuminated using the right rocker switch on the front panel. The light can be used for infants in a bassinet, incubator, open bed, or radiant warmer.

The light can be used independently of the roll stand. The light enclosure can be placed directly on an incubator with a flat-topped surface.

[1] Subcommittee on Hyperbilirubinemia. American Academy of Pediatrics clinical practice guideline: Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. Pediatrics. 2004; 114(1):297-316.

***NOTE**: 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 document. See Service Manual Chapter 7 Electromagnetic Specifications for details.*

There are two intensity settings, high and low, to provide the physician the option to treat the patient with intensive or standard levels of phototherapy. The desired setting is selected using the left rocker switch on the front panel of the light. The light output was factory calibrated with the neoBLUE® Radiometer to provide an initial intensity of 35 μW/cm^2/nm at the high setting and 15 μW/cm^2/nm at the low setting at a distance of 12 inches (30.5 cm) from the light enclosure to the baby. The light output can also be adjusted using the two potentiometers (located on the side of the light enclosure) to accommodate different distances. A lens panel protects the light from incidental debris or fluid exposure.

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) region of the spectrum, reducing the potential risk of skin damage. In addition, blue LEDs do not emit significant energy in the infrared (IR) region of the spectrum, minimizing concern about excessive warming of the infant. As with all phototherapy lights, protective eye shields such as the Natus Biliband® Eye Protectors must be used to protect the infant's eyes from excessive light exposure.

LEDs have minimal light output degradation over their lifetime with proper use. Nevertheless, the user can adjust the output of the LEDs for any degradation using the two potentiometers. Life testing has shown neoBLUE LEDs can emit high intensity phototherapy for over 50,000 hours. Actual results may vary based on environmental factors and adjustments to the potentiometers.

Timer

The neoBLUE light is equipped with a timer to track the total number of hours it is switched on. The timer will count up to a maximum of 9999999.9 hours. The decimal point will be flashing at a steady rate when the timer is counting. When the timer is not counting, the decimal point will not flash. The timer will count any time the lighted green on/standby switch is in the on position. The timer will count at the same rate regardless of the intensity setting at which the device is being used. The last digit refers to tenths of hours, with 0.1 = 6 minutes. To reset the timer, please refer to the service manual.

Phototherapy Roll Stand

The roll stand is designed to hold the neoBLUE light with a base designed to accommodate the weight distribution of the light enclosure at any height or angle.

The roll stand operates on a gas shock to maintain a safe pole height during adjustments.

The roll stand incorporates features to adjust the height, tilt and proximity of the light source as described in Section 3.1.

Power Requirement and Accessories

The light is mains-power operated. The power cord plugs into a receptacle at the power inlet at the back of the light enclosure. There are no single-use components for the light.

Lighted Green On/Stand-by Switch

The lighted green switch (between the target light switch and the intensity switch) is used to turn the device on or put it in stand-by mode. The switch should only be illuminated when in the on position. When in the stand-by position, line voltage is still present inside the device if the device is plugged in, but no DC voltage is being switched to the LED panel, fans or timer.

Accessory Pack

An accessory pack is included with each light enclosure. The accessory pack contains the following items: a CD, a power cord, vent filters and extra thumb screws and mounting posts for attaching the light enclosure to the roll stand.

2 SAFETY INFORMATION

2.1 Explanation of Terminology

This manual presents two types of precautionary information. The **Warning** and **Caution** statements are both important to the safe and effective use of the light. Each statement is categorized by using an introductory word in boldface as follows:

Warning! *A statement which describes serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.*

Caution*: A statement which includes information regarding any special care to be exercised by the practitioner, user, and/or patient for the safe and effective use of the device.*

Other explanatory information is highlighted with the word ***NOTE***. Information in this category is not considered precautionary.

NOTE*: Background information provided to clarify a particular step or procedure.*

2.2 General Safety Information

Before administering phototherapy, read all sections of this manual carefully. Observe all precautions to ensure the safety of the patient and those near the instrument. In addition, please refer to your hospital policy and protocol for phototherapy administration.

***NOTE**: Refer to the jaundice management guidelines or regulations in your country to determine best treatment path for neonatal hyperbilirubinemia; such as the AAP Guidelines (American Academy of Pediatrics Clinical Practice Guideline – Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation); or NICE guidelines (National Institute for Health and Clinical Excellence – Neonatal Jaundice).*

***NOTE**: Any serious incident that has occurred in relation to the device should be reported to Natus Medical Incorporated and the competent authority of the Member State in which the user and/or patient is established.*

***Warning!** The neoBLUE device should be used only by appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known risks and benefits of neonatal phototherapy equipment use.*

***Warning!** Incorrect use of the light, or the use of parts and accessories that are not manufactured or supplied by Natus Medical Incorporated, can damage the light, and may cause injury to the patient and/or user.*

***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/cm^2/nm), may not be appropriate for all infants (i.e. preterm infants ≤1000g).[2]*

***Warning!** Do not modify the equipment in any way that is not consistent with instructions in the user manual or service manual.*

***Warning! Placement directly on incubator**: The enclosure can be placed on flat surfaces only. Confirm all rubber feet are fully seated on the top of the enclosure 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.*

[2] 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

***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. While both modes require patient monitoring, manual mode requires constant attention. In manual mode, care must be taken to observe any changes in ambient conditions (drafts, sunlight, phototherapy light usage, etc) as small changes can have an effect on patient temperature. While patient servo also requires attention, the radiant warmer is designed to keep the patient's skin temperature controlled, reducing (but not eliminating) the need to monitor the patient. In addition, use of reflective foils may cause hazardous body temperatures. Monitor the infant's skin temperature per your hospital protocol during phototherapy to avoid fluctuations in body temperature.*

***Warning! Use with Radiant Warmer**: Do not place the neoBLUE light directly under radiant heat source.*

***Warning! Attachment of Light Enclosure**: When attaching the light to any floor stand other than the neoBLUE roll stand, confirm weight capacity and stability of the stand. (Section 8).*

***Warning!** Monitor infants regularly during treatment per your institution's protocols. Use the following guidelines:*

- Measure the patient's bilirubin level periodically.
- Turn the unit off when checking the baby's condition and visualizing skin color; blue light can hinder clinical observations by masking skin color changes, such as cyanosis.
- Monitor patient temperature and fluid status, especially when used with thermotherapy.
- Periodically verify that the baby's eyes are protected and free of infection.

***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. Patients adjacent to the light may also need to be protected with eye shields or equivalent.*

***Warning! Eye Protection:** It is important to select the appropriate size of eye protection for neonates and infants to ensure proper fit and prevent slippage. Refer to the instruction that comes with the eye protector for proper fit.*

***Warning! Skin Temperature**: The use of skin-controlled mode of the incubator or radiant warmer is recommended. In addition, use of reflective foils may cause hazardous body temperatures. Monitor the infant's skin temperature per your hospital protocol during phototherapy to avoid fluctuations in body temperature.*

***Warning! Heat Supply**: The light may impact the heat supply in thermotherapy devices (incubators, radiant warmers, or heated mattresses) and the patient's body temperature.*

***Warning! Ambient Conditions**: Varying ambient conditions, such as the ambient temperature and/or different radiation sources, may adversely affect the patient. Please refer to your hospital phototherapy protocol and procedure regarding appropriate ambient conditions.*

***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 yellow lens glasses are recommended and are available through Natus Medical Incorporated (P/N 900627) or online at www.safetyglassesusa.com.*

***Warning! Photoisomers**: Bilirubin Photoisomers may cause toxic effects.*

***Warning! Lens**: Do not use the light if the lens is missing or damaged. The lens is a plastic shield that protects the baby and the unit from incidental debris or fluids.*

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

***Warning! Combustible 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!** The use of cables or accessories other than the ones supplied by Natus Medical Incorporated is not recommended and could result in poor performance of this product. Only use cables and accessories provided by Natus Medical Incorporated.*

***Warning!** Do not use the light if any parts appear damaged or if there is any reason to believe that it is not functioning properly. Contact Natus Medical Technical Service or your authorized service provider.*

***Warning!** To avoid the risk of electric shock, this equipment must only be connected to a grounded outlet.*

***Warning!** Portable and mobile RF communications equipment can affect medical electrical equipment.*

***Warning!** In order to ensure proper dosage is delivered to the infant, it is recommended to measure the intensity before each use with a radiometer. Not measuring may lead to providing less intensity than the dose prescribed by the physician, which may extend the treatment duration.*

***Caution**: Use of nonstandard components: The unit uses a specific type of LED. Consult the manufacturer for repair and replacement of LEDs. Use of incorrect LEDs can adversely affect performance and/or damage the light.*

⚠ ***Caution***: ***Other equipment***: *Do not attach other equipment not supplied by Natus Medical Incorporated and indicated for use with the light to the neoBLUE system, or place anything on top of the light. The roll stand and light are not designed to support additional equipment. If other equipment must be used in conjunction with this product, the equipment or system should be monitored to verify normal operation in the configuration in which it will be used.*

⚠ ***Caution***: *To avoid overheating, do not cover vents by drapes.*

⚠ ***Caution***: *Use care when repositioning the roll stand around other equipment to prevent accidental change or damage to surrounding equipment.*

⚠ ***Caution***: *The neoBLUE light is a Class A device (CISPR 11, Group 1 Classification), which is allowed in all establishments other than domestic and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes. This light may cause radio interference, in which case adequate measures may be required to prevent interference. See Service Manual Chapter 7 Electromagnetic Specifications for details.*

2.3 Safety Symbols

Be aware of the following symbols, which appear on the light and/or the roll stand.

SYMBOL	MEANING
	On
	Stand-By
	Warning
	Caution
	Consult Instructions for Use
	Always protect the patient's eyes with eye shields or equivalent
	Single Use Only
	Keep Dry
REF	Catalog Number
SN	Serial Number
Medical Device	Medical Device
	Atmospheric Pressure Limitation
	Humidity Limitation
	Temperature Limit
EC REP	Authorized European Representative
	Date of Manufacturing
	Legal Manufacturer
	Fuse
	Device is cleared for the US market as requiring a prescription
	Disposal at end of operating life instructions
	Fragile
	This Side Up

Disposal Instructions

Natus Medical Incorporated is committed to meeting the requirements of the European Union WEEE (Waste Electrical and Electronic Equipment) Regulations 2014. These regulations state that electrical and electronic waste must be separately collected for the proper treatment and recovery to ensure that WEEE is reused or recycled safely. In line with that commitment Natus Medical Incorporated may pass along the obligation for take back and recycling to the end user, unless other arrangements have been made. Please contact us for details on the collection and recovery systems available to you in your region at www.natus.com.

Electrical and electronic equipment (EEE) contains materials, components and substances that may be hazardous and present a risk to human health and the environment when WEEE is not handled correctly. Therefore, end users also have a role to play in ensuring that WEEE is reused and recycled safely. Users of electrical and electronic equipment must not discard WEEE together with other wastes. Users must use the municipal collection schemes or the producer/ importers take-back obligation or licensed waste carriers to reduce adverse environmental impacts in connection with disposal of waste electrical and electronic equipment and to increase opportunities for reuse, recycling and recovery of waste electrical and electronic equipment.

Equipment marked with the crossed-out wheeled bin (WEEE symbol above) is electrical and electronic equipment. The crossed-out wheeled bin symbol indicates that waste electrical and electronic equipment should not be discarded together with unseparated waste but must be collected separately.

3 SAFETY INFORMATION

3.1 Light Enclosure and Roll Stand

Light enclosure: the light enclosure can be tilted by grasping the device on either side and torqueing to desired angle. Use an allen wrench to adjust the tension of the roll stand/enclosure attachment to facilitate positioning. To remove the light from the roll stand, loosen the top two thumb screws and lift the enclosure up and away from the roll stand.

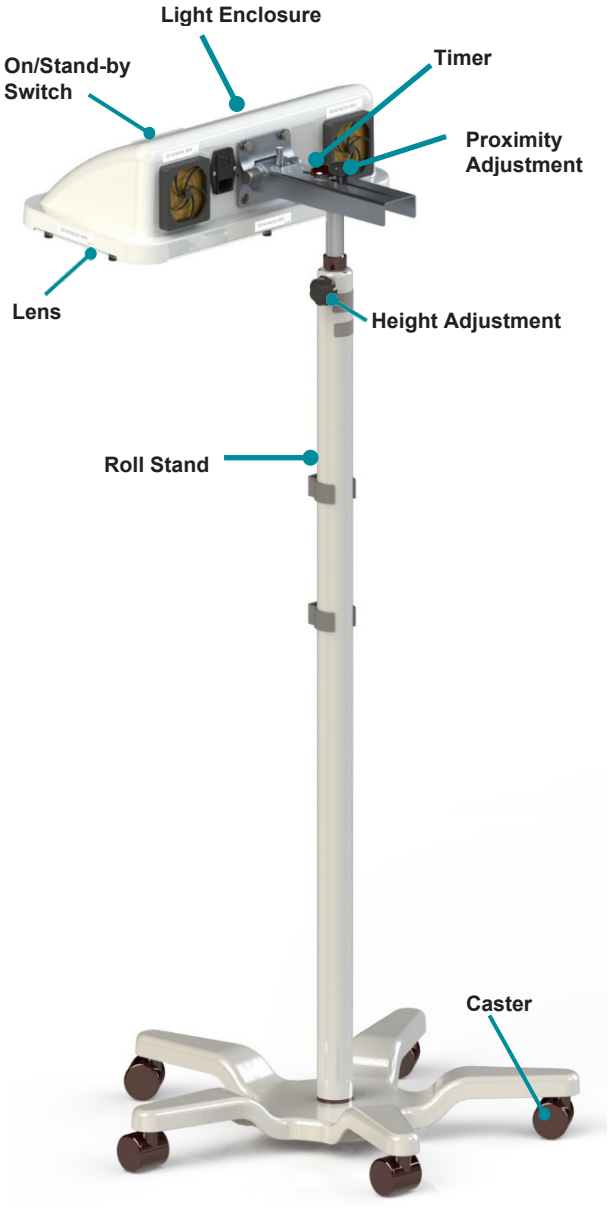
Lens: the lens is a plastic shield that protects the baby and the unit from incidental debris or fluids.

Height adjustment: this knob allows you to adjust the height of the light enclosure. First loosen the knob, then adjust the height of the light enclosure, and finally tighten the knob to lock the height.

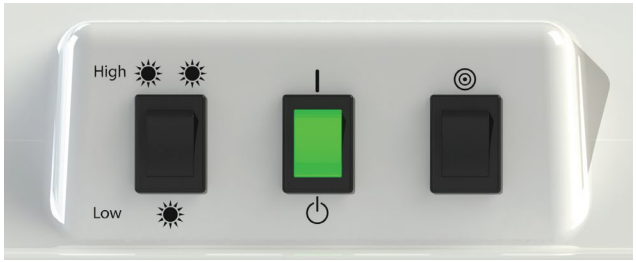
Proximity adjustment: this knob allows you to adjust the distance between the light enclosure and the roll stand post. To adjust, loosen the knob, adjust the position of the light enclosure, and then tighten the knob once the desired distance is achieved.

Locking casters: once the light is in place for phototherapy, the casters should be locked to prevent the light from rolling around freely. Casters lock and unlock with slight foot pressure on the locking tab (down to lock; up to unlock).

Roll stand base: the low profile circular base is designed to prevent tipping when the light is at any angle or distance from roll stand. Base fits under standard incubators to allow easy placement.



3.2 Front Panel Controls

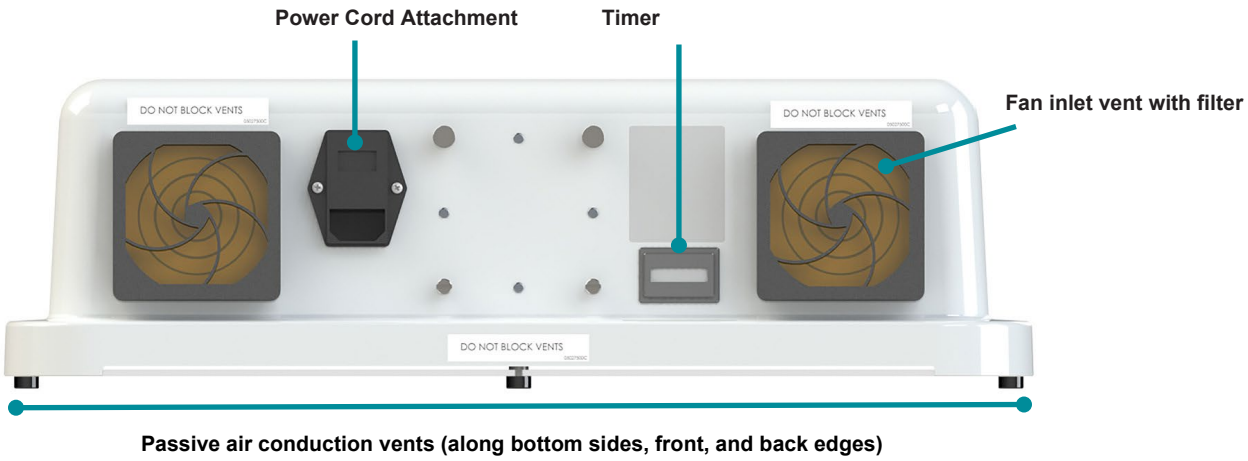


Irradiance Level Control: Use this switch to select between two intensity settings. Low (☼) / High (☼☼).

On/Stand-by Switch: Use this switch to turn the main power ON (|) or to Stand-by ( ). The switch is located in the front of the light enclosure between the irradiance level control and target illuminate switch.

Target Illumination Switch: To help center the light over the infant, press this switch to project a red light over the centrally illuminated area.

3.3 Rear Panel Controls



Timer: The neoBLUE light is equipped with a timer to track the total number of hours it is switched on. The timer will count up to a maximum of 9999999.9 hours. The decimal point will be flashing at a steady rate when the timer is counting. When the timer is not counting, the decimal point will not flash. The timer will count any time the lighted green on/standby switch is in the on position. The timer will count at the same rate regardless of the intensity setting at which the device is being used. The last digit refers to tenths of hours, with 0.1 = 6 minutes. To reset the timer, please refer to the service manual.

Vents: There are two fan inlet vents at the back of the light enclosure. The ventilation fans prevent the unit from overheating. The inflow vents have filters that should be cleaned on a regular basis (see section 6.3 Cleaning). Along the bottom front, sides, and back edges are passive air exhaust vents. If the fans cease to operate, contact Natus Technical Service or your authorized service provider.

Warning! *The use of cables or accessories other than the ones supplied by Natus Medical Incorporated is not recommended and could result in poor performance of this product. Only use cables and accessories provided by Natus Medical Incorporated.*

Caution*: To avoid overheating the light, do not cover vents (refer to Section 6.3, "Cleaning" for more information on vents)*

4 ASSEMBLY AND OPERATING INSTRUCTIONS

4.1 Assembly

The neoBLUE system consists of two products shipped in two separate boxes. One box contains the light enclosure and the other box contains the roll stand (post/attachment arm and base).

To assemble the light, follow these steps:

1. **Unpack the shipping boxes**. Check contents against the packing lists.
2. **Refer to assembly instructions** enclosed in the roll stand box.

4.2 Operating Instructions

1. **Check intensity**. Check the intensity of the light using a radiometer per your institution's procedures (see Section 6.1, "Checking the Light Intensity"). The intensity of the light was factory calibrated to deliver 35 µW/cm^2/nm at the High setting and 15 µW/cm^2/nm at the Low setting at a distance of 12 inches (30.5 cm) from the baby.

Warning! *In order to ensure proper dosage is delivered to the infant, it is recommended to measure the intensity before each use with a radiometer. Not measuring may lead to providing less intensity than the dose prescribed by the physician, which may extend the treatment duration.*

Warning! *Intensive phototherapy (≥30 µW/cm^2/nm), may not be appropriate for all infants (i.e. preterm infants ≤1000g).*[3]

2. **Prepare infant**. Infant may lie in an open crib, a bassinet, an incubator, or under a radiant warmer.

Warning! *Select only infants for whom phototherapy has been prescribed.*

[3] 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

3. **Shield infant's eyes** with protective eye shields designed for use during phototherapy.
   Natus Medical Incorporated suggests using: Biliband® Eye Protectors
   Sizes: Micro (P/N 900644)
   Premature (P/N 900643)
   Regular (P/N 900642)

***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! Eye Protection**: It is important to select the appropriate size of eye protection for neonates and infants to ensure proper fit and prevent slippage. Refer to the instruction that comes with the eye protector for proper fit.*

4. **Position light over infant**.

***NOTE**: The light was factory calibrated with the neoBLUE Radiometer to deliver intensive phototherapy at a distance of 12 inches (30.5 cm) from the baby. Refer to the Service Manual for information on adjusting the intensity if using the light at other distances.*

5. **Switch on power**, using the power switch in the front of the light enclosure.

***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.*

***Caution**: To avoid overheating, do not cover vents by drapes.*

6. **Press the target light 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.

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

***NOTE**: Refer to the jaundice management guidelines or regulations in your country to determine best treatment path for neonatal hyperbilirubinemia; such as the AAP Guidelines (American Academy of Pediatrics Clinical Practice Guideline – Management of Hyperbilirubinemia in the Newborn Infant 35 or More Weeks of Gestation); or NICE Clinical Guidelines (National Institute for Health and Clinical Excellence – Neonatal Jaundice).*

8. **Monitor the patient** during treatment.

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

• Measure the patient's bilirubin level periodically.

• Turn the unit off when checking the baby's condition and visualizing skin color; blue light can hinder clinical observations by masking skin color changes, such as cyanosis.

• Monitor patient temperature and fluid status, especially when used with thermotherapy.

• Periodically verify that the baby's eyes are protected and free of infection.

9. **When finished**, switch power to stand-by and remove light from the therapy area.

5 TROUBLESHOOTING GUIDE

***NOTE**: neoBLUE device Service Manual available separately. In the USA, contact Natus Technical Service at +1-888-496-2887 or E-mail: technical_service@natus.com*

International Support - Please contact your local Distributor. Distributor locations can be found at www.natus.com.

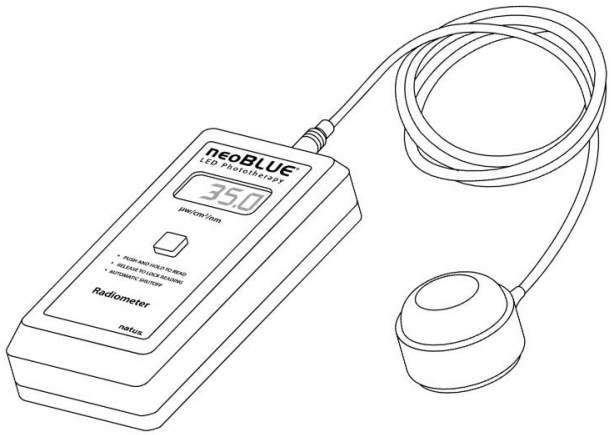
***Warning!** Disconnect power cord before opening the light for repair.*

PROBLEM	PROBABLE CAUSE	ACTION
The unit does not turn on; fan is off.	No power Defective switch Defective power supply	• Verify that unit is plugged in. • Check fuses in the fuse box. • Have a qualified technician check the components and replace as necessary.
Some LEDs are not lit.	One LED may have burned out, causing six LEDs to go off	• Have a qualified technician test the intensity level and readjust the intensity potentiometers to achieve the desired output, if required.
The light turns on but the fan is off.	Defective fan Defective wiring Fan is jammed due to debris	• Clean fan (Refer to Section 6.3) • Contact Natus Technical Service or authorized service provider if problem persists.
Target light switch does not work.	Defective circuitry	• Contact Natus Technical Service or authorized service provider.
The unit will not move around on the neoBLUE roll stand.	Casters are locked	• Ensure all five casters are unlocked

6 ROUTINE CLEANING AND MAINTENANCE

6.1 Checking the Light Intensity

It is recommended that the intensity of the light be checked before each use to ensure the light is providing the intended dose of treatment as prescribed by the physician. This measurement is taken at the central area of the effective surface area for phototherapy.



neoBLUE Radiometer

Natus Medical Incorporated recommends using a properly calibrated neoBLUE Radiometer for measuring the intensity of the neoBLUE light. If this meter is not available, it is important to measure the intensity with a radiometer specifically designed to measure the narrow wavelength spectrum of blue LEDs. Radiometers designed to measure the broadband spectrum found in fluorescent or halogen lights will result in inaccurate intensity measurements.

If the intensity measured falls below factory settings or hospital minimums due to degradation or increased distance, have a qualified technician test the intensity level and readjust the intensity to achieve the desired output, if required

***NOTE**: The intensity of the light is inversely related to the distance from the light source to the infant. Therefore, the intensity can also be adjusted for by moving the light closer or further from the infant.*

***NOTE**: The intensity of the light is not adversely affected if a few LEDs burn out. The LEDs are installed in groups of six, so failure of a single LED normally causes six to fail.*

6.2 Adjusting the Light Intensity

There are two intensity settings, high and low, to provide the physician the option to treat the patient with intensive or standard levels of phototherapy. The desired setting is selected using the left rocker switch on the front panel of the light. The light output was factory calibrated with the neoBLUE Radiometer to provide an initial intensity of 35 μW/cm^2/nm at the high setting and 15 μW/cm^2/nm at the low setting at a distance of 12 inches (30.5 cm) from the light enclosure to the baby. The light output can also be adjusted using the two potentiometers (located on the side of the light enclosure) to accommodate different distances or compensate for any degradation of the LEDs. Please refer to the Service Manual for instructions on how to adjust the light output.

If the desired intensity output cannot be attained after several adjustments of the potentiometers, contact Natus Technical Service or authorized service provider to replace the LED light panel.

⚠ ***Caution**: Only qualified personnel should perform service and repair. Use extreme care when working with exposed circuitry.*

6.3 Cleaning

⚠ ***Warning!** Disconnect the light from AC power before cleaning.*

Remove dust from the exterior of the light with a soft brush or soft cloth dampened with water. Sponge away remaining debris with a mild solution of detergent and water, a non-caustic commercial cleaner, or hospital disinfectant.

Clean the lens with a soft cloth dampened with water. If water alone is ineffective in removing fingerprints or other markings, use a mild solution of detergent and water, a non-caustic commercial cleaner, or hospital disinfectant.

⚠ ***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 component parts in any liquid.

***NOTE**: The following hospital disinfectants are safe to use on this product (Cavicide/CaviWipes, PDI Sani-Cloth wipes, Clorox Germicidal wipes, Sporicidin, 5% bleach, 70% isopropyl).*

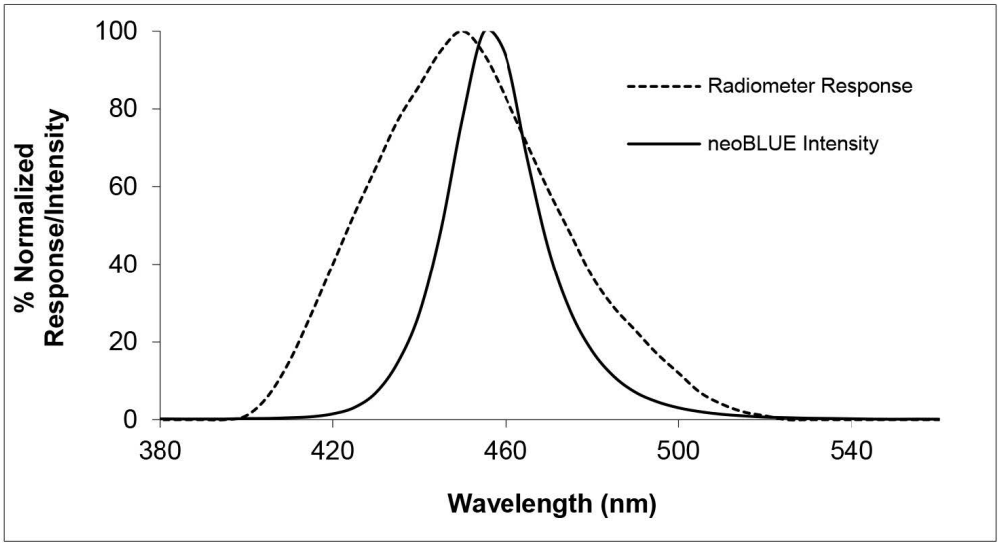
***NOTE**: To ensure correct operating temperature, the vent filters on the back of the light should be kept clear and free of dust.*

As part of routine maintenance, the vent filters should be cleaned every month:

- Remove black filter cover.
- Remove filter and run under water to rinse away dust.
- Allow filter to air dry before placing back in the vent.
- Place filter back in vent and snap filter cover back in place.

7 TECHNICAL REFERENCE

The following graph shows the normalized spectra of the blue LEDs and the spectral sensitivity of the radiometer.



The light output was factory calibrated with the neoBLUE Radiometer to provide an initial intensity of 35 µW/cm^2/nm at the high setting and 15 µW/cm^2/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.

Natus Medical Incorporated recommends using the neoBLUE Radiometer for measuring the intensity of the neoBLUE device. If this meter is not available, it is important to measure the intensity with a radiometer specifically designed to measure the narrow wavelength spectrum of blue LEDs. Radiometers designed to measure the broadband spectrum found in fluorescent or halogen lights will result in inaccurate intensity measurements.

8 SPECIFICATIONS

Light Source

Blue and Yellow LEDs

Wavelength

Blue: Peak between 450 and 475 nm

Yellow: Peak between 585 and 595 nm

Intensity

Peak intensity at 12 in (30.5 cm)

Low setting 15 ±2 μW/cm^2/nm

High setting 35 ±3.5 μW/cm^2/nm

Variation in intensity over 6 hrs

< 10% (within illumination area)

Effective surface area at 12 in. (30.5 cm)

20 x 10 in (50 x 25 cm)

Intensity ratio

> 0.4 (minimum to maximum)

Heat output at 12 in (30.5 cm) over 6 hrs

< 18° F (10° C) warmer than ambient

Classification of ME Equipment:

Protection against electric shock: Class 1

Electrical Ratings

100-240V~, 50/60Hz, 3A

Fuses

M4AL250 (100-120V device REF 001103)

M2AL250 (200-240V device REF 001314)

Safety

Leakage current < 100 μA

Audible Noise < 60 dB

Dimensions

Maximum Height

< 6 ft (1.83 m)

Weight

< 10.0 lbs (4.5 kg) (light enclosure only)

< 40 lbs (18 kg) (with roll stand)

Roll Stand

Height of lens from ground

adjustable from 42 to 59 ± 3 inches

(1.07 m to 1.50 m ± 7.6 cm)

Center of lens from post

adjustable from < 9 to 13 ± 1 inches

(23 cm to 33 cm ± 2.5 cm)

Tilt adjustment of enclosure

0º (horizontal) to approx. 40º

Clearance of base from floor

< 4 inches (10.2 cm)

Base

5 legs with locking casters

Environmental

Operating Temperature/Humidity

59° F to 95° F (15° to 35° C) / 10% to 90% non -condensing

Operating & storage Altitude / atmospheric pressure

-1000 feet to +10000 feet (700 hPa to 1060 hPa)

Storage Temperature/Humidity

32° F to 122° F (0°C to 50° C) / 10% to 90% non-condensing

Shipping Temperature/Humidity

-22° F to 122° F (-30°C to 50°C) / 10% to 90% non-condensing

Shipping Altitude / atmospheric pressure

-1000 feet to +15000 feet (570 hPa to 1060 hPa)

Particular Standards:

IEC 60601-2-50 (2016); CAN/CSA-C22.2 No. 60601-1 (2012)

Base Standards Requirements

IEC 60601-1 Ed 3.1

ANSI/AAMI ES60601-1:2005 +A1

CSA C22.2#60601-1:2014 Ed.3.1

CLASSIFIED C UL US 4FE5

Additional Standards Requirements

IEC 60601-1-6:2010, Ed 3 + A1

IEC 62366:2007, AMD1:2014

IEC 60601-1-2 ED 4.0: 2014-02

AIM Standard 7351731 Rev 2.0: 2017-02-03

LED phototherapy equipment with respect to electrical shock, fire and mechanical hazards only in accordance with:

ANSI/AAMI ES60601-1 (2005)/(R) 2012 and A1; 2012, AAMI 60601-2-50 AMD 1

CAN/CSA-C22.2 NO. 60601-1-14,

CAN/CSA-C22.2 NO. 60601-2-50-10