

neoBLUE® compact

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**User Manual**

**natus**®



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



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



Customer Service: +1-800-303-0306  
Customer Service Fax: +1-650-802-6620  
E-mail: customer\_service@natus.com

Technical Service: +1-800-303-0306  
Technical Service Fax: +1-650-802-8680  
E-mail: technical.service@natus.com

International Support - Please contact your local Distributor. Distributor locations can be found at [www.natus.com](http://www.natus.com)

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# 1 Product Description

*The neoBLUE® compact LED Phototherapy System can be used in three different configurations: the light source (light) can be used alone, with the neoBLUE compact Arm, and with the neoBLUE compact Rollstand.*

## *Intended Use*

The neoBLUE compact LED Phototherapy System is intended for the treatment of neonatal hyperbilirubinemia. The light can be used for infants in a bassinet, incubator, open bed, or radiant warmer.

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

## *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.<sup>1</sup>

## *Clinical Benefit*

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

## *Intended Patient Population*

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 compact LED Phototherapy System is a portable phototherapy light that delivers a narrow band of high-intensity blue light via light emitting diodes (LEDs) to provide treatment for neonatal hyperbilirubinemia.

## *Light Source*

The neoBLUE compact light consists of a lightweight plastic light enclosure. The light can be used independently by placing it directly on top of an incubator or it can be used with the Arm and Rollstand. The light can be easily removed and re-attached to the Arm without tools, for quick and easy versatility.

When used with the Arm, the light can be tilted and adjusted both horizontally and vertically. The Arm can be attached to the pole mount accessory on most

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<sup>1</sup> 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.

incubators and radiant warmers. The Arm attached to the Rollstand, can be used for infants in a bassinet, incubator, open bed, or radiant warmer.

There are two intensity settings, high and low. The desired setting is selected using the buttons on the control panel of the light. The light output was factory calibrated with the neoBLUE® Radiometer to provide an initial intensity of 35  $\mu\text{W}/\text{cm}^2/\text{nm}$  at the high setting and 15  $\mu\text{W}/\text{cm}^2/\text{nm}$  at the low setting at a distance of 35 cm (13.75 in) from the light enclosure to the baby. The light output can also be adjusted. The lower portion of the enclosure includes a built-in lens which protects the light from incidental debris or fluid exposure. The blue LEDs emit the majority of light in the range of 450 – 500 nm (peak wavelength 450-470 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, so there is no UV exposure to the infant. 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. The blue LEDs are mixed with a small amount of light from the white LEDs to soften the appearance of the blue light for sensitive individuals. As with all phototherapy lights, protective eyeshades must be used to protect the infant's eyes from excessive light exposure.

The neoBLUE compact light is also equipped with a white exam light feature that provides approximately 10,000 lux of neutral white light for general examinations.

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 control panel of the light. The light is expected to operate on factory setting intensity levels for over 40,000 hours. Actual results may vary based on environmental factors and intensity adjustments.

### *Treatment and Device Timers*

The neoBLUE compact light is equipped with a treatment timer to track the total number of treatment hours per patient, and a device timer to track the total number of hours the blue LEDs operate. The treatment timer is located on the control panel and can be reset by holding down the reset button next to the display. The device timer is located on the underside of the light near the LEDs. To reset the device timer if LEDs are replaced, please refer to the Service Manual. The timer will count up to a maximum of 99999.9 hours. 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.

### *Power Requirement*

The light is mains-power operated. The power cord plugs into the power inlet at the side of the light enclosure; or into the power inlet located on the Arm when attached to the Arm or Rollstand. The other end of the power cord is plugged into the wall receptacle. Power transform in different regions is accomplished internally and automatically by the power supply unit built in the light device. There is a Power Supply Connection Indicator on the keypad control panel that glows green when power is supplied to the device.

### *On/Standby Switch*

When in the standby position, line voltages are 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.

### *Accessories*

The following accessories are included with each light: a USB Flash Drive containing the User Manual and Service Manual and a power cord.

### *Arm (optional)*

The neoBLUE compact Arm is designed to attach to poles with 0.75 to 1.5 inch (1.91 to 3.81 cm) diameters.

### *Rollstand (optional)*

The neoBLUE compact Rollstand is designed to hold the neoBLUE compact light and Arm with a base designed to accommodate the weight distribution of the light enclosure at any height or angle.

## 2 Safety Information

### 2.1 Explanation of Terminology

This manual presents three types of precautionary information. The three types of statements carry equal weight; that is, they are of equal importance to the safe and effective use of the light. Each statement is categorized by using an introductory word in boldface as follows:

 **Warning!** *Identifies conditions or practices that might present danger or possible injury to the patient and/or user.*

 **Caution:** *An instruction that, if not followed, can result in a condition that could damage the light.*

**Important!** *An instruction provided to help ensure correct clinical results and provide quality assurance to the phototherapy procedures.*

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

The neoBLUE compact LED Phototherapy System can be used in three different configurations: the light source (light) can be used alone, with the neoBLUE compact Arm, and with the neoBLUE compact Rollstand. All configurations were tested for safety and stability and no differences were noted between various configurations.

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 procedure for phototherapy administration.

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.

**Note:** *Refer to the jaundice management guidelines or regulations in your country to determine the 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 the manufacturer and the competent authority of the Member State in which the user and/or patient is established.*

 **Warning!** The neoBLUE compact 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 infant phototherapy equipment use.

 **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 ( $>30 \mu\text{W}/\text{cm}^2/\text{nm}$ ), may not be appropriate for all infants (i.e. preterm infants  $<1000\text{g}$ ).<sup>2</sup>

 **Warning!** Maintain a minimum treatment distance of 35 cm (13.75 in) between the light and infant for optimal uniformity.

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

 **Warning! Attachment of Arm with Pole Mount:** When attaching the light to any floor stand other than the neoBLUE compact Rollstand, the user must validate that it conforms to Regulatory/Safety Standards noted in Specifications (Section 8).

 **Warning! Attachment of Arm with Pole Mount:** Ensure that the pole mount is properly seated around the pole prior to use to prevent slippage during use. Ensure that all screws and bolts are secure prior to use.

 **Warning! Weight Limitations of Arm:** The Arm has been validated to hold the weight of the light enclosure only. Do not hang anything from the Arm or power cord.

 **Warning! Placement directly on incubator:** Confirm all suction cup feet are fully seated on the top of the enclosure to prevent slippage. Position the light in the center of the incubator top, not on an angle or side of the incubator. 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.

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<sup>2</sup> 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 policy during phototherapy to avoid fluctuations in body temperature.*

 **Warning! Use with Radiant Warmer:** *Do not place the light directly under radiant heat source. The light should be placed in line with the side of the heat element and angled toward the infant.*

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

- Measure the patient's bilirubin level periodically.
- Turn the blue light off and white exam light on, 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 or while using the white exam light, always protect the baby's eyes with eye 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! 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 policy 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 policy 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 compact system in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects. Guard Dog Bones glasses are recommended and are available through Natus Medical Incorporated (P/N 900627) or online at [www.safetyglassesusa.com](http://www.safetyglassesusa.com).

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

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

 **Warning!** Do not modify the equipment in any way that is not consistent with instructions in the User Manual or Service Manual.

 **Warning!** Do not position the device in a way that blocks the power inlet at the light or Arm (when used with the Arm) or makes it difficult to disconnect the power cord.

 **Caution: Other equipment:** Do not attach other equipment not supplied by Natus Medical Incorporated and indicated for use with the light to the neoBLUE compact system, or place anything on top of the light. The Rollstand, Arm hardware 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:** Use care when repositioning the Rollstand around other equipment to prevent accidental change or damage to surrounding equipment.

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

 **Caution:** This device is rated IPX0 indicating that no water ingress protection is provided.

**Important! 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.

**Important!** When replacing LEDs, replace all LEDs at the same time.

**Important!** 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.

**Important!** The light was factory calibrated with the neoBLUE® Radiometer to deliver intensive phototherapy at a distance of 35 cm (13.75 in) from the baby. The intensity level should be prescribed by the physician for each patient. Refer to the Service Manual for information on adjusting the intensity if using the light at other distances.

## 2.3 Safety Symbols

Be aware of the following symbols, which appear on the light, manual, or label.

Symbol	Meaning
	On/Standby
	High Intensity Setting
	Low Intensity Setting
	White Exam Light
	Treatment Timer Reset
	Always protect the baby's eyes with eye patches or equivalent
	Power Supply Connection Indicator
	Service Indicator

Symbol	Meaning
	Warning
	Caution
	Consult Instructions for Use
	Authorized European Representative
	Date of Manufacturing
	Legal Manufacturer
	Disposal at end of operating life instructions
	Catalog Number
	Serial Number
	Lot Number
	Atmospheric Pressure Limitation
	Humidity Limitation
	Temperature Limit
	Device is cleared for the US market as requiring a prescription
Medical Device	Medical Device

## **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](http://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 Components and User Controls

### 3.1 Light Enclosure

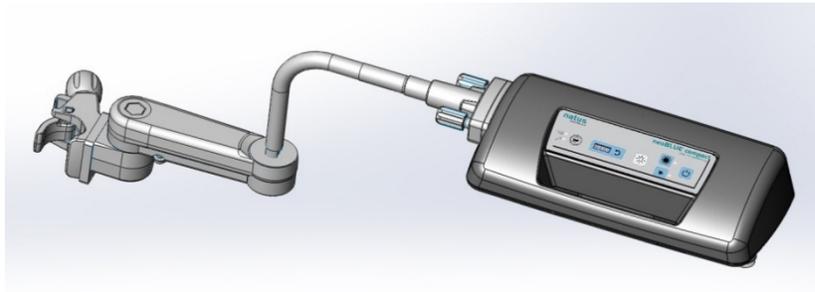
The neoBLUE compact LED Phototherapy System can be placed on top of an incubator. Components include the light enclosure and power cord.



**Vents:** There is one fan outlet vent at the back of the light enclosure. The ventilation fan prevents the unit from overheating. On the bottom of the enclosure is a passive air conduction inlet vent. This inflow vent has a filter that should be cleaned on a regular basis (see section 6.3 Cleaning). If the fan ceases to operate, contact Natus Technical Service or your authorized service provider.

### 3.2 Arm (optional)

The neoBLUE compact LED Phototherapy System can be mounted to the optional neoBLUE compact Arm for use with incubators and infant warmers.



**Arm:** The adjustable Arm allows positioning of the light in multiple locations and angles. No tools are required. The light can be positioned vertically by moving it up and down the pole.

**Note:** *The optimal position for the Arm is parallel to the desired light height.*

**Light Enclosure:** To remove the light from the Arm hardware, loosen the two captive thumb screws and pull the light enclosure away.

**Note:** *The power cord located within the Arm hardware will unplug from the light enclosure when removing it from the Arm.*

### 3.3 Rollstand (optional)

The neoBLUE compact LED Phototherapy System and Arm can be mounted to the optional neoBLUE compact Rollstand for use with incubators, infant warmers, bassinets, or open beds.

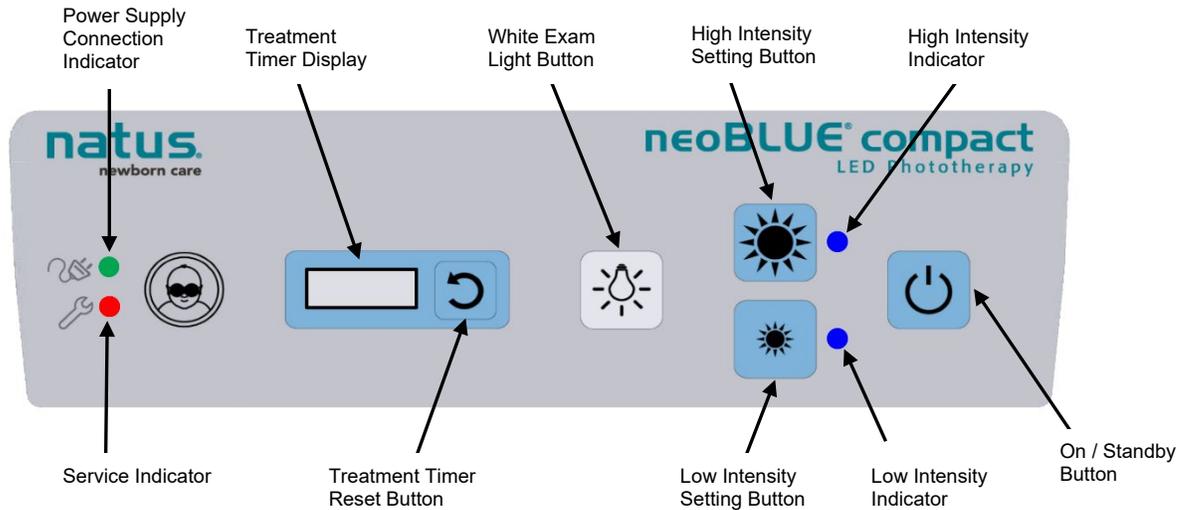


**Height Adjustment:** Adjust the height of the light enclosure by adjusting the gooseneck portion of the Arm and/or by moving the location of the Arm clamp up or down the Rollstand.

**Locking Casters:** Once the light is in place for phototherapy, these casters should be locked to prevent the light from rolling around freely. Casters lock and unlock with slight foot pressure on the locking tab.

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

### 3.4 Panel Controls



**Power Supply Connection Indicator:** This indicator light will glow green when power is connected to the neoBLUE compact device.

**Treatment Timer Display:** The neoBLUE compact light is equipped with a treatment timer, located on the control panel to track the total number of blue light treatment hours per patient. The timer will count up to a maximum of 999.9 hours.

**White Exam Light Button:** Use this button to turn the white exam light On/Off. To resume blue light treatment after using the white exam light, use the blue On/Standby button.

**High/Low Intensity Setting Buttons:** Use these two buttons to choose between High or Low Intensity settings.

**High/Low Intensity Indicator:** One of these indicator lights will glow blue depending on which intensity setting is selected. The neoBLUE compact light will remember the current setting after being turned off or switched to the white exam light.

**On/Standby Button:** Use this button to turn the blue treatment light On or to Standby.

**Treatment Timer Reset Button:** The treatment timer can be reset to zero by holding down the Treatment Timer Reset button for two seconds.

**Service Indicator:** This indicator light will glow red if the device requires service (refer to the Service Manual).

**Device Timer:** The neoBLUE compact light is equipped with a device timer, located on the bottom of the light to track the total number of hours the blue light is switched on. The timer will count up to a maximum of 99999.9 hours. 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.

## 4 Assembly and Operating Instructions

### 4.1 Assembly

The neoBLUE compact light, Arm, and Rollstand are shipped in separate boxes whether ordered separately or as a set.

- 1 **Unpack the shipping boxes.** Check contents against the packing lists.
- 2 **Attach the suction cups to the light.** Install the four suction cups supplied with the light into the four threaded inserts on the underside of the light enclosure before using the product. This step does not require any tools.

**Note:** The neoBLUE compact Arm does not require any assembly. The Rollstand requires some assembly. Follow the instructions supplied with the Rollstand.

### 4.2 Setting up the device

To use the light on top of an incubator without an Arm or Rollstand follow these steps:



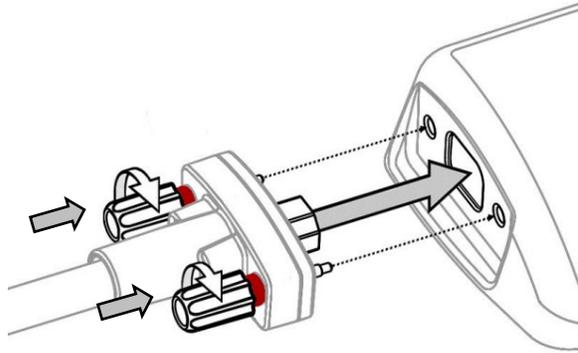
- 1 **Attach the light to the top of the incubator.** Position the light enclosure in the center of the incubator top and press to secure the four suction cups.
- 2 **Attach the power cord.** Attach the power cord into the power inlet located on the side of the light enclosure and plug into an AC outlet.

**⚠ Warning! Placement directly on incubator:** Confirm all suction cup feet are fully seated on the top of the enclosure to prevent slippage. Position the light in the center of the incubator top, not on an angle or side of the incubator. 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.

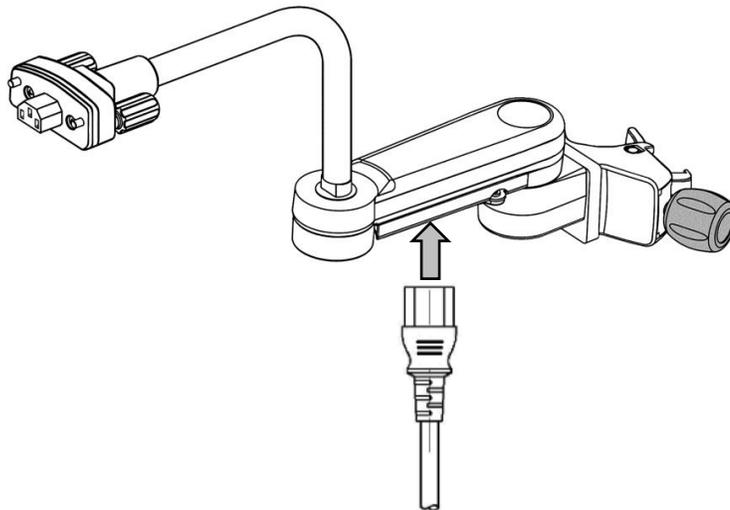
To assemble the light to the Arm follow these steps:

- 1 **Mount the light enclosure to the Arm.** Attach the power cord (located within the Arm hardware) into the light enclosure power inlet, then push and screw in the two captive knobs, ensuring they are fully tightened.

**Note:** *The shaft of each captive knob is colored red. When fully tightened the red shaft should not be visible.*



- 2 **Attach the Arm.** For use with an incubator or radiant warmer, attach the Arm to the manufacturer's specified location on the incubator or radiant warmer. For use with the neoBLUE compact Rollstand follow the steps below.
- 3 **Attach the power cord.** Attach the power cord into the power inlet located on the underside of the Arm next to the Arm clamp, and plug into an AC outlet.



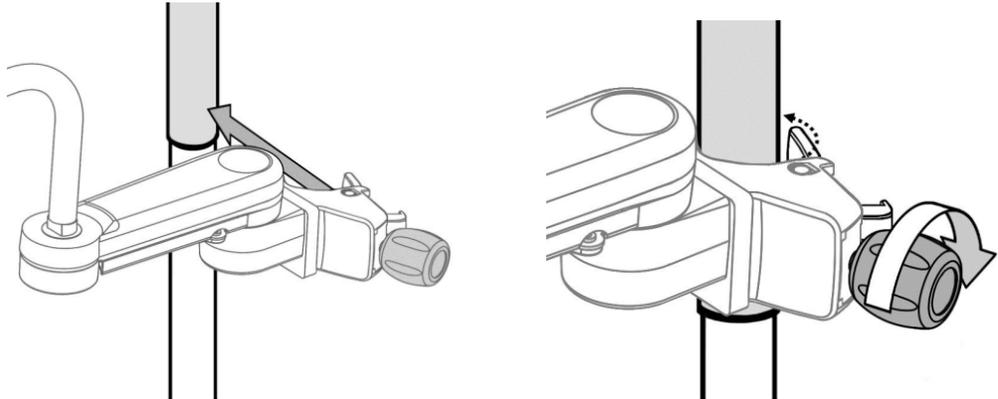
**Warning!** **Attachment of Arm with Pole Mount:** *When attaching the light to any floor stand other than the neoBLUE compact Rollstand, the user must validate that it conforms to Regulatory/Safety Standards noted in Specifications (Section 8).*

**Warning!** **Weight Limitations of Arm:** *The Arm has been validated to hold the weight of the light enclosure only. Do not hang anything from the Arm or power cord.*

**⚠ Warning! Use with Radiant Warmer:** Do not place the neoBLUE compact light directly under radiant heat source. The light should be placed in line with the side of the heat element and angled toward the infant.

To assemble the light and Arm hardware to the Rollstand, follow these steps:

- 1 **Attach the Arm to the Rollstand.** Secure Arm clamp to the pole at the top of the Rollstand.



- 2 **Attach the power cord.** Attach the power cord into the power inlet located on the underside of the Arm next to the Arm clamp, and plug into an AC outlet.

### 4.3 Operating the device

- 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  $35 \mu\text{W}/\text{cm}^2/\text{nm}$  at the **High** setting and  $15 \mu\text{W}/\text{cm}^2/\text{nm}$  at the **Low** setting at a distance of 35 cm (13.75 in) from the baby.

**⚠ Warning!** Maintain a minimum treatment distance of 35 cm (13.75 in) between the light and infant for optimal uniformity.

**⚠ Warning!** Intensive phototherapy ( $>30 \mu\text{W}/\text{cm}^2/\text{nm}$ ), may not be appropriate for all infants (i.e. preterm infants  $<1000\text{g}$ ).<sup>1</sup>

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

**Important!** The light was factory calibrated with the neoBLUE<sup>®</sup> Radiometer to deliver intensive phototherapy at a distance of 35 cm (13.75 in) from the baby. The intensity level should be prescribed by the physician for each patient. Refer to the Service Manual for information on adjusting the intensity if using the light at other distances.

- 2 Shield infant's eyes** with protective eye shields designed for use during phototherapy.

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 or use of the white exam light, always protect the baby's eyes with eye patches or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection.

- 3 Position light over infant.**

When using on top of an incubator without an Arm or Rollstand, position the light enclosure in the center of the incubator top positioned over the infant.

When using with the Arm, the light enclosure can be positioned over the infant by using the combined movements of the pivoting Arm, gooseneck, and swivel joint near the light enclosure.

The light can be positioned vertically by moving it along the pole.

- 4 Turn on the blue treatment light.** Press  On/Standby button on the control panel.

- 5 Select High or Low Intensity.** Press  High or  Low Intensity setting buttons, as appropriate for the patient.

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

- 6 To track treatment time, reset timer to zero.** Press and hold  Treatment Timer Reset button for approximately two seconds.

- 7 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 blue treatment light 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.

- 8 **Turn on white exam light as needed.** Press  exam light button on.
- 9 **Turn off white exam light when finished.** Press  exam light button off, or press the  On/Standby button to resume blue treatment light.
- 10 **Turn off blue treatment light when finished.** Press  On/Standby button.

## 5 Troubleshooting Guide

**Note:** The neoBLUE compact Service Manual is available separately.

 **Warning! Disconnect electrical power:** Always switch off the power and disconnect the power cord when repairing or cleaning the light.

Problem	Probable Cause	Action
The unit does not turn on; fan is off.	No power Defective switch Defective power supply	<ul style="list-style-type: none"> <li>• Verify that unit is plugged in.</li> <li>• Verify the Power Supply Connection Indicator is illuminating green.</li> <li>• Have a qualified technician check the components and replace as necessary.</li> <li>• Contact Natus Technical Service or authorized service provider if problem persists.</li> </ul>
The light turns on but the fan is off.	Defective fan Defective wiring Fan is jammed due to debris	<ul style="list-style-type: none"> <li>• Clean fan (Refer to Section 6.3)</li> <li>• Have a qualified technician check the components and replace as necessary.</li> <li>• Contact Natus Technical Service or authorized service provider if problem persists.</li> </ul>
Service indicator light is illuminated	Multiple causes	<ul style="list-style-type: none"> <li>• Have a qualified technician refer to the Service Manual Troubleshooting for Service Indicator flow chart.</li> <li>• Contact Natus Technical Service or authorized service provider if problem persists.</li> </ul>
The unit will not move around on the neoBLUE Rollstand.	Casters are locked	<ul style="list-style-type: none"> <li>• Unlock the five casters.</li> </ul>

*Refer to the Service Manual Troubleshooting Guide for additional information.*

## 6 Routine Cleaning and Maintenance

### 6.1 Checking the Light Intensity

It is recommended that the intensity of the light be checked per your hospital protocol, or at least every six months to ensure proper light intensity. Have a qualified technician test the intensity level and readjust the intensity to achieve the desired output, if required. Checking intensity before each use is recommended; however, as LEDs have very gradual degradation over time, it is not mandatory.

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

### 6.2 Adjusting the Light Intensity

If the intensity of light falls below hospital-defined minimums due to degradation or increased distance from the light enclosure to the infant, then the light should be readjusted. Please refer to the neoBLUE compact Service Manual for more information.

**Note:** The light will continue to operate with minimal degradation over time. Timing of adjustments is per hospital protocol.

**Important!** The light was factory calibrated with the neoBLUE® Radiometer to deliver intensive phototherapy at a distance of 35 cm (13.75 in) from the baby. The intensity level should be prescribed by the physician for each patient. Refer to the Service Manual for information on adjusting the intensity if using the light at other distances.

### 6.3 Cleaning

 **Warning! Disconnect electrical power:** Always switch off the power and disconnect the power cord when repairing or cleaning the light.

 **Warning!** Do not clean the light while it is positioned over or near the patient.

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.

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

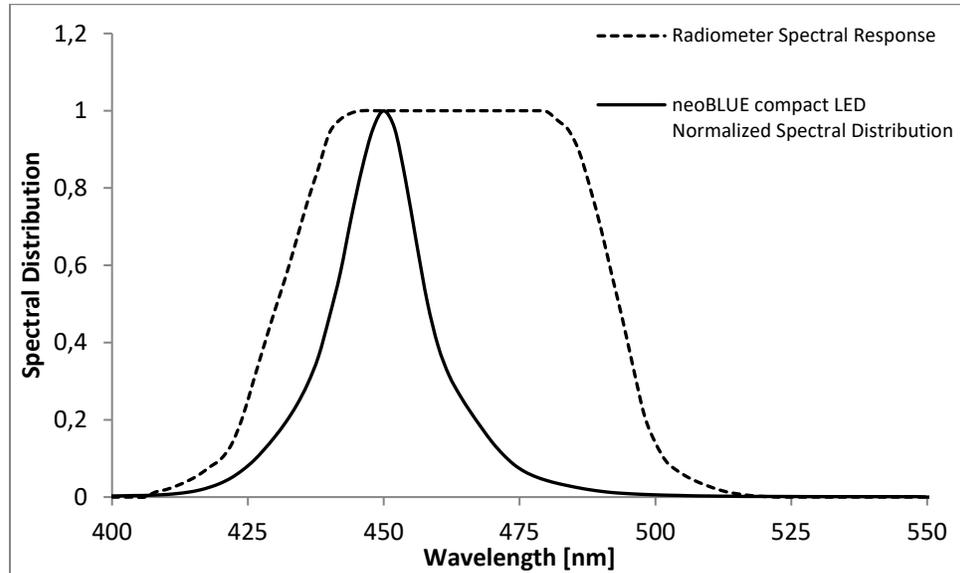
**Note:** *To ensure correct operating temperature, the vent filter on the underside of the light should be kept clear and free of dust.*

As part of routine maintenance, the vent filter should be cleaned once a month, or as needed.

- Remove stainless steel 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 re-attach filter cover.

## 7 Technical Reference

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



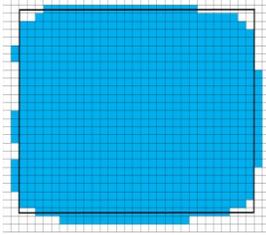
**Measurements for this light were made using a standard radiometer.**

The light output was factory calibrated with the neoBLUE® Radiometer to provide an initial intensity of 35  $\mu\text{W}/\text{cm}^2/\text{nm}$  at the high setting and 15  $\mu\text{W}/\text{cm}^2/\text{nm}$  at the low setting at a distance of 35 cm (13.75 in) from the light enclosure to the baby. This measurement is taken near 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 to provide higher intensity to accommodate increased distances. To adjust the neoBLUE compact light to the desired intensity when changing the distance, please refer to the Service Manual.

Because your facility may use a different radiometer to measure the light intensity output, it is necessary to understand how your reading may differ from the neoBLUE Radiometer reading.

## 8 Specifications

<b>Light Source</b>	Blue and White LEDs
Wavelength	Blue: Peak between 450 and 470 nm
Intensity	Peak intensity at 35 cm (13.75 in)
Factory setting	
Low	15 ±2 μW/cm <sup>2</sup> /nm (total irradiance 1200 μW/cm <sup>2</sup> )
High	35 ±2 μW/cm <sup>2</sup> /nm (total irradiance 2800 μW/cm <sup>2</sup> )
Adjustable setting	
Low	Approx. 10-35 μW/cm <sup>2</sup> /nm
High	Approx. 30-55 μW/cm <sup>2</sup> /nm
Variation in intensity over 6 hrs	< 1% (based on peak value within illumination area)
Effective surface area at 35 cm (13.75 in)	>700 cm <sup>2</sup> (108.5 in <sup>2</sup> ) Approx. 29 x 25 cm (11.4 x 9.8 in)
	
Intensity ratio	> 0.4 (minimum to maximum within effective surface area)
Heat output at 35 cm (13.75 in) over 6 hrs	< 3° F (1.7° C) warmer than ambient on mattress surface
<b>White Exam Light</b>	
Color Temperature	Approx. 4300K
Illuminance	Approx. 10,000 lux / 35 cm (13.75 in)
<b>Electrical Mains</b>	0.7A, 100-240V~, 50/60 Hz
<b>Safety</b>	
Leakage current	< 100 μA
Audible Noise	< 40 dB
<b>Weight</b>	
Light	< 1.2 kg (2.6 lbs)
Arm	< 1.8 kg (4.0 lbs)
Rollstand	< 10.9 kg (24 lbs)
<b>Rollstand (with light and Arm)</b>	
Height of lens from ground	adjustable from approx. 1.24 to 1.57 m (49 to 62 in)
Center of lens from post	adjustable up to approx. 61 cm (24 in) at fully extended Arm
Tilt adjustment of enclosure	total rotation angle of Arm's interface block approx. 55°
Clearance of base from floor	< 10.2 cm (4 in)
Base	5 legs with locking casters

### Environmental

Operating Temperature/Humidity	41° F to 95° F (5 to 35° C) / 10% to 90% non-condensing
Storage Temperature/Humidity	-22° F to 122° F (-30 to 50° C) / 5% to 95% non-condensing
Altitude / atmospheric pressure	-1000 feet to +20,000 feet (50 kPa to 106 kPa)

### Regulatory Standards

IEC 60601-1: Edition 3.1  
IEC 60601-2-50: Edition 2  
IEC 60601-1-2: Edition 4 (EMC)  
IEC 60601-1-6: Edition 3.1 (Usability)



Medical – Applied current / energy equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES60601-1 (2005) + AMD 1 (2012), CAN/CSA-C22.2 No. 60601-1 (2014), ANSI/AAMI/IEC 60601-2-50, CAN/CSA-C22.2 No. 60601-2-50 (2010). Control number 4FE5.