# neoBLUE® blanket

LED Phototherapy

# User Manual

natus®

*(Revision Date 2020-05-27)*

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

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# 1. Product Description

The neoBLUE® blanket LED Phototherapy System consists of five components: the neoBLUE blanket phototherapy light box, the fiberoptic blanket with cable, the blanket mattress, the disposable mattress covers and the power supply.

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

## 1.1. Intended Use:

The neoBLUE blanket LED Phototherapy System is intended for the treatment of unconjugated hyperbilirubinemia in premature babies and neonates. It is intended for use with **patients up to 3 months of age, weighing less than 22 lb (10 kg)**.

## 1.2. Indications for Use:

The neoBLUE blanket LED Phototherapy System is indicated for the treatment of unconjugated hyperbilirubinemia in a hospital environment, and administered by trained professional medical staff, on the order of a physician, or in the home environment administered by a trained caregiver. The neoBLUE blanket device provides intensive phototherapy underneath the patient and can be used with a bassinet, open bed, radiant warmer, incubator, or while holding the patient.

## 1.3. 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.

***Note:*** *Under the direction of a physician, the neoBLUE blanket device may be used in the home environment. Refer to your hospital policy and procedure regarding user training for caregiver and service of the device when used at home.*

*The caregiver must be provided with the 'neoBLUE blanket Guide for Home Use' for adequate use of the device and must follow the direction provided by physician for duration of the treatment.*

## 1.4. Physical Characteristics

The neoBLUE blanket device is a portable phototherapy light that delivers a narrow band of high-intensity blue light via a blue light emitting diode (LED) to provide treatment for unconjugated hyperbilirubinemia.

Light Source

The blue LED emits 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. The blue LED does not emit significant energy in the ultraviolet (UV) region of the spectrum, so there is no concern about UV exposure to the patient. As with all phototherapy lights, protective eyeshades such as the Natus Biliband® Eye Protectors must be used to protect the patient's eyes from excessive light exposure.

The LED has minimal light output degradation over its lifetime with proper use. Nevertheless, the biomedical engineer can adjust the output of the LED using a potentiometer located at the

rear base of the light box. The LED is expected to operate on high intensity (≥30 µW/cm$^2$/nm) approximately 20,000 hours. Actual results will vary based on environmental factors and adjustments to the potentiometer. Due to the nature of the LED light source, this device does not require a pre-ageing period prior to initial use. It also does not require a stabilization (burn-in) period prior to each use.

The neoBLUE blanket system comes with a large or small size fiberoptic blanket. The life expectancy of the fiberoptic blanket will vary with use conditions and adjustments to the potentiometer.

Pole-Mounting Hardware (optional)
Optional hardware is available for pole-mounting applications. The neoBLUE blanket pole-mounting hardware is designed to attach to poles with 0.75 to 1.5 inch (1.91 to 3.81 cm) diameters.

### 1.5. Power Requirement Information

The neoBLUE blanket device can be directly connected to nominal voltages readily available throughout the world as the external power supply provided with this device is rated for use with 100-240 Volts at either 50 or 60 Hz. This external power supply provides 12 VDC to the light box and plugs in to a receptacle at the rear of the light box.

### 1.6. 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. [2]

Do not use the light box or fiberoptic blanket in or near high strength magnetic fields (for example, in or near MRI machines). This product is considered to be “MR Unsafe”.

## 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.*

***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 procedure 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 the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

## 2.3. Safety Symbols

*Be aware of the following symbols, which appear on the device/accessories.*

| Symbol | Meaning |
|---|---|
|  | Refer to instruction manual |
|  | Consult Instructions for Use |
|  | Caution |
|  | Warning |
|  | Type BF patient-applied part |
|  | On (power on) |
|  | Standby (power off) |
| IPX3 | Protected against spraying water |
| IP21 | Protected from condensation<br>Protected against insertion of fingers or become unsafe during dripping water |
|  | Protect the patient's eyes with eye patches or equivalent |
|  | Single-use only |
|  | Operating conditions |
|  | DC Voltage |

| Symbol | Meaning |
|---|---|
|  | Authorized European Representative |
|  | Manufacture Date |
|  | Manufacturer |
|  | Double-insulated (Class II) |
|  | Prescription use only |
|  | Do not use in MRI Environments |
|  | Waste Electrical and Electronic Equipment (WEEE) |
| Medical Device | Indication that device is a Medical Device |

**WEEE Statement**

Natus 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 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.

## Warning!

**Risk of injury to the patient under phototherapy treatment:**

- *Intensive phototherapy (≥30 µW/cm²/nm), may not be appropriate for all neonates (i.e. preterm neonates ≤1000g). [1]*
- *Duration of the treatment must be prescribed by the physician for each patient.*
- *Monitor all patients during intensive phototherapy treatment as directed by physician.*
  - *Measure the patient's bilirubin level periodically.*

    ***Note:*** *Turn the unit off when checking the patient'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.*
  - *Periodically verify that the patient's eyes are protected and free of infection.*
- *To avoid eye-damage during phototherapy treatment, protect the patient's eyes with appropriate size eye protection.*

  ***Note:*** *Refer to the instruction that comes with the eye protector for proper fit.*
- *Bilirubin photoisomers may cause toxic effects.*
- *To avoid any entanglement, always place the patient on the blanket mattress with their head opposite the end where the fiberoptic cable is attached.*
- *Incorrect use of the device, 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.*
- *Do not use without blanket mattress and disposable blanket cover (intended for single-use only). The device must be used with the supplied Natus blanket mattress and cover in place to ensure proper treatment uniformity.*
- *Do not use reflective foils to increase the effectiveness of phototherapy treatment; it may affect the patient's body temperature.*
- *In order to ensure proper dosage is delivered to the patient, 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.*
- *Follow physician instructions when using neoBLUE blanket system in conjunction with an overhead neoBLUE light or other intensive phototherapy systems.*

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## Warning!

**Risk of injury to the other patients or the operator:**

- *Do not look directly into the emitted light from the light box. Light output from the light box is intense and could lead to eye-damage.*
- *Do not use the device if any parts appear damaged or if there is any reason to believe that it is not functioning properly. Contact Natus Medical Incorporated Technical Service or your authorized service provider.*

- *Light sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the illuminated area. Using the neoBLUE blanket device in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects.*
- *The unit should be turned off when patient is not on the blanket mattress or when the caregiver is attending to the patient.*
- *To avoid overheating the light box, check that the air vents are not covered with blankets, clothing, dust and lint, or positioned against obstructing surfaces.*
- *When attaching the light box with the optional pole-mounting hardware to any pole or roll stand, confirm the weight capacity and stability of the overall assembly before using.*

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**Warning!**

**Risk of injury when using the device with other devices:**

- *The light box is not designed to be used in an oxygen-enriched environment such as an incubator.*

  ***Note:*** *It is acceptable to use the fiberoptic blanket mattress within an incubator with the light box positioned outside the incubator.*
- *Do not use the light box in the presence of gases that support combustion (for example, oxygen, nitrous oxide, or other anesthetic agents).*

  ***Note:*** *It is acceptable to use the fiberoptic blanket mattress in the presence of combustible gases.*
- *Do not use the light box or fiberoptic blanket in or near high strength magnetic fields (for example, in or near MRI machines). This product is considered to be "MR Unsafe".*
- *This system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the device or shielding the location.*
- *Device is suitable for hospital and home environment except for near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbance is high*
- *Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."*
- *Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation*
- *Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the neoBLUE blanket, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.*

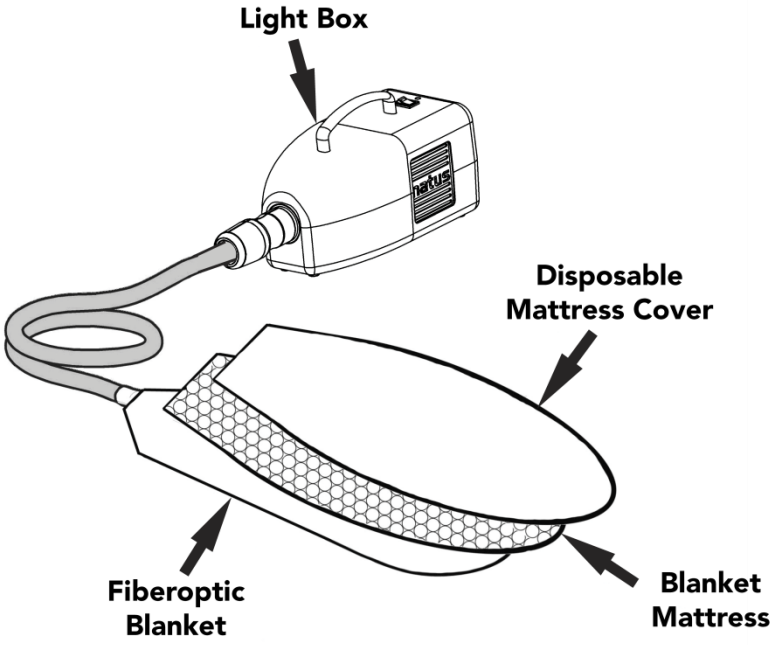
## ⚠ Caution:

- *When the over-temperature indicator light double blinks, the fiberoptic blanket is at the end of its useful life and needs to be replaced.*
- *Do not use the light box under a radiant warmer.*

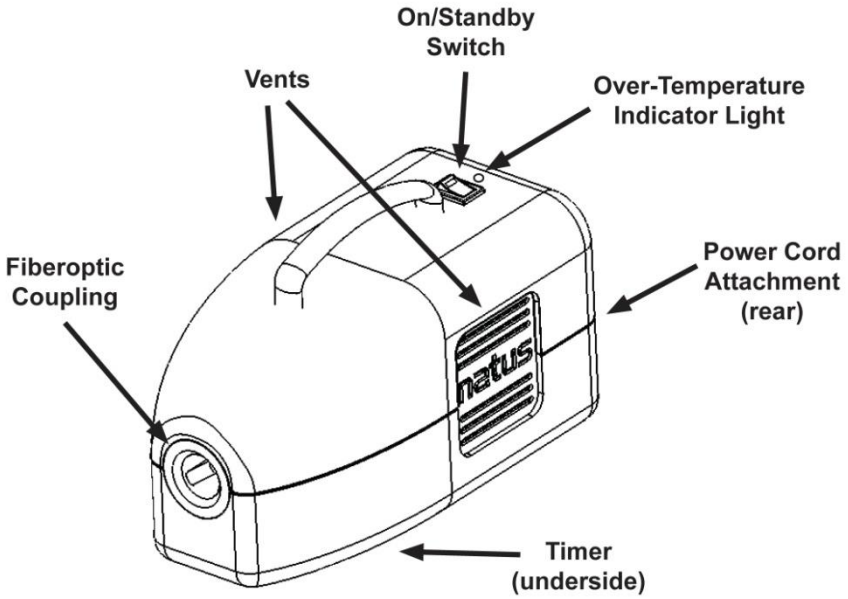
  ***Note:** When the light box is placed directly under radiant heat source, it can damage the light box and possibly trigger the over-temperature indicator light which may cause the blue treatment light to turn off.*
- *The light generated can degrade photosensitive medications. Do not place or store any drugs near or in the illuminated area.*
- *Never place flammable objects on the light box.*
- *When inserting or removing the fiberoptic cable from the light box, hold the light box with one hand to secure and prevent from moving.*
- *The use of power supply, cables or accessories other than the ones supplied by Natus Medical Incorporated is not recommended and could result in poor performance and change the EMC performance with respect to emissions and immunity of this product. Only use with cables and accessories provided by Natus Medical incorporated.*
- *Only qualified personnel should perform service and repair of the light box and LED. Consult Natus Medical Incorporated for repair and replacement.*
- *The neoBLUE blanket device is a Class B device (CISPR 11 Classification), which is allowed in domestic establishments when used under the jurisdiction of a health care professional.*
- *Degradation of the performance of this equipment could result if precautions not taken regarding EMC environment and RF communications equipment. See Service manual Appendix B for details*
- *Do not clean the light box, blanket or mattress with caustic or abrasive cleaners, alcohol, acetone, or other solvents. Always switch off the power and disconnect the power cord from the light box when cleaning the device.*
- *While the light box is splash resistant to IP21 and blanket pad is protected against spraying water to IPX3 requirements per standard IEC60529, avoid spraying liquids directly onto the light box, and do not allow them to seep into the interior.*
- *Varying environmental conditions, may adversely affect the performance of this equipment. Please be aware the operating temperature and humidity for the neoBLUE blanket light box is 41°- 86° F (5°- 30° C) / 10% - 90% non-condensing; and the operating altitude and atmospheric pressure is 700 hPa to 1060 hPa (about -1,000 to +10,000 feet).*

## 3. Components and User Controls

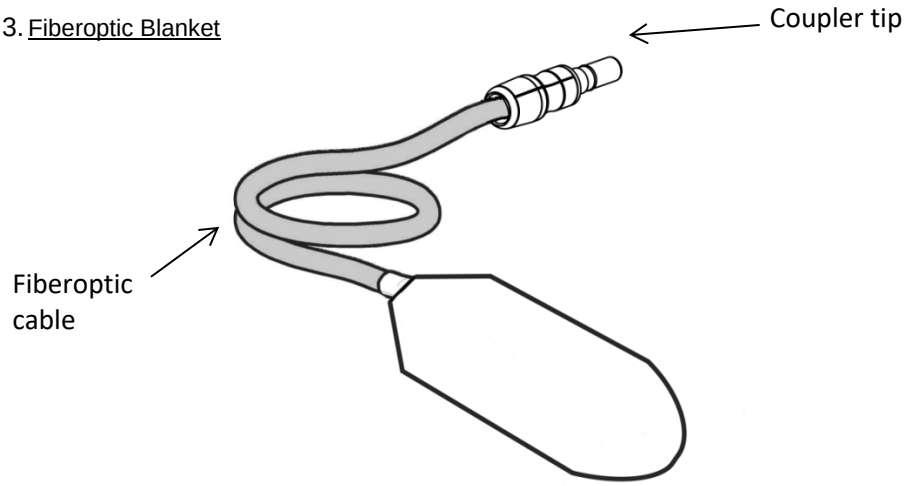
### 3.1. neoBLUE blanket LED Phototherapy System




### 3.2. Light Box



3.3. Fiberoptic Blanket




3.4 Controls

**On/Standby Switch:** Use this switch to turn the unit ON ( **|** ) or place in STANDBY (⏻). The switch is located on the top of the light box. The green indicator light located on the switch, when lit, indicates the unit is ON. The unit will not emit the blue phototherapy treatment light until the switch is ON and a fiberoptic cable is fully inserted into the fiberoptic coupling in the light box.

**Power Cord Attachment:** The power cord attachment is at the rear of the light box.

**Vents:** There are vents located at the sides of the light box. A ventilating fan prevents the LED from overheating.

**Over-Temperature Indicator Light**: The Over Temperature Indicator Light located next to the switch at the rear of the light box can indicate two different temperature related conditions with the light box. One indication is for a condition when the temperature inside the light box, especially the therapy LED, is getting too warm. In this case, the amber indicator light will blink ON and OFF and the blue treatment light will automatically turn Off to reduce the temperature while the fan will continue to run. Should this happen, the vents should be checked to ensure they are not blocked. When the unit has cooled down sufficiently, the blue treatment light will turn back on automatically. The amber indicator light will continue blinking to indicate that an overheating situation has occurred. This amber indicator light can be reset by toggling the On/Standby switch to Standby and then back On.

A second condition is if the lens interface overheats. In that event, the amber indicator light will double-blink, however, the blue treatment light will continue operating. In the event that the interface continues to heat and reaches a cut-off temperature, the amber indicator light will continue to double-blink but the blue therapy light will turn Off. The blue therapy light and the amber indicator light can be reset by toggling the On/Standby switch to Standby and back On once the light box has sufficiently cooled down.

***Warning!*** *To avoid overheating the light box, check that the air vents are not covered with blankets, clothing, dust and lint, or positioned against obstructing surfaces.*

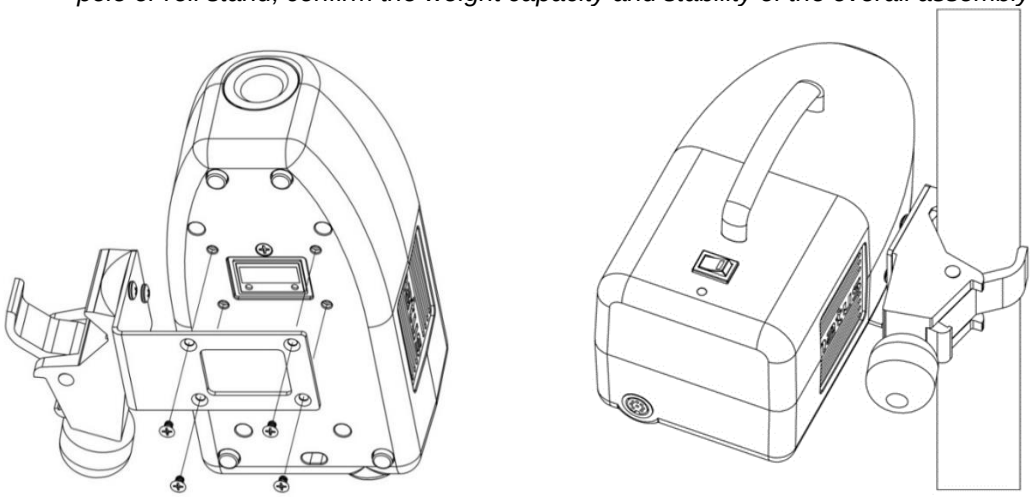
***Caution:*** *When the over-temperature indicator light double blinks, the fiberoptic blanket is at the end of its useful life and needs to be replaced.*

**Timer:** The neoBLUE blanket is equipped with a timer to track the total number of hours the blue therapy light 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 that light is emitted from the light box. The last digit refers to tenths of hours, with 0.1 = 6 minutes.

## 3.5 Pole-Mounting Hardware (optional)

The neoBLUE blanket Light Box can be mounted to poles (such as the pole attachment accessory on incubators and patient warmers) by using the optional pole-mounting hardware. This hardware is designed to clamp to poles with 0.75 to 1.5 inch (1.91 to 3.81 cm) diameters.

***Warning!*** *When attaching the light box with the optional pole-mounting hardware to any pole or roll stand, confirm the weight capacity and stability of the overall assembly before using.*



## 4. Assembly and Operating Instructions

4.1. Preparing the neoBLUE blanket LED Phototherapy System for use:

1. **Position fiberoptic blanket with mattress** in a bassinet, open bed, radiant warmer, or incubator.
2. **Position light box and insert fiberoptic cable** into the fiberoptic coupling.

***Note:*** *If using an incubator, position fiberoptic cable through one of the incubator ports then insert into light box located outside the incubator.*

***Note:*** *Place the light box away from patient, on a flat, stable, surface, free from obstruction and clutter, or mount to a pole using optional hardware.*

***Warning!*** *When attaching the light box with the optional pole-mounting hardware to any pole or roll stand, confirm the weight capacity and stability of the overall assembly before using.*

***Warning!*** *To avoid overheating the light box, check that the air vents are not covered with blankets, clothing, dust and lint, or positioned against obstructing surfaces.*

***Caution:*** *When inserting or removing the fiberoptic cable from the light box hold the light box with one hand to secure and prevent from moving.*

3. **Connect power supply** to suitable wall outlet and to light box. Power supply cords should be safely routed.
4. **Apply disposable cover**, by slipping over the blanket mattress. Replacement covers are consumable products to be discarded after single-use (replacement covers can be ordered from Natus Medical Incorporated).

***Warning!*** *Do not use without blanket mattress and disposable blanket cover (intended for single-use only). The device must be used with the supplied Natus mattress and cover in place to ensure proper treatment uniformity.*

***Note:*** *The mattress comes already installed over fiberoptic blanket. The mattress is semi-durable (replacement mattresses can be ordered from Natus Medical Incorporated).*

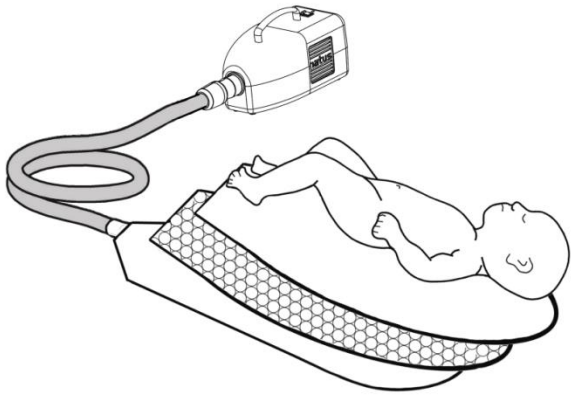
5. **Switch on power**, by moving the power switch to the ON ( | ) position.
6. **Check intensity** of the light using a radiometer per your institution's procedures. Refer to Section 6.1, "Checking the Light Intensity." The light intensity output of the neoBLUE blanket system was factory set to 35 ±5 µW/cm$^2$/nm using a neoBLUE Radiometer.

4.2. Administering phototherapy treatment:

***Warning!*** *Intensive phototherapy (≥30 µW/cm$^2$/nm), may not be appropriate for all patients (i.e. preterm patients ≤1000g).*[1]

***Warning!*** *Duration of the treatment must be prescribed by the physician for each patient.*

***Warning!*** *In order to ensure proper dosage is delivered to the patient, 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.*



7. **Shield patient's eyes** with protective eye shields prior to initiating phototherapy.

   Natus suggests using:

   Biliband® Eye Protectors

   *Sizes: Micro (P/N 900644)*
   *Premature (P/N 900643)*
   *Regular (P/N 900642)*

***Warning!*** *To avoid eye-damage during phototherapy treatment, protect the patient's eyes with appropriate size eye protection.*

***Note:*** *Refer to the instruction that comes with the eye protector for proper fit.*

***Note:*** *During periods when the patient is being held and positioned so that their eyes cannot be exposed to the light, protective eye shields can be removed.*

8. **Place patient on top of neoBLUE blanket covered mattress.**

***Warning!*** *To avoid any entanglement, always place the patient on the blanket mattress with their head opposite the end where the fiberoptic cable is attached.*

9. **Monitor patient during treatment.**

***Warning!*** *Monitor all patients during intensive phototherapy treatment as directed by physician.*

- *Measure the patient's bilirubin level periodically.*

  ***Note:*** *Turn the unit off when checking the patient'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.*
- *Periodically verify that the patient's eyes are protected and free of infection.*

***Warning!*** *Light sensitive individuals may experience headache, nausea, or mild vertigo if they stay too long in the illuminated area. Using the neoBLUE blanket device in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects.*

***Warning!*** *The unit should be turned off when patient is not on the mattress or as necessary when the caregiver is attending to the patient.*

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

## 5. Troubleshooting Guide

***Note:*** *Service Manual available separately on CD. In the USA, contact Natus Technical Service at +1 (888) 496-2887 or +1 (650) 802-0400, or E-mail: technical_service@natus.com. Outside of the USA, contact your local distributor.*

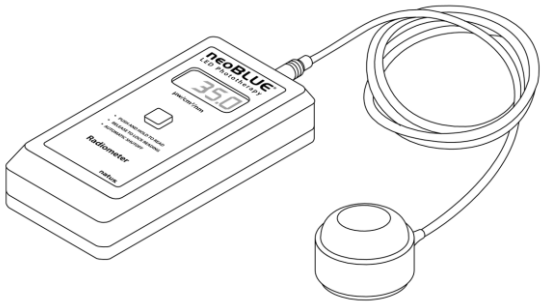
***Caution:*** *Only qualified personnel should perform service and repair of the light box and LED. Consult Natus Medical Incorporated for repair and replacement.*

| Problem | Probable Cause | Action |
|---|---|---|
| The unit does not turn on, fan is off. | No power<br>Defective switch<br>Defective power supply | • Verify that unit is plugged in.<br>• Verify that the plug into the device is making good contact and is secure.<br>• Have a qualified technician check the components and replace as necessary. |
| The blue light does not turn on, but fan is on. | Fiberoptic cable is not attached to light box.<br>Circuit board is damaged | • Insert fiberoptic cable into fiberoptic coupling in light box.<br>• Contact Natus Technical Service or authorized service provider if problem persists. |
| The blue light turns on, but fan is off. | Defective fan<br>Defective wiring | • Contact Natus Technical Service or authorized service provider if problem persists. |
| Amber indicator light is blinking (single blink pattern). Blue light may be on or off. | Device LED has overheated, caused by:<br>Blocked vents,<br>Device being used in operating temperature above 30ºC or<br>Circuit board is damaged<br>Fan failure | • Remove any material that may be blocking airflow through the vents.<br>• Use the device in a cooler environment.<br>• Contact Natus Technical Service or authorized service provider if problem persists. |
| Amber indicator light is blinking (double blink pattern). Blue light may be on or off. | Internal lens interface has overheated, caused by:<br>Fiberoptic pad is damaged at coupler tip and is at the end of its useful life | • Replace fiberoptic pad.<br>• Contact Natus Technical Service or authorized service provider if problem persists. |

## 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 near the center of the effective treatment area on top of the mattress and disposable cover.




***neoBLUE Radiometer***

Natus recommends using a properly calibrated neoBLUE Radiometer for measuring the intensity of the neoBLUE blanket 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 setting or hospital minimum have a qualified technician test the intensity level and readjust the intensity to achieve the desired output, if required.

***Note:*** *The light intensity output of the neoBLUE blanket system was factory set to 35 ±5 µW/cm$^2$/nm using a neoBLUE Radiometer.*

6.2. Adjusting the Light Intensity

The light output can be adjusted using a potentiometer located at the rear base of the light box. Please refer to the Service Manual for instructions on how to adjust the light output.

⚠ ***Caution:*** *Only qualified personnel should perform service and repair of the light box and LED. Consult Natus Medical Incorporated for repair and replacement.*

If the desired intensity output cannot be attained after several adjustments of the potentiometer, contact Natus Technical Service or authorized service provider.

6.3. Cleaning

⚠ ***Caution:*** *While the light box is splash resistant to IP21 and blanket pad is protected against spraying water to IPX3 requirements per standard IEC60529, avoid spraying liquids directly onto the light box, and do not allow them to seep into the interior.*

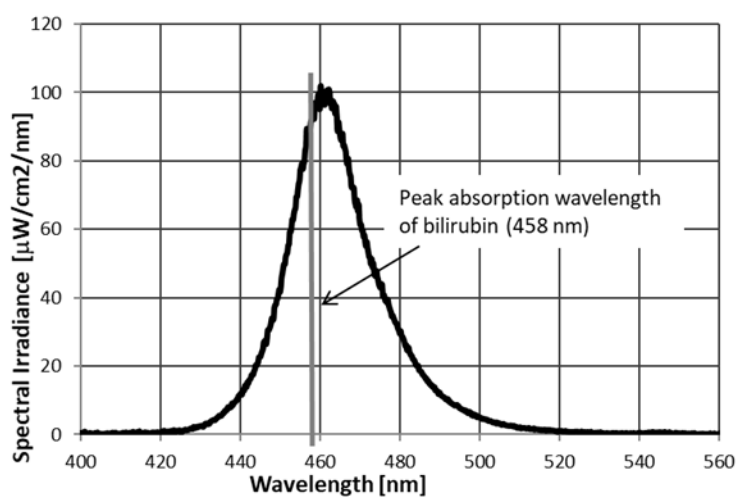
⚠ ***Caution:*** *Do not clean the light box, blanket or mattress with caustic or abrasive cleaners, alcohol, acetone, or other solvents. Always switch off the power and disconnect the power cord from the light box when cleaning the device.*

Using a soft cloth dampened with a mild detergent solution or with soap-and-water, wipe the exterior of the neoBLUE blanket, including the light box, fiberoptic blanket / cable, mattress and power cord. Cleaning the neoBLUE blanket device and mattress may also be accomplished with standard hospital disinfectants.

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

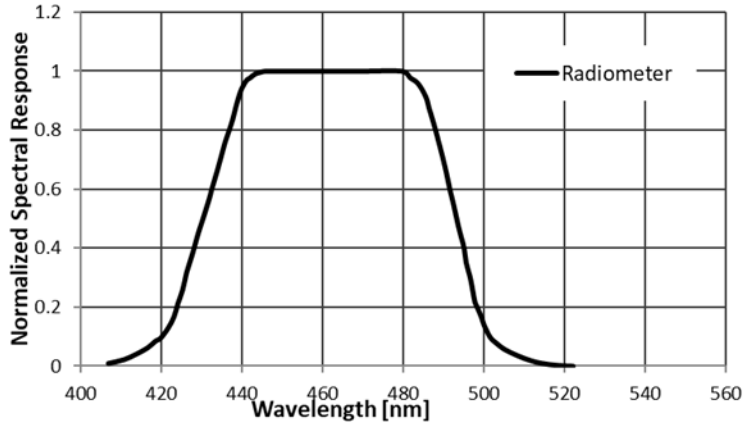
## 7. Technical Reference

The following graph shows the spectral irradiance for bilirubin of the neoBLUE blanket LED Phototherapy System; and the peak absorption wavelength of bilirubin (458 nm). [3]




The intensity of the light is factory set to 35 ±5 µW/cm$^2$/nm at the patient surface. This measurement is taken with a radiometer near the center of the effective surface area for phototherapy. The following graph shows the nominal response characteristics of the neoBLUE Radiometer, which corresponds to the peak absorption spectrum of bilirubin.

***Note:*** *During the life of the fiberoptic pad the intensity readings can vary from the factory setting up to 10%. Please refer to the Service Manual for instructions on how to adjust the light output.*



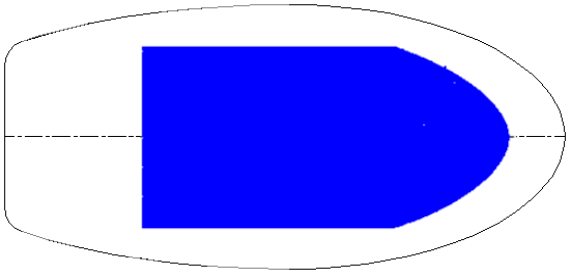

Natus recommends using the neoBLUE Radiometer for measuring the intensity of the neoBLUE LED Phototherapy System. If this meter is not available, it is important to measure the intensity with a radiometer specifically designed to measure the narrow wavelength spectrum of blue LEDs. Radiometers designed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

## 8. Specifications

### 8.1. Light Source

Blue LED

| | |
|---|---|
| Wavelength Blue: | Peak between 450 and 475 nm |
| Peak intensity at patient surface: | 35 ±5 µW/cm$^2$/nm at factory setting (total irradiance 2800 µW/cm$^2$) |
| Variation in intensity over 6 hrs: | < 10% (within effective treatment area) |
| Light emitting area (large blanket): | Approximately 9.5 in (24.1 cm) x 14.5 in (36.8 cm), 114 in$^2$ (734 cm$^2$) |
| Light emitting area (small blanket): | Approximately 6.75 in (17.1 cm) x 12.75 in (32.4 cm), 75.7 in$^2$ (488 cm$^2$) |
| Effective treatment area (large blanket): | >77.5 in$^2$ (500 cm$^2$) |
| Effective treatment area (small blanket): | >38.75 in$^2$ (250 cm$^2$) |



| | |
|---|---|
| Intensity ratio: | > 0.4 (minimum to maximum) |
| Heat output: | 104° F (40° C) maximum surface temperature |

### 8.2. Power Supply Specifications

*Input*

Voltage: 100 – 240 V~
Current: 1.6 A
Frequency: 50 – 60 Hz

*Output*

Voltage: 12 V ⎓
Power: 72 W maximum
Current: 6.0 A

### 8.3. Safety

Total patient leakage current < 100 µA
Audible Noise ≤ 44 dB(a)

| | |
|---|---|
| Use around flammable gasses | This product is “non-AP/APG” |
| Use around magnetic fields | This product is “MR Unsafe” |

### 8.4. Dimensions

| | |
|---|---|
| Size - Light Box (W x L x H): | 4.75 in x 9.25 in x 5.5 in (12.1 cm x 23.5 cm x 14 cm) |
| Weight - Light Box: | 3 lbs. (1.36 kg) |

8.5. Environmental

| | |
|---|---|
| Operating Temperature/Humidity: | Light box: 41° to 86° F (5 to 30° C) / 10% to 90%, non-condensing<br>Blanket: 41° to 100° F (5 to 38° C) / 10% to 90%, non-condensing |
| Storage Temperature/Humidity: | 32° to 122° F (0 to 50° C) / 10% to 90%, non-condensing |
| Shipping temperature/humidity: | -30 to 65 C (-22 to 149 F) / 10% to 90% non-condensing |
| Operational Altitude / atmospheric pressure: | 700 hPa to 1060 hPa (about -1,000 to +10,000 feet) |
| Storage altitude / pressure: | 700 to 1060 hPa (about -1000 to 10000 ft) |
| Shipping altitude / pressure: | 570 to 1060 hPa (about -1000 to 15000 ft) |

8.6. Safety Standards

Electrical Safety: IEC 60601-1 ED 3.1 2012,
ANSI/AAMI ES60601-1: 2005/ (R) 2012 and A1: 2012,
CAN/CSA C22.2 No 60601-1: 14
CAN/CSA-C22.2 No 60601-2-50-10
EMC [Class B]: IEC 60601-1-2: ED 4 2014-02
Device specific safety: IEC 60601-2-50 ED 2.1 AAMI 60601-2-50 AMD 1
Home Healthcare: IEC 60601-1-11 ED 2 2015-01
Usability: IEC 60601-1-6 ED 3.1 2013-10, IEC 62366 ED 1.1 2014-01
Biocompatibility: ISO10993

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5010416

Conforms to AAMI STD ES60601-1
AAMI STD HA60601-1-11;
AAMI IEC STD 60601-2-50;
IEC STD 60601-1-6.
Certified To CSA STD C22.2 No.
60601-1; 60601-1-11; 60601-2-50

*[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*

*[2] 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.*

*[3] Vreman HJ, et al. Light-emitting diodes: a novel light source for phototherapy. Pediatric Research. 1998; 44(5):804-809*