

neoBLUE[®] blanket

LED Phototherapy

Guide for Home Use

natus.[®]

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

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



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



INTRODUCTION

Before using the neoBLUE blanket device for your baby's phototherapy, you should have been trained by a nurse, doctor, or Home Medical Equipment (HME) specialist. Before starting to use the device, please read all sections of this Guide for Home Use.

What is jaundice?

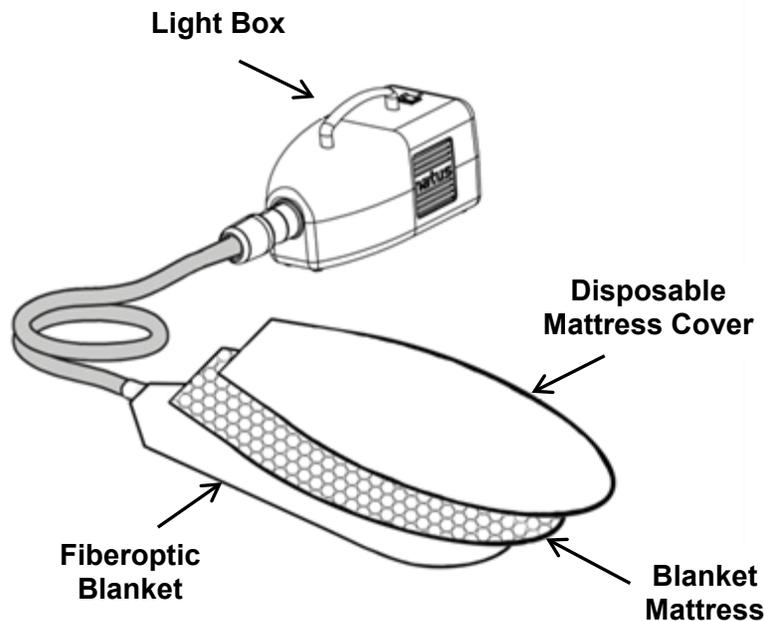
Jaundice is the yellowish discoloration of your baby's skin and/or eyes. More than half of normal, term infants develop jaundice. For most babies, jaundice appears on the second to third day of life and is gone by the end of the first week of life.

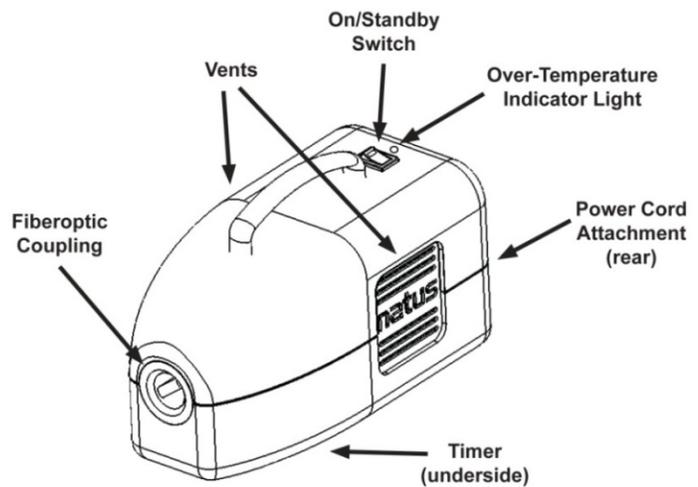
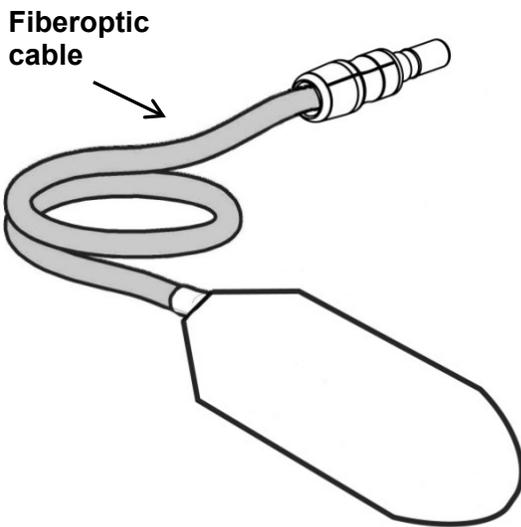
Jaundice usually develops because your baby's liver is not yet fully mature, and is not able to breakdown and dispose of a substance called "bilirubin". Bilirubin is produced naturally as red blood cells recycle. Because your baby is brand new, and their liver is still developing, they may not be able to process bilirubin well enough. When this happens, bilirubin builds up and appears as jaundice.

What is a neoBLUE blanket LED Phototherapy System?

The neoBLUE blanket device is a special blue fiberoptic light for treating babies with jaundice. Babies are placed on top of the blanket to expose their skin to the blue light. Scientific research has shown that blue light is the most effective for treating jaundice. When the light shines on the skin it alters the bilirubin, making it easier for your baby to dispose.

The neoBLUE blanket device consists of the light box, the fiberoptic blanket, the blanket mattress, the disposable mattress covers and the power supply (not shown).





INSTRUCTIONS

1. Position the fiberoptic blanket with mattress in a crib or bed.

Note: Ensure that the pad is positioned in the mattress so the blue light will shine up on the top side where your baby will be positioned. There is also a label which says "This side towards patient"



2. Position the light box on a table top or other flat surface next to your baby's crib or bed and insert the end of the fiberoptic cable into the light box.
3. Connect the power supply to a wall outlet and to the light box. Make sure the cords are positioned safely, so they do not cause a tripping hazard and are away from your baby.

Note: Take proper care to route power cords and cables such that they do not pose any hazard, including tripping hazard to or from non-care givers such as children and pets.

4. Apply a disposable cover to the blanket mattress.

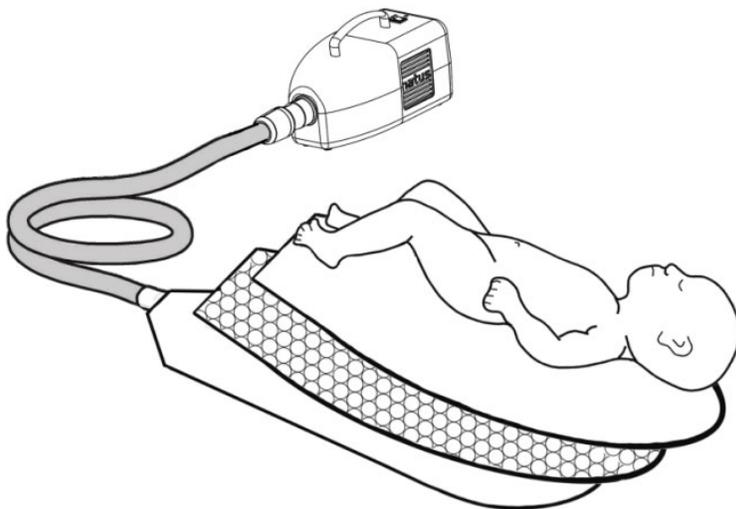
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- Cover your baby's eyes with protective eye shields prior to starting phototherapy.

Note: Protective eye shields should have been provided with the device by the hospital or HME.

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



- Place your baby on top of the neoBLUE blanket covered mattress with their head at the opposite end from where the cable is attached (see below).



- To start treatment for your baby, move the power switch to the ON (|) position. Do not look directly into the blue light.

Note: Baby blankets can be placed around your baby as needed. Ensure that they do not block the blue light treatment to your baby.



8. Follow the instructions from your doctor or healthcare professional for monitoring your baby and for the amount of time needed for treatment.
9. When finished, switch power to standby and remove the neoBLUE blanket device from your baby.

SAFETY INFORMATION

 **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.

 **Warning!** 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.

 **Warning!** During treatment, protect your baby's eyes with eye shields when their eyes can be exposed to the blue light.

 **Warning!** To avoid injury due to the cable wrapping around your baby, always place them on the mattress with their head at the other end from where the cable is attached.

 **Warning!** People who are sensitive to blue light may experience headache, nausea or mild vertigo if they stay near the light too long. Using the neoBLUE blanket device in an area well lit or wearing glasses with yellow lenses can make these potential effects go away.

 **Warning!** The unit should be turned off when your baby is not on the mattress.

 **Warning!** Do not use without blanket mattress and disposable blanket cover. The device must be used with the supplied Natus mattress and cover in place to ensure proper treatment.

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

Note: To avoid overheating the light box, do not place device near fireplace or radiant heater

 **Caution:** Never place flammable objects on the light box.

 **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.

 **Caution:** Use the device only with the power supply provided with the device.

 **Caution:** 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).

CLEANING

If needed, the neoBLUE blanket device can be cleaned by using a soft cloth dampened with mild detergent or soap and water. Use this cloth to wipe the device, including the light box, fiberoptic blanket / cable, mattress and power cord.

 **Caution:** Always turn off the power and disconnect the power cord from the outlet when cleaning the device.

 **Caution:** Do not spray any liquid directly onto the light box.

HELP WITH PROBLEMS

What if the blue light does not turn on?

Check to make sure the power cord is plugged into the wall outlet and into the power supply. Check to make sure the power supply is plugged into the rear of the light box. Note: When the green light located on the top of the switch is lit, the unit has power but is in Standby mode. However, the unit will not turn on the blue treatment light until the switch is ON and the fiberoptic cable is properly inserted into the light box.

What if the blue light turns off during use?

Check to see if the over-temperature indicator light located next to the ON/Standby switch at the rear of the light box is blinking amber. This means the unit has overheated. The vents on the light box should be checked to ensure they are not blocked. When the unit has cooled down, the blue light turns back on by itself.

Note: The indicator light will continue blinking amber to indicate that an overheating event has occurred. This indicator light may be reset by turning the On/Standby switch to Standby and then back On.

Note: If the device has turned itself off and does not turn back on within 10-15 minutes, contact the hospital or HME specialist that provided this device to you. (If this happens, there should be a yellow blinking light on top of the unit.)



Warning! Do not use the device if any parts appear damaged or if there is any reason to believe the device is not working properly. Contact the hospital or HME specialist that provided you this device.

SAFETY SYMBOLS

Please be advised of the following symbols that appear on the device/accessories.

Symbol	Meaning
	Refer to instruction manual/ booklet
IPX3	Protected against spraying water
IP21	Protected against insertion of fingers or become unsafe during dripping water
	Operating instructions
I	On (power on)
	Standby (power off)

Symbol	Meaning
	Caution
	Warning
	Protect the baby's eyes with eye patches or equivalent
	Single-use only
	Prescription use only