

Urgent Field Safety Notice (FSN)
neoBLUE blanket LED Phototherapy System Recall

Dear Valued Customer:

Information on Affected Device

Device Description:

The neoBLUE blanket LED Phototherapy System is a portable phototherapy system that consists of five components: the neoBLUE blanket phototherapy light box, fiber optic blanket with attached cable, blanket mattress, disposable mattress covers, and power supply. The neoBLUE blanket LED Phototherapy System delivers a narrow band of high-intensity blue light via a blue light emitting diode (LED), in order to provide treatment for neonatal hyperbilirubinemia.

Commercial name:

neoBLUE blanket LED Phototherapy System

Primary clinical purpose of device:

Intended Use:

The neoBLUE blanket LED Phototherapy System is 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).

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.

Device Catalogue numbers:

006244 neoBLUE blanket LED Phototherapy System, Large; US power cord
006895 neoBLUE blanket LED Phototherapy System, Small; US power cord
007299 neoBLUE blanket LED Phototherapy System, Large; EU power cord
007300 neoBLUE blanket LED Phototherapy System, Small; EU power cord
007296 neoBLUE blanket LED Phototherapy System, Large; UK power cord
007298 neoBLUE blanket LED Phototherapy System, Small; UK power cord
007301 neoBLUE blanket LED Phototherapy System, Large; AUS power cord
007302 neoBLUE blanket LED Phototherapy System, Small; AUS power cord

Affected serial numbers:

Serial numbers up to and including SN 004282, plus SN 004424, 004447, 004450, 004460, 004465, 004472, 004488, 004492, 004533, 004545, 004550, 004552, 004554, 004577, 004642, 004671, 004679, 004684, 004688, 004694, 004720, 004722, 004790, 004796, 004801, 004803, 004807, 004808, 004824, 004855.

Reason For Safety Corrective Action

Description of issue:

This notification is related to a prior notification, October 2016, regarding the neoBLUE blanket LED Phototherapy System. At that time, Natus Medical informed you of a potential issue of discoloration/degradation/melting of the fiber optic bundle at the pad connector which is inserted in the neoBLUE blanket light box. Natus Medical completed a redesign of the device and is initiating this field action to replace those systems shipped from 2011 through March 21, 2016. Newer systems shipped after March 21, 2016 do not need to be replaced. Natus will provide an updated literature kit for each of the newer devices.

Hazard giving rise to the FSCA:

There is no hazard giving rise to the FSCA. The FSCA is one of reliability as the device degrades sooner than anticipated, and may result in extended patient treatment time. The overall health risk is low, and there have been zero reported injury related events to date. The FSCA is being conducted to prevent any further degradation, to improve the reliability of the device, and to deliver the updated User Manual to customers.

Type of Action Required

Please review the following information to help you identify the light box serial numbers and the difference between new and old blanket pads. Complete and return the attached Reply Form to **your Natus Distribution Partner** who will determine whether to send you a replacement neoBLUE blanket system or an updated literature kit.

Replacement of older systems shipped prior to March 21, 2016:

Natus intends to replace the neoBLUE blanket LED Phototherapy System, which includes the light box, pad kit, and literature kit for all systems containing a light box with serial number up to and including SN 004282, plus SN 004424, 004447, 004450, 004460, 004465, 004472, 004488, 004492, 004533, 004545, 004550, 004552, 004554, 004577, 004642, 004671, 004679, 004684, 004688, 004694, 004720, 004722, 004790, 004796, 004801, 004803, 004807, 004808, 004824, 004855. If you have one of these light boxes, you will receive a current neoBLUE blanket LED Phototherapy System with large pad as a replacement for each neoBLUE blanket light box that is still in use in your facility. You will be requested to return the affected light box to **your Natus Distribution Partner** when the replacement is available, and to dispose of all older version pads.

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The replacement system will contain a large pad unless you request the small pad. Orders for additional pads will be filled when pads are available, and may be delayed by several months as Natus works through the field action.

Shipment of updated literature kits:

An updated literature kit, including a User Manual, Guide for Home Use, and Service Manual, is included with each system. Customers who purchased any other serial number up to xxxx005686 will receive an updated literature kit for each device purchased.

General Information

FSN Type: Recall

This notification is related to a prior notification, October 2016; CAPA002580 Phase I, regarding the neoBLUE blanket LED Phototherapy System. At that time, Natus Medical informed you of a potential issue of discoloration/degradation/melting of the fiber optic bundle at the pad connector which is inserted in the neoBLUE blanket light box. Natus Medical completed a redesign of the device and is initiating Phase II of this field action to replace the affected systems.

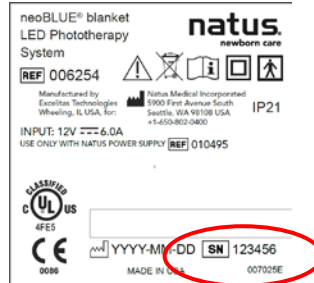
Further advice or information: Please contact **your Natus Distribution Partner** if you have any further questions.

The Competent Authority of your country was informed regarding this communication.

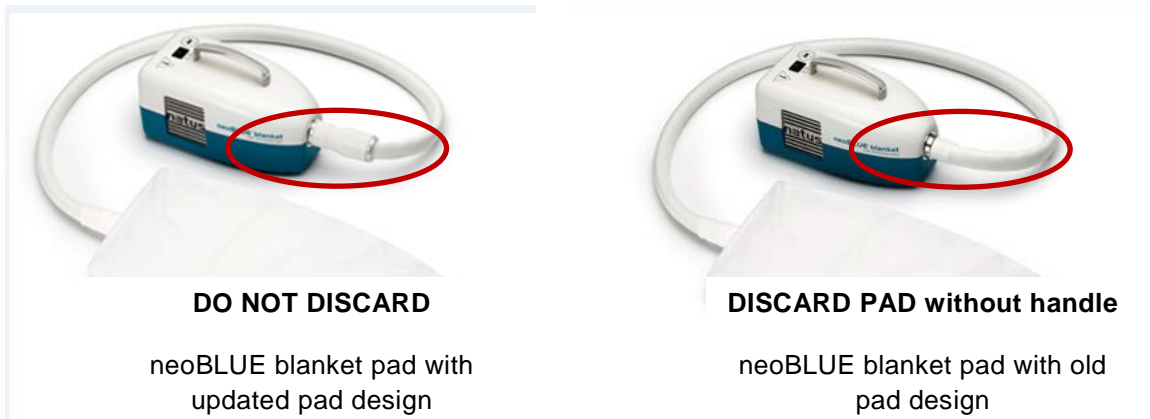
Attached: Replacement Process, Reply Form

Replacement of your neoBLUE blanket System is a five step process:

1. **Identify all neoBLUE blanket light boxes at your facility.**
2. **Use the Reply form on the following page to record the Serial Number found on the label located on the underside of the light box.** Use as many reply forms as are necessary to record the serial numbers of all light boxes in your facility. Return of the form to **your Natus Distribution Partner** is essential in order to begin the replacement process.



3. Depending on the Serial Number of your device, **your Natus Distribution Partner** will send you a replacement neoBLUE blanket LED Phototherapy System with large pad or an updated literature kit for each neoBLUE blanket light box identified at your facility.
4. **After you receive the replacement, please return each requested neoBLUE blanket light box in the box which contained the replacement light box to your Natus Distribution Partner.**
**Note: Replacement is intended to be free of charge; however, customers will be subject to a charge if the affected neoBLUE blanket light box is not returned.*
5. **Please discard the older version pads.** The older pads are easy to identify as they do not have the new handle incorporated for ease of use on the cable near the connection to the light box.



In order to process the replacements, we kindly request that you complete the attached reply form to identify the serial numbers of the light boxes in your facility, and return the completed form to **your Natus Distribution Partner**. We will contact you regarding the exchange of your systems or to send you a literature kit.



REPLY FORM

Verification of neoBLUE blanket LED Phototherapy System quantities

Please identify the neoBLUE blanket light boxes in your facility and record the serial number on the light box serial number label for each neoBLUE blanket light box. Completely fill out all the required shipping information and the replacement neoBLUE blanket systems and/or literature kits will be shipped to the address indicated on this form at no charge. NOTE: The replacement is intended to be free of charge; however, customers will be subject to a charge if the affected neoBLUE blanket light box is not returned.

Please identify all the neoBLUE blanket light box serial number(s) at your facility and record below:

SN _____	SN _____	SN _____
SN _____	SN _____	SN _____
SN _____	SN _____	SN _____
SN _____	SN _____	SN _____

_____ **This facility hereby states that these serial numbers are the only neoBLUE blanket light boxes in service at our facility**
(Initial here)

_____ **This facility hereby states that there are no neoBLUE blanket light boxes in our facility**
(Initial here
If applicable)

Contact Name: _____ Date: _____

Signature: _____

Shipping information for replacement neoBLUE blanket systems and/or literature kits:

Facility Name: _____

Ship to Address: _____

Attention To: _____

PO Number (if required for Receiving): _____

Contact Name: _____

Contact Title: _____

Contact Phone Number: _____

Contact Email: _____

Scan and email completed form to your Natus Distribution Partner