FSN Ref: CAPA002580
December 2018

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

Attention Natus Medical Distribution Partners:

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.

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Seattle, WA 98103 USA
www.natus.com

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 the affected systems.

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.

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Type of Action Required

Natus requests your assistance to obtain information from the customers in your territory who have taken possession of a neoBLUE blanket LED Phototherapy System. Please review the accompanying customer letter which provides more detail regarding which systems will be replaced and which systems will require an updated literature kit, how the customer can report to you the neoBLUE blanket systems which are in use, and how to request a device exchange or literature kit. Natus additionally requires proof of destruction of the returned devices in order for you to receive the replacement free of charge.

Please note that the serial number of the system and the serial number of the light box are the same.

Natus is requesting the following from you:

1. Identify the customers in your territory that may be in possession of a neoBLUE blanket system/light box. A list of affected serial numbers in your territory is attached.
2. Replace the highlighted words “Natus Distribution Partner” with the name and address of your facility on the last page of the customer letter, and anywhere else where it may make sense to you for the way in which you notify your customers. The customers will be returning the form to you.
3. Distribute the attached customer letter to the customers who may be in possession of the neoBLUE blanket systems.
4. Record the disposition of each neoBLUE blanket light box using the associated columns in the Serial Number List. Natus needs to know if the systems are in use, discarded, or unaccounted for.
5. Complete the information required on the DP reply form.
6. Email or FAX both the completed Serial Number List and the completed Reply Form to Natus – you may use as many copies of the form as you need. Please complete this exercise as soon as possible to enable Natus to efficiently provide you with the replacements.
7. Natus will send you the number of neoBLUE blanket LED Phototherapy Systems or literature packets – based on the serial numbered devices you have identified.
8. Depending on the serial number, either exchange the replacement neoBLUE blanket system for the customer’s affected version – or deliver an updated literature pack to your customers.
9. Destroy the recovered neoBLUE blanket light box(s) per the attached procedure and return the requested items to Natus. Request that the customer recycle the old design blanket pads (without a handle).
10. Once a replacement neoBLUE blanket system is sent to you, Natus requests proof of destruction within 3 months. If you find that you require more time, please contact Natus at the email address below.

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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 Natus_Quality_Programs@natus.com if you have any further questions.

Natus will email the Competent Authority of your country to inform them within 24 hours of sending you this communication.

Please refer to attached Example Customer Letter and Serial Number List for your territory.

Attached: Reply Form

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REPLY FORM

neoBLUE blanket LED Phototherapy Systems

Please complete the shipping information in the blanks below and return to Natus with the completed Serial Number List which contains the serial numbers and dispositions of the neoBLUE blanket systems shipped to your territory. Please note, that the serial number label is located on the underside of the light box.

Replacement neoBLUE blanket Phototherapy Systems or literature kits for the devices located by you will be shipped to you at no charge to the address indicated on this form. **NOTE: Distributors may be subject to charge if they do not provide the required proof within three months, that the required neoBLUE blanket light boxes were disabled and discarded**. Instructions for disabling the light are included with this notification.

Shipping information for replacement neoBLUE blanket Phototherapy Systems and literature kits:

Distribution Partner 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 Natus_Quality_Programs@natus.com or

FAX to (206) 767-0573.

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