



URGENT: MEDICAL DEVICE RECALL/EXCHANGE 2nd Generation neoBLUE LED Phototherapy Lights

March 2017

Dear Valued Customer:

You are receiving this information as our records indicate you may have one or more second generation neoBLUE LED Phototherapy Systems (sometimes referred to as the neoBLUE 2 system). This notification is to inform you that Natus is initiating a recall of the second generation neoBLUE 2 lights (sold from 2003 to 2008). Please read carefully through the following pages to determine how to identify and separate the second generation neoBLUE light from the current neoBLUE light, how to report to Natus the currently active devices at your facility, and how to request an exchange for an updated device.

This recall is related to an earlier field corrective action which informed customers that the neoBLUE 2 LED Replacement Board Kit distributed 2012 to 2015 for the neoBLUE 2 systems were manufactured using individual LEDs of higher intensity output than the original LEDs. This resulted in an overall light intensity for these systems that was higher than the original product specification. Customers were advised at that time to compensate for this higher intensity by increasing the distance between the phototherapy light and the patient.

Natus is initiating this field corrective action in order to replace all the earlier generation neoBLUE 2 lights which will eliminate the possibility that a neoBLUE light may have a replacement board installed which allows it to be used at a higher overall light intensity than the devices were originally cleared to deliver. Accordingly, customers of record will receive a current neoBLUE light as a replacement for each neoBLUE 2 light that is still in use in their facilities. The replacement light will be provided free of charge, provided the older neoBLUE 2 light is returned. This recall does not involve replacing the roll stands.

Please review the attached information to help you to identify the affected neoBLUE 2 light(s) (with the black band) and complete the attached Reply Form to receive a replacement neoBLUE light.

Natus appreciates your support of this activity and apologizes for this inconvenience.

Regards,

Natus Technical Service

Replacement of your light is a four step process:

1. **Identify any affected neoBLUE 2 light(s)** per the photos below

The neoBLUE systems affected by this recall are all neoBLUE 2 systems. This field action does NOT AFFECT the current generation neoBLUE system. The easiest way to tell the difference between the two generations of neoBLUE systems is the **black band** around the enclosure base of the neoBLUE 2 system as seen below:



neoBLUE 2 system
with the black band
**TO BE RECORDED AND
RETURNED**



Current neoBLUE system with
the white band
NOT AFFECTED

2. **Use the Reply form on the following page to record the Serial Number found on the back panel of the light enclosure(s).** Use as many reply forms as are necessary to record all affected lights.



3. Natus will send you a replacement neoBLUE light for each affected neoBLUE 2 light identified at your facility
4. Return each affected neoBLUE 2 light in the box which contained the replacement light
Note: Replacement is free of charge provided the affected neoBLUE 2 light is returned to your Distributor.



REPLY FORM

For exchange of 2nd generation neoBLUE LED Phototherapy Systems

Please identify those affected neoBLUE 2 lights in your facility and locate the serial number label on the back of the enclosure as described on the previous page. Record the serial number below for each neoBLUE 2 light. Completely fill out all the required shipping information and the replacement neoBLUE light(s) will be shipped to the address indicated on this form at no charge. NOTE: Customers may be subject to charge if they do not return the older neoBLUE 2 light to their Natus Distribution Partner.

Please identify the neo/BLUE 2 system serial number(s) at your facility and record below:

SN _____ SN _____ SN _____

Contact Name: _____ Date: _____

Signature: _____

Shipping information for replacement neoBLUE light(s)

Facility Name: _____

Ship to Street Address: _____

City, State and Zip Code: _____

Attention To: _____

PO Number (if required for Receiving): _____

Contact Name: _____

Contact Title: _____

Contact Phone Number: _____

Email: _____

Return the completed form to your **Natus Distribution Partner.**