



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 _____

SN _____ SN _____ SN _____

SN _____ SN _____ SN _____

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.**

Instructions to Disable neoBLUE 2 Light

These instructions are written for use by ROW Distribution Partners to use at their facility, and by Natus Seattle to use in the Seattle location. All end users/customers of the neoBLUE devices will be returning them either to the Seattle location or to their applicable Natus Distribution Partner. The Distribution Partner is required to send the following items to Natus Seattle as proof of the disablement of each light:

- Photograph of the SN Plate
- Actual SN Plate
- Ferrite Coil removed from the light per procedure below

The neoBLUE Phototherapy Systems affected by this Field Corrective Action are the older-version neoBLUE systems. The later model neoBLUE systems are not affected. The easiest way to tell the difference between these two generations of neoBLUE systems is the black band around the base of the neoBLUE 2 enclosure as shown below:



neoBLUE 2 system with
the black band
TO BE DISABLED



Current neoBLUE system
with the white band
NOT AFFECTED
NOT TO BE DISABLED

Instructions for disabling the light are described on the following pages. The following tools will be needed for completing the disabling process:

TOOLS NEEDED

Philips screwdriver
Wire cutters
Digital Camera
Flat-edge knife (such as a putty knife)

PROCEDURE

1. Photograph the serial number label (see Figure 1) on the back side of the light enclosure. Please ensure that the serial number is legible in the photo. **This photograph is one of the three items required to be returned to Natus for each light disabled.**

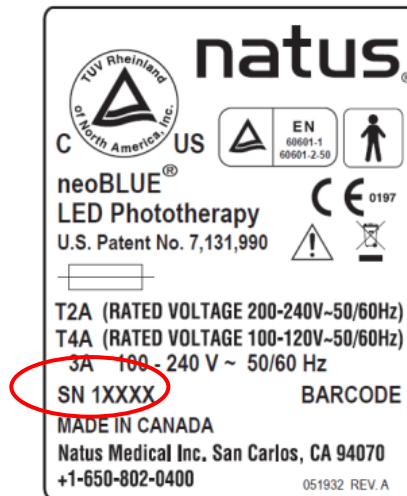


Figure 1 – neoBLUE Serial Number label

2. Remove the Serial Number Label from the enclosure (see illustrative steps below). **This Serial Number Label is the second of three items required to be returned to Natus for each light disabled.**
 - a. Disconnect the power source from the unit and remove the unit from any mounting mechanism. Place the light enclosure on a work bench with the translucent diffuser facing upwards.
 - b. Use the flat-edge knife to carefully lift an edge of the Serial Number Label, as shown in Figure 2 below.



Figure 2 – Use flat-edge knife to lift Serial Number Label

- c. Gradually peel the Serial Number Label from the enclosure, as shown in Figure 3 below.



Figure 3 – Peel Serial Number Label from enclosure

- d. Remove the Serial Number Label from the enclosure, as shown in Figure 4 below.



Figure 4 – Remove Serial Number Label from enclosure

3. Ensure power source is still disconnected and place unit on a flat surface with the diffuser facing upwards (as shown in Figure 5). Using a Philips screwdriver, remove the six screws securing the diffuser (indicated by arrows in Figure 5) and remove the diffuser from the unit, setting it aside.

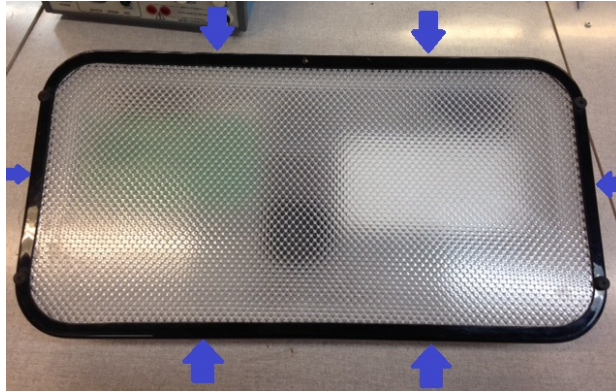


Figure 5 - Unit with diffuser facing upwards.

4. With the diffuser removed, the LED Printed Circuit Board Assembly (PCBA) is exposed. Referring to Figure 6, remove the screws holding the LED PCBA to the enclosure.



Figure 6 - Unit with enclosure removed and LED PCBA exposed.

5. After the screws are removed, gently lift the LED PCBA away from the enclosure (Figure 7) and unplug the connector from the back of the LED PCBA (Figure 8).

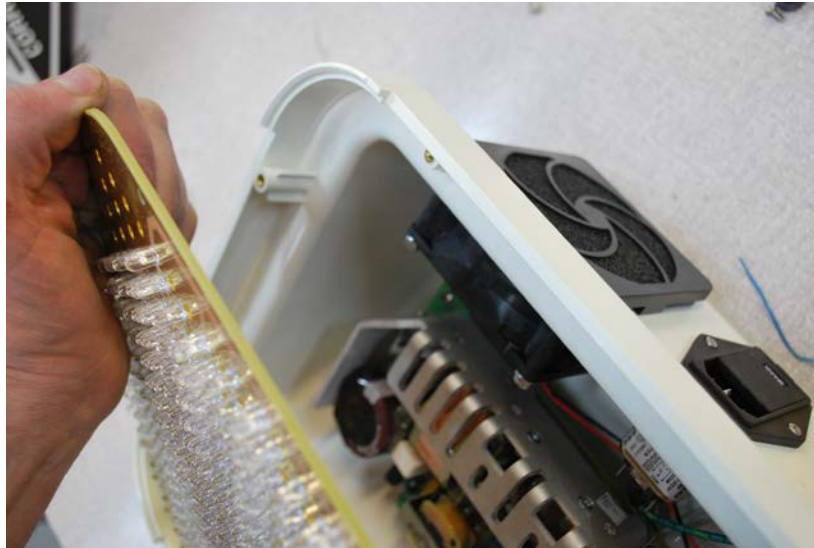


Figure 7 - Lift LED PCBA away from enclosure.

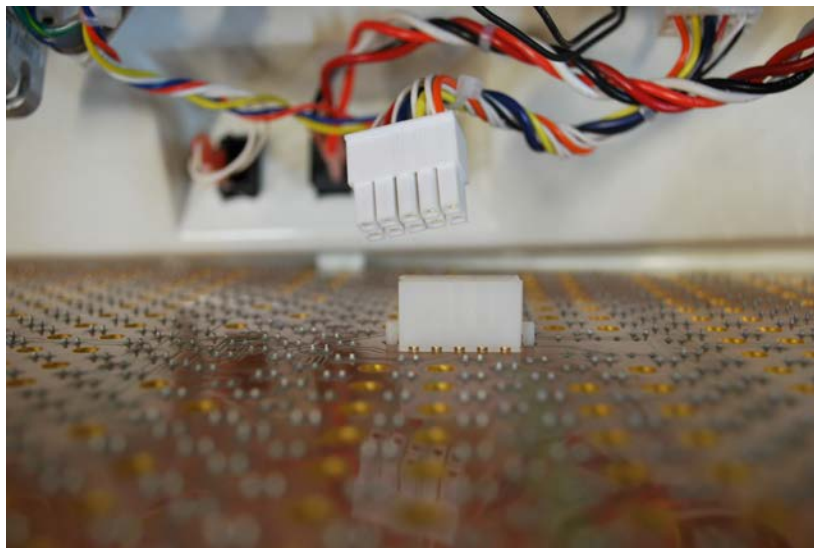


Figure 8 - Unplugged connector on rear of LED PCBA.

The power supply Printed Circuit Board Assembly (PCBA) and constant current PCBA are now exposed. See Figure 9.



Figure 9 - Unit with diffuser and LED PCBA removed.

6. To disable the neoBLUE 2 device, use the wire cutters to cut the black and red wires at both ends between the power supply PCBA and the constant current PCBA as shown by the white arrows in Figure 10.

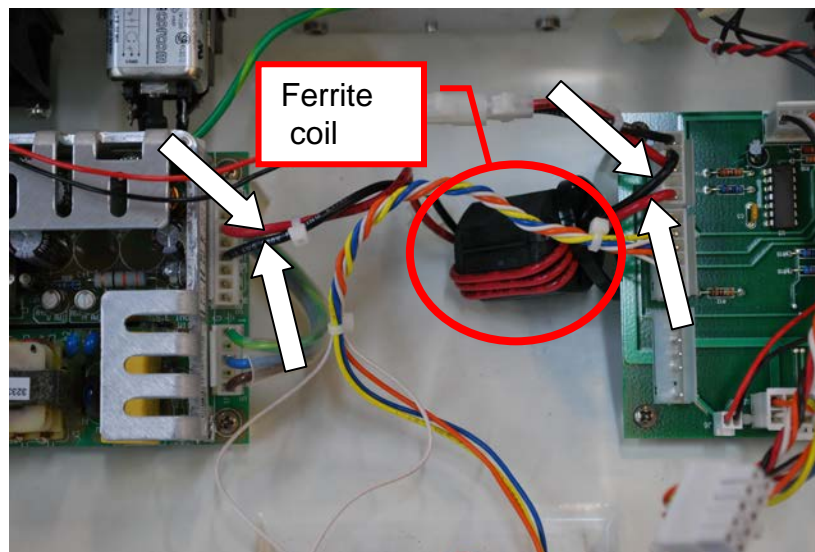


Figure 10 - Location of wires to cut & identification of the ferrite coil.

7. Remove the ferrite coil, and return to Natus with the Serial Number label and the photograph of the Serial Number as physical evidence that the unit is disabled.
8. Dispose of all neoBLUE 2 light components in accordance with existing customer practice and local regulations for disposal of electronic waste.



Serial Number List neoBLUE 2 Systems Shipped to your Territory

The following is a list of second generation neoBLUE LED Phototherapy Systems which were shipped to your territory from 2003 to 2008. Natus requests that you identify the customers of these neoBLUE systems and provide a disposition for each serial number on this list. Disposition possibilities may include:

- In use at a facility – will require a replacement
- No longer in service – discarded
- Cannot account for this serial number

Please return this completed neoBLUE 2 Systems Serial Number list and the Reply Form to Natus. Natus will then ship to you the number of devices you have requested for exchange.

***Please note that Natus requires the appropriate disabled parts to be returned to Natus after the exchange is made with your customers. Disabling instructions are included in this email. Distribution Partners may be subject to charge for the new systems if the neoBLUE 2 serial number labels and ferrite coils of the disabled neoBLUE 2 units are not returned to Natus as proof of destruction.**

**<Technical Service to fill in and modify this chart as needed for each DP>
<example below>**

Item	Serial Number	Ship Date	In Use at facility – will require replacement	Retired from service – verified to be discarded	Cannot locate	Other
040906	15560	04/23/2007				
040906	16526	06/27/2007				
040906	16565	07/23/2007				
040906	16566	07/23/2007				
040906	16572	08/22/2007				
040906	16573	08/22/2007				
040906	17278	01/22/2008				
040906	17628	03/12/2008				
040906	17629	03/12/2008				
040906	17718	03/25/2008				

Completed by _____

Signature: _____ Date: _____