



## **URGENT: MEDICAL DEVICE RECALL/EXCHANGE** 2<sup>nd</sup> Generation neoBLUE LED Phototherapy Systems

March 2017

Dear Natus Distribution Partner:

You are receiving this information because our records indicate that you or previous distribution partners in your current territory took delivery of one or more second generation neoBLUE Phototherapy System (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 lights (sold from 2003 to 2008). Please review the accompanying customer letter which describes how to identify and separate the second generation neoBLUE light from the current neoBLUE light, how the customer can report to you the lights which are in use, and how to request an exchange for an updated neoBLUE light. Natus additionally requires proof of destruction of the returned devices in order for you to receive the replacement free of charge.

Natus requests your assistance to obtain information from the customers in your territory who have taken possession of a second generation neoBLUE system, and to provide proof that each of the affected neoBLUE lights was destroyed. Each customer of a second generation neoBLUE system is to receive a replacement neoBLUE light in exchange for each neoBLUE 2 light that is still in use in their respective facilities.

Natus is requesting the following from you:

1. Identify the customers in your territory that may be in possession of a neoBLUE 2 system (sold from 2003 to 2008). 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 have taken possession of a neoBLUE 2 system.
4. Record the disposition of each neoBLUE 2 light 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 the completed Serial Number List and the completed Reply Form to Natus – you may use as many copies of the form as you need. Natus requests a completed list within 3 months. If you find that you require more time, please contact Technical Service.
7. Natus will send you a replacement neoBLUE light for each affected neoBLUE 2 light identified and in use by your customers.

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8. Exchange the current neoBLUE light for the older version neoBLUE 2 light at the customer facility. This recall does not involve replacing the roll stands.
9. Destroy the recovered neoBLUE 2 lights per the attached procedure and return the proof to Natus. Once a replacement light is sent to you, Natus requests proof of destruction within 3 months. Again, if you find that you require more time, please contact Technical Service.

Natus appreciates your support of this activity and apologizes for this inconvenience. If you have further questions, please contact Technical Service by email at [Natus\\_Quality\\_Programs@natus.com](mailto:Natus_Quality_Programs@natus.com) or by phone at 1-888-496-2887.

Regards,

Natus Technical Service

Attachments:

Customer Letter

Instructions to Disable neoBLUE 2 Light(s)

neoBLUE 2 Systems Serial Number List for your Territory



## REPLY FORM

For exchange of 2<sup>nd</sup> Generation neoBLUE LED Phototherapy Systems

Please complete the shipping information in the blanks below and return to Natus with the completed form "neoBLUE 2 Systems Serial Numbers" which contains the serial numbers and dispositions of the neoBLUE Systems shipped to your territory.

\_\_\_\_\_ Indicate the total number of neoBLUE 2 lights inventoried and verified to be **still in use** at facilities. This number will be the same as the total number of devices in the "neoBLUE 2 Systems Serial Number List" in the column which shows systems still in use.

Replacement neoBLUE lights will be 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 neoBLUE 2 lights have been disabled and discarded.** Instructions for disabling the light are included with this notification.

### Shipping information for replacement neoBLUE light(s)

Distribution Partner Name: \_\_\_\_\_

Ship to Address: \_\_\_\_\_  
\_\_\_\_\_

Attention To: \_\_\_\_\_

PO Number (if required for Receiving): \_\_\_\_\_

Contact Name: \_\_\_\_\_

Contact Title: \_\_\_\_\_

Contact Phone Number: \_\_\_\_\_

Email: \_\_\_\_\_

**Scan and email both forms to [Natus\\_Quality\\_Programs@natus.com](mailto:Natus_Quality_Programs@natus.com) or FAX to 847-949-6031**