

## **URGENT RECALL NOTIFICATION / FIELD SAFETY NOTICE**

### **neoBLUE LED Board Replacements**

November 5, 2014

**Re: LED panels for neoBLUE<sup>®</sup> LED Phototherapy Systems**

Dear valued neoBLUE system customer:

You are receiving this information because our records indicate you purchased at least one LED Board Kit to replace the LED panel on a second generation neoBLUE LED Phototherapy System. This second generation light (aka neoBLUE 2 system) was sold by Natus from 2003 to 2008. Natus then replaced that version with the third generation light (aka neoBLUE 3 system), selling from 2008 to present. The easiest way to tell the difference between these two generations of neoBLUE systems is the black band around the enclosure base of the neoBLUE 2 system as seen below:



neoBLUE 2 system



neoBLUE 3 system

In November 2011, the LEDs used in the original neoBLUE 2 system became obsolete and were replaced by more efficient LEDs that produced higher intensity phototherapy treatment. The electronic design of the neoBLUE 2 light does not allow the intensity of these newer LEDs to be adjusted down to the original factory settings, therefore the intensity will be greater if used at the same level (low-high) at the same distance from the infant. While some customers may prefer using these lights at the higher intensity levels, some are concerned that patients may receive more intensity than desired.

DOC-012737B



This information was included in the Technical Bulletin (p/n 008353) sent with the replacement LED Board Kit. These kits also include labels (p/n 011561), added to help users know the intensity and recommended treatment distance of their particular device(s). Since there have been different revisions of the Technical Bulletin and not everyone received the labels, we strongly urge you to read the attached Technical Bulletin and use the enclosed labels on your neoBLUE 2 systems.

Natus requests that that this information be distributed to all associated parties within your organization.

Please note: the neoBLUE 3 system and its replacement panel sold today are not affected by this issue. If there are any questions regarding this advisory letter or the attached Technical Bulletin, please call Natus Technical Service at 888-496-2887.

Sincerely,

A handwritten signature in black ink that reads "Dan Robertson". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Dan Robertson  
Global Marketing Manager  
Natus Medical Incorporated

**Attachments:**

008353 - Technical Bulletin, LED Board Kit for neoBLUE 2 Systems  
011561 - Label, neoBLUE Intensity / Height