




**URGENT: FIELD SAFETY NOTICE
PRODUCT LABELING CHANGE
neoBLUE[®] LED Phototherapy System**

June 2016

Re: neoBLUE LED Phototherapy System labeling change

Dear Valued Customer:

You are receiving this information because our records indicate that you purchased at least one of our neoBLUE LED Phototherapy Systems. The purpose of this field corrective action is to provide a warning to clinicians who are treating jaundiced preterm infants, <35 weeks of gestation, with intensive phototherapy as defined by the 2004 AAP Clinical Practice Guideline as intensity >30 $\mu\text{W}/\text{cm}^2/\text{nm}$. This new warning is consistent with an expert panel recommendation published in 2012 in the Journal of Perinatology. Based on the recommendation provided in this article,¹ Natus is adding the following warning to the Instruction for Use for our neoBLUE LED Phototherapy System.

 **Warning!** Intensive phototherapy (>30 $\mu\text{W}/\text{cm}^2/\text{nm}$) may not be appropriate for all infants (i.e. preterm infants ≤ 1000 g).

Enclosed with this letter, please find a User manual addendum that includes the new Warning. **Please attach the addendum to your neoBLUE user manual.**

In addition, Natus has updated the product Quick Guide to the neoBLUE LED Phototherapy System to include this Warning. Natus' objective with this new Quick Guide is to provide instructions at the point of care including intensity, height information, warnings, and safety information. Your Authorized Natus Distributor can provide this to your facility in any of the following languages: English, French, Italian, German, and Spanish. Natus requests that this information be distributed to all associated parties within your organization that use or service this product.

If there are any questions regarding this letter and addendum, please call Natus Technical Service at 888-496-2887.

Sincerely,




Dan Robertson
Global Marketing Manager
Natus Medical Incorporated

¹ Maisels MJ, Watchko JF, Bhutani VK, Stevenson DK. An approach to the management of hyperbilirubinemia in the preterm infant less than 35 weeks of gestation. *Journal of Perinatology* (2012) 32, 660-664

Addendum
(March 2016)

neoBLUE[®] LED Phototherapy System

The following warning is being added to the current neoBLUE LED Phototherapy System user manual. Please add this addendum to all existing neoBLUE LED Phototherapy System user manuals for devices still in use in your facility.

 **Warning!** *Intensive phototherapy ($>30 \mu\text{W}/\text{cm}^2/\text{nm}$) may not be appropriate for all infants (i.e. preterm infants $\leq 1000 \text{ g}$).*