




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

March 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 $>30 \text{ uW/cm}^2/\text{nm}$. 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 ($>30 \text{ uW/cm}^2/\text{nm}$) may not be appropriate for all infants (i.e. preterm infants $\leq 1000 \text{ g}$).*

Enclosed with this letter, please find:

- Quick Guides (2 ea) which provide operating steps, information about measuring intensity, and warnings (PN 051693)
- User manual addendum
- Customer reply form

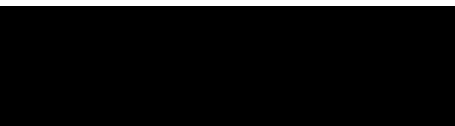
Please attach the updated Quick Guide to your neoBLUE LED Phototherapy System (replacing your old Quick Guide) and attach the addendum to your neoBLUE user manual.

Natus designed the neoBLUE LED Phototherapy System with both high and low intensity settings to allow physicians to provide different levels of intensity, depending on the clinical circumstance. Natus' objective with this new Quick Guide is to provide instructions at the point of care including intensity, height information, warnings, and safety information. Two (2) copies of the Quick Guide are included; if you need more Quick Guides for your facility, you can order them using the Customer Reply form.

Natus requests that this information be distributed to all associated parties within your organization that use or service this product. Please note: this communication is in addition to any prior labeling changes that you may have received from Natus.

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 $\leq 1000 \text{ g}$).*