

Urgent Field Safety Notice
neoBLUE[®] blanket system performance

Attn: Natus Medical Incorporated International Distribution Partner

October 12, 2016

Natus is sending this safety notice to you as we are contacting all customers who purchased an updated neoBLUE blanket system between March 2016 and August 2016 to ensure they have an updated Technical Bulletin. The need for this action is described in the attached customer letter and Technical Bulletin.

Our records indicate that your company has taken delivery of one or more neoBLUE blanket systems from March 2016 to August 2016, serial numbers between xxxx004283 and xxxx005241. Affected part numbers are shown here:

006244 neoBLUE blanket LED Phototherapy System with Large blanket/pad; US power cord
006895 neoBLUE blanket LED Phototherapy System with Small blanket/pad; US power cord
007299 neoBLUE blanket LED Phototherapy System with Large blanket/pad; EU power cord
007300 neoBLUE blanket LED Phototherapy System with Small blanket/pad; EU power cord
007296 neoBLUE blanket LED Phototherapy System with Large blanket/pad; UK power cord
007298 neoBLUE blanket LED Phototherapy System with Small blanket/pad; UK power cord
007301 neoBLUE blanket LED Phototherapy System with Large blanket/pad; AUS power cord
007302 neoBLUE blanket LED Phototherapy System with Small blanket/pad; AUS power cord

Please identify all customers who purchased one of the systems noted above, and forward the updated technical bulletin and customer letter to both the Biomedical Department and the Neonatal Intensive Care Unit (NICU) of the affected customers.

Please complete and return the attached reply form when all customers have been informed.

Natus apologizes for any inconvenience. Please understand that this is part of our commitment to providing only the highest quality products to our customers and their patients. If there are any questions about this notice, please contact Natus Technical Service Technical_Service@natus.com.

Regards,

Natus Technical Service

Attachments:

DOC-021016 - Technical Bulletin, neoBLUE blanket system performance
DOC-021310 – ROW Letter to Customers neoBLUE blanket



URGENT FIELD SAFETY NOTICE
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REPLY FORM

In order to comply with this Corrective Action, Natus Medical Incorporated requests that you please complete this form and email it to Natus_Quality_Programs@natus.com, or Fax the form to the number shown below.

Natus Medical Incorporated
Attn: Technical Service
Fax: (847-949-6031)

Distribution Partner Name: _____

Contact Name: _____

Contact Title: _____

Address: _____

Contact Telephone: _____ Email: _____

By signing below, I confirm that my company has received the customer letter and Technical Bulletin for the updated neoBLUE blanket system; that we have translated them as needed, and have sent the letter and technical bulletin to all customers who purchased the neoBLUE blanket systems we received between March and August 2016.

Signature of contact: _____

Date: _____