



## **PRODUCT RELIABILITY ALERT** **neoBLUE<sup>®</sup> blanket system performance**

**Re: Fiberoptic pad for neoBLUE<sup>®</sup> blanket LED Phototherapy Systems**

Dear valued customer:

You are receiving this information because our records indicate you purchased at least one neoBLUE blanket LED Phototherapy System. This product was introduced to the market by Natus in August 2011 and is still being sold today.

Natus has received feedback from some customers about early failure of the neoBLUE blanket system fiberoptic pads. These failures involve discoloration and melting of the fiberoptic bundle at the connector that is inserted in the neoBLUE blanket light box. Included with this letter is a Technical Bulletin, DOC-013760, that further describes the issue and addresses many of the questions you might have.

Natus is working on a long term solution to this issue and will contact all customers once the solution is available. For now, please distribute this information to all parties who use and/or maintain the neoBLUE blanket system in your facility.

As stated in the Technical Bulletin, U.S. customers should contact Natus Technical Service at 888-496-2887 with any questions regarding this notification. International customers should contact their local distributor.

Finally, included in the Technical Bulletin is a Light Intensity Output Conversion Chart for facilities using a different radiometer than the neoBLUE Radiometer to measure light output of the phototherapy system. Please note that this chart included in the previous revision of our neoBLUE blanket Service Manual had an error which has been corrected. If your device came with Service Manual part number 007604 Rev C, please defer to the conversion chart found in this Technical Bulletin.

Sincerely,

Natus Medical Incorporated

Attachments:

DOC-013760 (Technical Bulletin, neoBLUE blanket system performance)

DOC-013758A

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# TECHNICAL BULLETIN

## neoBLUE<sup>®</sup> blanket system performance

Dear Natus Customer:

Natus Medical has received feedback from some customers about early failure of the neoBLUE<sup>®</sup> blanket system fiber optic pads. These failures involve discoloration/degradation followed by eventual melting of the fiber optic bundle at the connector that is inserted in the neoBLUE blanket light box. Natus' investigations have shown that this failure occurs after extended exposure to the intense light source within the box, at which time the pad no longer provides the therapeutic treatment for which it is intended. Following the guidelines of this technical bulletin will help to prevent failures from occurring on customer systems.

Natus is working on a solution to this issue and will advise all customers as soon as it is available.

### ***Which neoBLUE blanket systems are affected?***

All systems shipped since the release of the product in 2011 can exhibit this failure.

### ***Is the neoBLUE blanket system safe to use?***

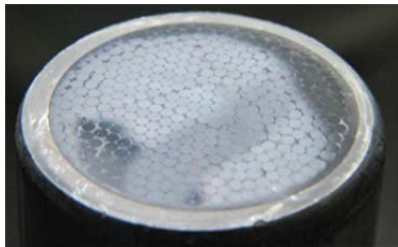
The neoBLUE blanket system is safe to use. Following the guidelines of this technical bulletin will help to prevent failures from occurring on customer systems.

The failure occurs because of heat buildup at the fiber optic cable connector inside the neoBLUE blanket light box. This may be accompanied by a hot plastic smell; however the device is constructed of fire-retarding materials and there is no danger of fire. This localized heating is internal to the light box and does not affect the patient or the caregiver.

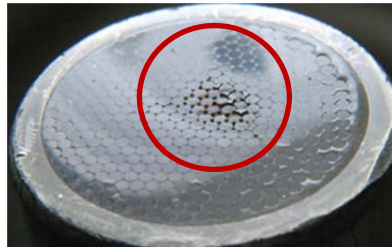
### ***How do I inspect the pad before use?***

Before each use, remove the pad from the light box, examine the cable end connector, and compare to the following images:

- **Good Pad** (Figure 1): A pad in good condition has a polished surface which is smooth to the touch, and the color of both the fibers and the fill material between the fibers is clear throughout.
- **Failing Pad** (Figure 2): A pad which is approaching failure will have a slightly noticeable degradation that feels rough to touch at the center of the smooth polished surface. Discoloration may or may not be apparent.
- **Failed Pad** (Figure 3): The surface degradation will eventually cause the fibers to melt and deform. Once this occurs the pad no longer provides the therapeutic treatment for which it is intended. If allowed to progress to this stage, there is a chance the light box will also be damaged.



**Figure 1: Good Pad**  
Good condition, continue to use.



**Figure 2: Failing Pad**  
Symptoms are present. Pad may need to be replaced.



**Figure 3: Failed Pad**  
Fibers melted and extruded. Do not use. Replace pad.

**What should I do if I find signs of degradation or melting on the fiber optic pad connector?**

Compare the fiber optic cable connector to the photos shown above. If there is visible discoloration and/or the fiber optic bundle surface feels rough and uneven as described in Figure 2 above, discontinue using the device and contact Natus Technical Service at 888-496-2887. International customers should contact their distributors.

**What can I do to slow down the degradation process?**

Test data shows that this degradation and eventual melting can occur on all pads, given enough usage. Total run time and light box output settings have a large influence on the degradation rate. The process can be slowed by making sure the system is turned off whenever it is not in use and by adjusting it to factory settings.

Systems which are *set higher* than factory settings will progress faster than those *set at* factory settings.

The settings can be checked by measuring the light output of the system using a neoBLUE Radiometer, following instructions in the service manual. The system is set at the factory to an output level of 30 to 35µW/cm<sup>2</sup>/nm. If your device output exceeds this, it is recommended that the output be adjusted down to factory settings.

Facilities using a different brand of radiometer must correlate readings to the neoBLUE Radiometer. The following table provides a light intensity output conversion chart for several common brands.

**NEOBBLUE LIGHT INTENSITY OUTPUT CONVERSTION CHART**

<b>Radiometer:</b>	<b>Natus<sup>®</sup> neoBLUE<sup>®</sup> Radiometer *</b>	<b>Olympic<sup>®</sup> Bili- meter<sup>®</sup></b>	<b>Ohmeda Bili- blanket<sup>®</sup> Meter II</b>	<b>Joey<sup>®</sup> Dosimeter Model JD100</b>
<b>Intensity: (µW/cm<sup>2</sup>/nm)</b>	15	9	14	32
	20	13	19	43
	25	16	23	53
	30	19	28	64
	35	22	32	75
	40	25	37	86
	45	28	42	96
	50	31	46	107
	55	35	51	118
	60	38	56	128
	65	41	60	139

\* This Radiometer (P/N 53870) is used for measuring the neoBLUE light intensity output prior to shipment.

**Who do I contact if I have questions?**

Direct all questions to Natus Technical Service, 888-496-2887.