

# TECHNICAL BULLETIN

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

### Dear Natus Customer:

Natus Medical recently completed a reliability update to the neoBLUE blanket system as a result of previous feedback received from customers regarding early failure of the neoBLUE<sup>®</sup> blanket system fiberoptic pads. These failures involved discoloration/degradation followed by eventual melting of the fiberoptic cable end that is inserted in the neoBLUE blanket light box. Natus' investigations showed that this failure occurs after extended exposure to the intense light source within the light box, at which time the pad no longer provided the therapeutic treatment for which it is intended.

Beginning in March 2016, Natus shipped out the updated version of the neoBLUE blanket system which is intended to prevent melting of the fiberoptic cable end. The updated fiberoptic cable end of the blanket was improved to reduce the degradation and increase its useful life. Built in protection was added to the updated light box (beginning with serial number xxxx004283) which checks the condition of the fiberoptic cable end. If the fiberoptic cable end starts to overheat, the updated light box over-temperature indicator light will double blink. Additionally, if the fiberoptic cable end continues to heat, the blue therapy light in the updated light box will turn off.

Natus is continuing to make improvements to the neoBLUE blanket system. Please contact Natus if you should experience any further issues.

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

All systems shipped since the release of the product in 2011 can exhibit the symptoms of discoloration/degradation.

Updated light boxes (serial number xxxx004283 or greater) have protection built in to turn off the device if an overheat condition is detected.

Updated fiberoptic blankets (Lot Nxxxx16-xx or greater) have an improved fiberoptic cable end to reduce the degradation and increase its useful life.

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

The neoBLUE blanket system is safe to use.

The guidelines listed below were established prior to the improvements discussed in this Technical Bulletin. As a precaution, Natus recommends continuing to follow the guidelines established below to ensure the most effective use of the neoBLUE blanket system and to prevent any potential failure from occurring on customer systems.

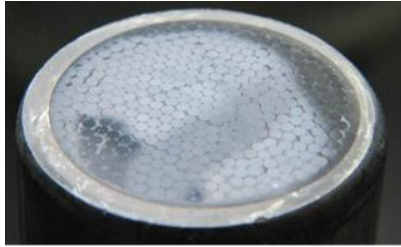
Previous degradation/discoloration occurred because of heat buildup at the fiberoptic cable end inside the neoBLUE blanket light box. This may be accompanied by a hot plastic smell; however the device is constructed of fire-retarding materials and there is no danger of fire. This localized heating is internal to the light box and does not affect the patient or the caregiver.

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

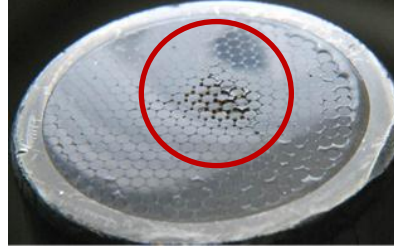
Before each use, remove the pad from the light box, examine the fiberoptic cable end, and compare to the following images:

- **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**  
Melt has occurred. Do not use. Replace pad.

### ***What should I do if I find signs of degradation or melting on the fiberoptic cable end?***

Compare the fiberoptic cable end to the photos shown above. If there is visible discoloration and/or the fiberoptic cable end 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, please contact your distributors.

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

Test data shows that this degradation and 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  $35\mu\text{W}/\text{cm}^2/\text{nm}$ . If your device output exceeds this, it is recommended that the output be adjusted down to factory settings.

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

Direct all questions to Natus Technical Service, 888-496-2887, or to your distributor if you are an international customer.