



URGENT FIELD SAFETY NOTICE

GE Healthcare

3000 N. Grandview Blvd. - W440
Waukesha, WI 53188, USA

<Date of Letter Deployment>

GEHC Ref# 32072

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator
Director of Biomedical Engineering

RE: Giraffe Blue Spot PT Lite Phototherapy Systems—Light Output May Fall Below the Recommended Minimum Output Due to Fiber Protrusion.

This document contains important information for your product. Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

We have recently become aware of a problem with some Giraffe Blue Spot PT Lite phototherapy systems built between 2014 and Jan 2018, having a light output falling below the recommended minimum output for the Giraffe Blue Spot PT. This problem has been associated with exposure of the light pipe to elevated temperatures, which is contra-indicated in the Operation, Maintenance, and Service Manual. There have not been any reported harms or adverse events associated with the Giraffe Blue Spot PT Lite.

Safety Instructions

Continued use of the Giraffe Blue Spot PT Lite per the Operation, Maintenance, and Service Manual with periodic measurement of irradiance output during the phototherapy treatment will not result in any patient harm.

However, if the device is not used per the Instructions for Use and with periodic irradiance measurement during the treatment, there is a possibility that the phototherapy treatment level being administered is below the minimum output (less than $27\mu\text{W}/\text{cm}^2/\text{nm}$) of the device. This could result in a less than anticipated reduction in patient Bilirubin levels and require additional (or alternate) phototherapy devices to maintain expected phototherapy treatment.

Please notify all end users, that have received the above listed product that to ensure the patient gets proper levels of treatment they should take the following actions.

1. Immediately check all your device outputs using a BiliBlanket Meter II bilimeter and continue to do so prior to every use, as listed in the Instructions for Use as well as during the treatment session. Instructions as to how to measure your device's output are provided in both the Operation, Maintenance, and Service Manual Section 2.1 "Pre-Use Checkout Procedure" and in the Quick Reference Guide attached to every unit and are detailed below in Appendix 1.

Take out of service any units found to have irradiance levels less than $27\mu\text{W}/\text{cm}^2/\text{nm}$ and await the free kit to correct the unit that GE Healthcare will be sending for all potentially affected units.

Elevated heat can cause the light pipe optical fiber to protrude through its reflector aperture, creating an unfocused spot with less than $27\mu\text{W}/\text{cm}^2/\text{nm}$ output as described above. The photos below show the effect and can be used in conjunction with the BiliBlanket Meter II bilimeter to identify units with a low light condition due to elevated heat exposure.



Normal / Focused Output Light

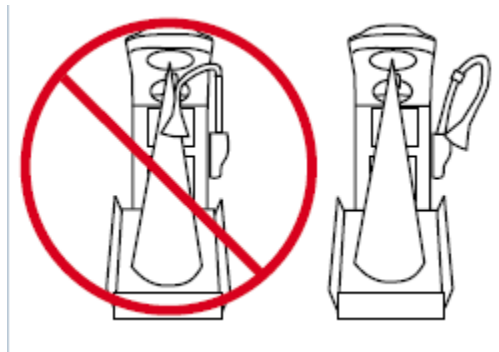
Shade is 15 in. (38 cm) from mattress pad
 Output has well-defined edges
 Output is a 14 in. (35.5 cm) dia. circle
 Light intensity uniform



Abnormal / Unfocused Output Light

Shade is 15 in. (38 cm) from mattress pad
 Output has diffused, ill-defined edges
 Output is a 16-19 in. (40.6-48.2 cm) dia. circle
 Dull center surrounded by an intense band

- As previously stated, exposing the shade head to elevated heat from the warmer is contra-indicated with this device. To prevent potential damage to light pipes due to elevated heat, we remind that care should be taken to position the light pipe, as shown in the Instructions for Use Section 2.2 "Operation" and in the Quick Reference Guide, keeping the light pipe Shade head outside the direct path of warmers (see figure below).



Affected Product Details

Giraffe Blue Spot PT Lite phototherapy systems built between 2014 and Jan 2018 with the following serial numbers:

System serial numbers beginning with QAAT, QAAU, QAAV, QAAW and QAAX from QAAX60001 to QAAX60155.

Light pipe serial numbers beginning with BLPT, BLPU, BLPV, BLPW and BLPX from BLPX00001 to BLPX00243.

System GTIN numbers are 00840682116572 and 00840682116541.

Location of System Serial number and year of manufacturing



To locate the Light Pipe serial number, remove the light pipe by referring to Service Manual Section 7.4.1



Product Correction

To correct any existing devices experiencing low light output due to fiber protrusion and to prevent potential future low light output due to fiber protrusion, **GE Healthcare will send a kit to fix all potentially affected units free of charge** beginning early February 2020. The kit will include the replacement shade with installation instructions. A resident biomed technician can easily and quickly install the replacement shade in a few minutes. For devices with fiber protrusion and outputs below $27\mu\text{W}/\text{cm}^2/\text{nm}$, this replacement will bring your device's back to a factory new output between $36\mu\text{W}/\text{cm}^2/\text{nm}$ and $56.25\mu\text{W}/\text{cm}^2/\text{nm}$. The kit will also include a Preventive Maintenance addendum to the existing Operation, Maintenance, and Service Manual.

Contact Information

If you have any questions or concerns regarding this notification, please contact GE Healthcare Service or your local Service Representative.

GE Healthcare confirms that this notice has been notified to the appropriate Regulatory Agency.

Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions, please contact us immediately per the contact information above.

Sincerely,

Handwritten signature of Laila Gurney in blue ink, featuring a long horizontal flourish extending to the right.

Laila Gurney
Senior Executive, Quality & Regulatory
GE Healthcare

Handwritten signature of Jeff Hersh in blue ink, consisting of stylized initials 'JH'.

Jeff Hersh, PhD MD
Chief Medical Officer
GE Healthcare

Appendix - 1

Measuring Output (As shown in the Instructions for Use Chapter 2.1)

1. Connect the power cord to an appropriate power source. The standby/on indicator will light green to indicate standby mode.
2. Press the standby/on switch to turn on the therapeutic light. The standby/on indicator will change from green to blue and the over-temperature/under-temperature indicators will briefly illuminate.
3. Keep your hand close to the exhaust vent when the device is on to feel the air flow coming out of the device to confirm that the fan is operating.
4. Focus the therapeutic light so that the spot diameter is 35.5 cm or when the shade is 38 cm from the bed surface.
5. Using a calibrated Biliblanket Light Meter II, measure the light at the 5 points indicated in Figure 2-1 and calculate their average. Confirm that the average is at least $27 \mu\text{W}/\text{cm}^2/\text{nm}$.

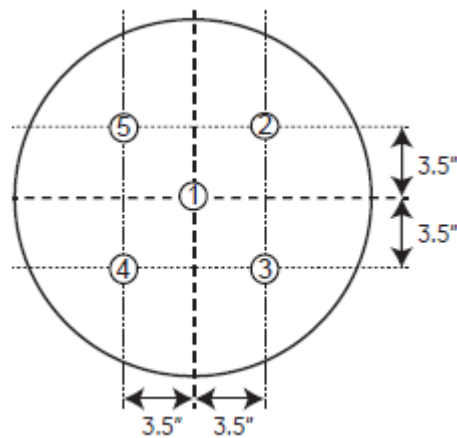


Figure 2-1 Light Measurement Points

6. Divide the lowest reading by the highest reading. If the LED light is functioning properly, the result should be greater than 0.4. If the result is not greater than 0.4, contact service.



**MEDICAL DEVICE NOTIFICATION ACKNOWLEDGEMENT
RESPONSE REQUIRED**

Please complete this form and return it to GE Healthcare promptly upon receipt and no later than 30 days from receipt. This will confirm receipt and understanding of the Medical Device Correction Notice and required actions to be taken Ref# 32072.

Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Email Address: _____

Phone Number: _____

We acknowledge receipt and understanding of the accompanying Medical Device Notification, and that we have taken appropriate actions in accordance with that Notification.

Please provide the name of the individual with responsibility who has completed this form.

Signature: _____

Printed Name: _____

Title: _____

Date (DD/MM/YYYY): _____

**Please return completed form to FAX NUMBER: +1-410-630-5579, or scanning or taking a photo of the completed form e-mailing to: MIC.Recall32072@ge.com
You may obtain this e-mail address through the QR code below:**

