



**URGENT MEDICAL DEVICE
CORRECTION**

GE Healthcare
GE Healthcare Finland Oy
Kuortaneenkatu 2
Helsinki
FI-00031 GE
FINLAND

Date

GEHC Ref # 36064

To: Healthcare Administrator / Risk Manager
Chief of Nursing
Director of Biomedical Engineering
Home Healthcare Provider

RE: **GE Healthcare TruSat Pulse Oximeter Power Supply potential risk of shock and burn.**

GE Healthcare has recently become aware that the plastic enclosure on the external power supply of the TruSat Pulse Oximeter is prone to breakage, and overheating. The issue may impact patient or user safety.

Please ensure that all potential users in your facility or patients using TruSat Pulse Oximeter in home care settings are made aware of this safety notification and the recommended actions.

**Safety
Issues**

The plastic enclosure on the external power supply for the TruSat Pulse Oximeter may break, exposing the electrical board and line voltage. The exposed electrical board and line voltage poses a risk to the user or caregiver if they touch the power supply while it is plugged in. Touching the broken power supply while plugged in may result in a burn or electrical shock.

Additionally, the plastic enclosure of the external power supply used with the TruSat Pulse Oximeter may get hot and become deformed. The hot surface poses a risk to the user or caregiver and may result in a severe burn.

**Safety
Instructions**

If you see visible signs of external power supply plastic enclosure breakage, immediately unplug the power supply, discontinue use and contact your local supplier. **DO NOT TOUCH AN EXPOSED ELECTRICAL BOARD.**

If there are no visible signs of enclosure breakage, the device can be operated safely by securing the power supply. Securing the power supply will prevent a fall, which could cause breakage. If the power supply does fall, ensure that it is unplugged from the electrical socket prior to touching or examining the enclosure.

If the surface of the external power supply enclosure feels unusually warm to the touch during use or becomes deformed, immediately unplug the external power supply from the electrical socket, discontinue use and contact your local supplier. **LET THE EXTERNAL POWER SUPPLY COOL DOWN BEFORE HANDLING THE EXTERNAL POWER SUPPLY.**

If the external power supply plastic enclosure does not feel unusually warm and is not

showing signs of deformation, the device can be operated safely.

If in doubt, please discontinue use of the device.

Please ensure that all potential users in your facility or patients using TruSat Pulse Oximeter in home care settings are made aware of these safety instructions.

Affected Product Details

This action applies to all external power supplies used with TruSat Pulse Oximeters sold under the GE or Datex-Ohmeda brand name.

AFFECTED EXTERNAL POWER SUPPLIES

There are three affected external power supplies. They are delivered either with TruSat Pulse Oximeter or as independent spare parts. The affected reference (REF) and part numbers (PART NO) are as follows:

	REF	PART NO
1. TruSat DC Power Supply	6050-0006-579	TR9CE1250LRDP-Y-MED
2. TruSat DC Power Supply	2050496-001	TR9CE1250LR2P-Y-MED
3. TruSat DC Power Supply (fixed US cord)	M1051426	TR9HE1250LRDP-Y-MED

The power supplies can be identified with the information provided in the appendix.

Product Correction

GE Healthcare will replace all affected external power supplies with a new power supply at no charge to you. GE Healthcare will ship the replacement power supplies directly, or contact to you in order to confirm the number of power supplies needed.

Contact Information

If you have any questions regarding this medical device correction or the identification of affected items please contact *(to be localized by each region)*, or your local Service Representative.

We apologize for any inconvenience this may cause. 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.

Thank you,



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Chief Medical Officer
GE Healthcare
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Appendix:

The power supplies can be identified with the information provided below:

1. TruSat DC Power Supply

<p>Text on the device plate:</p> <p>GlobTek, Inc. MEDICAL POWER SUPPLY FOR TRUSAT PULSE OXIMETER PART NO: TR9CE1250LRDP-Y-MED</p>	
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2. TruSat DC Power Supply

<p>Text on the device plate:</p> <p>GlobTek®, Inc POWER SUPPLY FOR MEDICAL USE PART NO: TR9CE1250LR2P-Y-MED</p>	
<p>Text on the yellow label:</p> <p>REF 2050496-001 GE Healthcare Finland Oy Kuortaneenkatu 2 FI-00510 Helsinki Finland +358 10 394 11</p>	

3. TruSat DC Power Supply (fixed US cord)

Text on the device plate:

GlobTek®, Inc.

MEDICAL POWER SUPPLY FOR
TRUSAT PULSE OXIMETER
PART NO: TR9HE1250LRDP-Y-MED

