



## URGENT MEDICAL DEVICE CORRECTION

Monitoring Solutions  
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Date: April 22, 2010

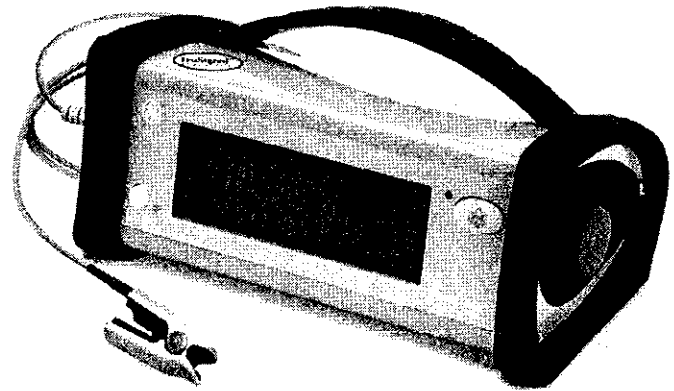
GEHC Ref #: 36050

To: Director of Biomedical Engineering

RE: **Potential safety risk when using GE Healthcare TruSat Pulse Oximeter with External Power Supply**

GE Healthcare has recently become aware that the TruSat Pulse Oximeter with external power supply does not comply with current safety standards. It is possible that the external power supply could leak electrical current. This current could cause third degree burns or an abnormal heart rhythm that, if untreated, could lead to death.

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



Safety  
Issues

There is a potential electrical safety risk to the user when the device is running on the external power supply and the power supply connector (see figure 1) is damaged or improperly connected on the TruSat. Defects in the power supply can then create an electrically conductive path to the heart.

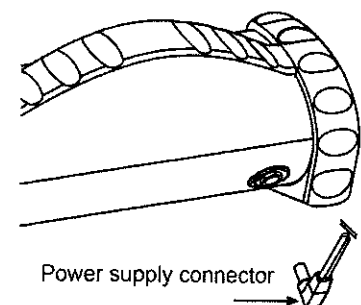


Figure 1: TruSat Power Supply connector



Affected  
Product  
Details

This action applies to TruSat oximeters with external power supplies sold under the GE or Datex-Ohmeda brand name (figure 2). The reference numbers for the affected TruSat oximeters are listed below. The reference number (REF) can be found printed on a transparent sticker on the bottom of the oximeter.

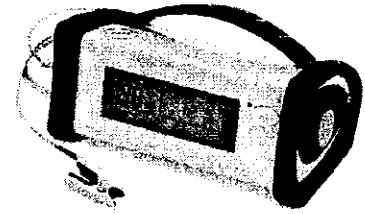


Figure 2, TruSat Oximeter

**Reference numbers of TruSats shipped with affected Power Supply:**

6051-0000-190  
6051-0000-191  
6051-0000-192  
6051-0000-193

The affected external power supply (figure 3) delivered with the TruSat can be identified with the information provided below (figure 4).

**AFFECTED EXTERNAL POWER SUPPLY:**

GlobTek, Inc.  
MEDICAL POWER SUPPLY FOR TRUSAT PULSE  
OXIMETER  
PART NO: TR9CE1250LRDP-Y-MED

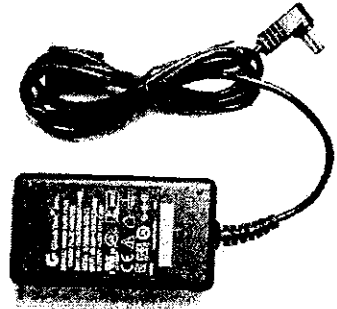


Figure 3, External Power Supply

**NOTE:** There are power supplies not affected by this issue. Those external power supplies are identified as:

PART NO: TR9HE1250LRDP-Y-MED

Note the difference in the fourth character: "H". If you have this power supply, you can continue to use the TruSat oximeter without safety instructions.

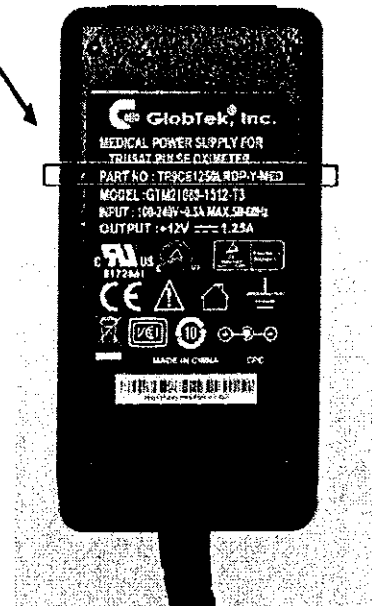


Figure 4, External Power Supply device plate

Product  
Correction

GE will replace all affected external power supplies with a new power supply. The replacement power supply is designed to meet the requirements for medical devices.

To ensure that you will receive the new power supply, please complete and return the attached reply form.

Safety  
Instructions

In the **home environment**, only operate the TruSat oximeter on internal batteries and with the external power supply disconnected. Do not bring the power supply to the home environment.

Charge the TruSat outside the home environment, while it is not in use. When charging the unit, ensure the following conditions are met:

- a) The external power green LED on the oximeter's front panel is continuously on, or
- b) The TruSat is charged with a separate isolation transformer connected between the power supply and the mains power

In a **clinical setting**, ensure the following conditions are met while using the device:

- a) The external power green LED on the oximeter's front panel is continuously on, or
- b) The TruSat is operated on internal batteries and the external power supply is disconnected, or
- c) The TruSat is used with a separate isolation transformer supplying mains power to the TruSat

**Note:**

*If the green LED on the oximeter's front panel does not stay lit, discontinue use and discard that specific power supply immediately. This applies to both the clinical setting and the home environment.*

By following the recommended actions above you may continue using the product until the replacement power supply is available for your oximeter. If in doubt, please discontinue use of the device.

Contact  
Information

If you have any questions regarding this medical device correction or the identification of affected items please contact Technical Support at 1-800-558-7044, 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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