URGENT FIELD SAFETY NOTICE

GE HealthCare

Date of Letter Deployment

GE HealthCare Ref. # 39004

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

RE: **TruSignal SpO2 Sensors – potential reduction of energy reaching patient during defibrillation, potential contact with unintended voltage, or inaccurate measurement**

Safety Issue #1

Affected TruSignal SpO2 Sensors (see Table 1 below) can potentially reduce the amount of electrical energy reaching the patient during external defibrillation, which could limit successful defibrillation and restoration of a normal rhythm. If this issue occurs during an external defibrillation event, it could go unnoticed by the caregiver and could contribute to an adverse patient outcome.

There have been no injuries reported due to this issue.

Safety Issue #2

Affected TruSignal SpO2 Sensors (see Table 1 below) that have been saturated with fluids, can expose the patient to unintended voltage if the patient comes in contact with a faulty external power source while wearing the affected sensor. This could contribute to an adverse patient outcome.

There have been no injuries reported due to this issue.

Actions to be taken by Customer /User for Safety Issue # 1 and #2

1. Use an alternate method for SpO2 monitoring such as TruSignal Sensors not impacted by this field action, or an alternate SpO2 device, if possible
2. If alternate methods are not possible, the affected TruSignal SpO2 Sensors can be used for monitoring if they have not been saturated with fluids
3. If defibrillation is necessary, when the affected TruSignal SpO2 Sensors are being used, please follow the instructions below:
   I. Remove the affected TruSignal SpO2 Sensor (see Table 1 below) from the patient
   II. Defibrillate the patient, per hospital protocol
   III. Reattach the affected TruSignal SpO2 Sensor after defibrillation is no longer needed

Safety Issue #3

Affected TruSignal Adult/Pediatric SpO2 Sensors (see Table 1 below) may contain additional material that can block the emitter or detector areas potentially leading to an inaccurate SpO2 reading, which could contribute to an adverse patient outcome.

There have been no injuries reported due to this issue.

Actions to be taken by Customer /User for Safety Issue #3

1. Before using Adult/Pediatric SpO2 Sensors (see Table 1), confirm that the sensor does not contain additional material covering the emitter or detector (See Figure 1).

2. If any additional material is present, discard the sensor and select another sensor. (An image of a non-impacted TruSignal SpO2 Sensor is shown in Figure 2.)

Figure 1: Defective TruSignal Adult/Pediatric Sensor with material blocking emitters and detectors.

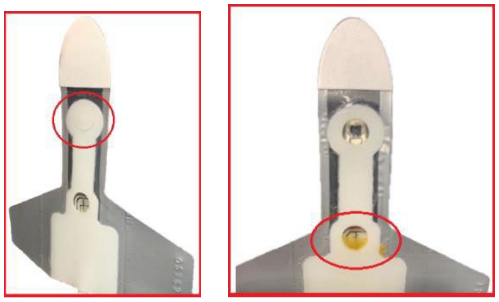
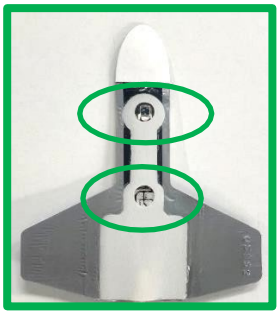


Figure 2: Non-impacted TruSignal Adult/Pediatric Sensors with clean emitters and detectors.



Please ensure all potential users in your facility are made aware of this safety notification and the recommended actions.

Please retain this document for your records.

Please complete and return the attached acknowledgement form to Recall.39004@ge.com

Affected Product Details

Please see Table 1 below to identify the affected sensors. REF/Catalog numbers and GTIN Identification numbers are located on the product label.

Table 1: Affected TruSignal sensors

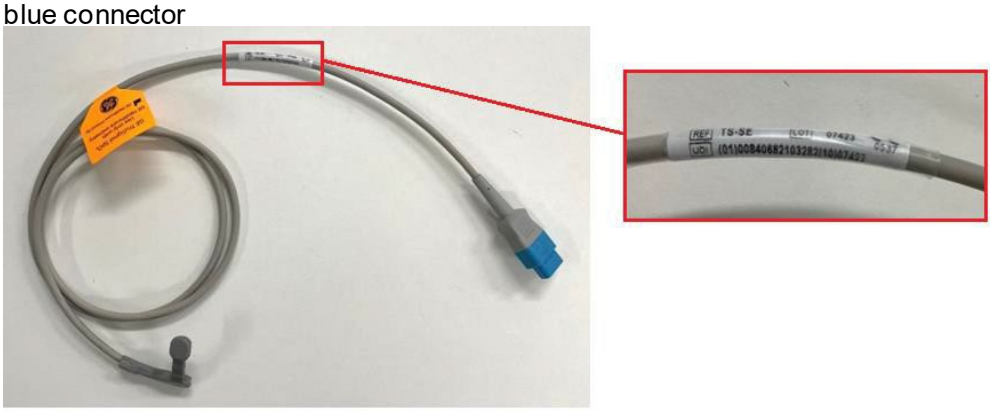
REF/ Catalog Number	Description	GTIN	Safety Issue	Sensor Type
TS-AP-10 TS-AP-25	TruSignal Adult/Pediatric sensor	00840682103220	1, 2, 3	Disposable
TS-AF-10 TS-AF-25	TruSignal AllFit sensor	0840682103176	1, 2	Disposable
TS-SE-3	TruSignal Sensitive Skin sensor	00840682103282	1, 2	Reusable
TS-W-D	TruSignal Wrap sensor	00840682103121	1, 2	Reusable
TS-E-D	TruSignal Ear sensor	00840682103251	1, 2	Reusable
TS-E2-GE	TruSignal Integrated Ear sensor with GE Connector	00840682103138	1, 2	Reusable
TS-E4-GE	TruSignal Integrated Ear sensor with GE Connector	00840682103428	1, 2	Reusable
TS-E4-N	TruSignal Integrated Ear sensor with Datex Connector	00840682103381	1, 2	Reusable
TS-E4-H	TruSignal Integrated Ear sensor with Ohmeda Connector	00840682103367	1, 2	Reusable

For disposable sensors, the product name, model number and GTIN are located on the product packaging as shown in Figure 3.

Figure 3: REF/Catalog number, product name & GTIN on Disposable Sensors pouch

For reusable sensors, if the packaging is not available, the product name, model number and GTIN can be found on the product itself as shown in Figure 4.

Figure 4: REF/Catalog number & GTIN on Reusable Sensors wrap label closer to blue connector



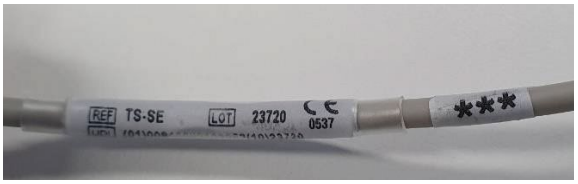
Parts not impacted by this correction

If you receive any of the devices listed in Table 1 marked with a green circle on the packaging (See Figure 5), these have been inspected by GE HealthCare in manufacturing and are not affected by the 3 issues in this correction.

Figure 5: Identification of non-impacted Disposable sensors

In addition to the green circle on their packaging, reusable sensors will also include an additional wrap label with three asterisks (***) next to the GTIN label (See Figure 6). This means that they were inspected by GE HealthCare in manufacturing and are not impacted by the 3 issues in this correction.

Figure 6: Identification of non-impacted Reusable sensors



INTENDED USE: TruSignal pulse oximetry sensors and interconnect cables are intended for use for continuous non-invasive arterial oxygen saturation (SpO2) and pulse rate monitoring. The devices are indicated for use under guidance of qualified medical personnel only.

Product Correction	After GE HealthCare receives the attached reply form, GE HealthCare will contact you to arrange for replacing the affected products at no charge to you. Please destroy all affected devices per your facility procedures.
Contact Information	If you have any questions or concerns regarding this notification, please contact GE HealthCare Service or your local Service Representative.

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,

…
GE HealthCare

…
GE HealthCare

GE HealthCare

GE HealthCare Ref. # 39004

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.

*Customer/Consignee Name: _____

Street Address: _____

City/State/ZIP/Country: _____

*Customer Email Address: _____

*Customer Phone Number: _____

It is important that we confirm our customers have received this correction notice. <u>This step needs to be completed before the replacement and shipping process can commence</u>. Please check one of the following and complete the requested information and send back via one of the methods below:

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification and have identified that we **<u>do not</u>** have any of the affected products listed in the table below.

OR

☐ We acknowledge receipt and understanding of the accompanying Medical Device Notification and have identified that we **<u>do</u>** have affected products in our possession, and we have taken the appropriate actions. **We acknowledge that we will destroy affected products on receipt of replacement products**.

Complete the table below to indicate quantity of affected products in your possession that need replacements

REF/ Catalog Number	Description	Number of devices to be replaced
TS-AF-10*	TruSignal AllFit sensor, Box of 10	Boxes
TS-AF-25*	TruSignal AllFit sensor, Box of 25	Boxes
TS-AP-10	TruSignal Adult/Pediatric sensor, Box of 10	Boxes
TS-AP-25	TruSignal Adult/Pediatric sensor, Box of 25	Boxes
TS-E-D	TruSignal Ear sensor	Sensors
TS-E2-GE	TruSignal Integrated Ear sensor with GE Connector	Sensors
TS-E4-GE	TruSignal Integrated Ear sensor with GE Connector	Sensors
TS-E4-N	TruSignal Integrated Ear sensor with Datex Connector	Sensors
TS-E4-H	TruSignal Integrated Ear sensor with Ohmeda Connector	Sensors
TS-SE-3	TruSignal Sensitive Skin sensor, Box of 3	Boxes
TS-W-D	TruSignal Wrap sensor	Sensors

Note: *
How many of the TS-AF replacements requested will be used for following patient population:

- Pediatric (3-20 Kg) _____boxes
- Neonatal (< 3 Kg) _____boxes

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

Signature: _____

*Printed Name: _____

*Title: _____

*Date (DD/MM/YYYY): _____

*Indicates Mandatory Fields

Please return completed form by scanning or taking a photo of the completed form and email to: Recall.39004@ge.com

You may obtain this e-mail address through the QR code below: