# URGENT Field Safety Notification

Tempus Pro Monitor
Unexpected Device Error When Used With Tempus Pro Video Laryngoscope

15-AUG-2023

**This document contains important information for the continued safe and proper use of your equipment**

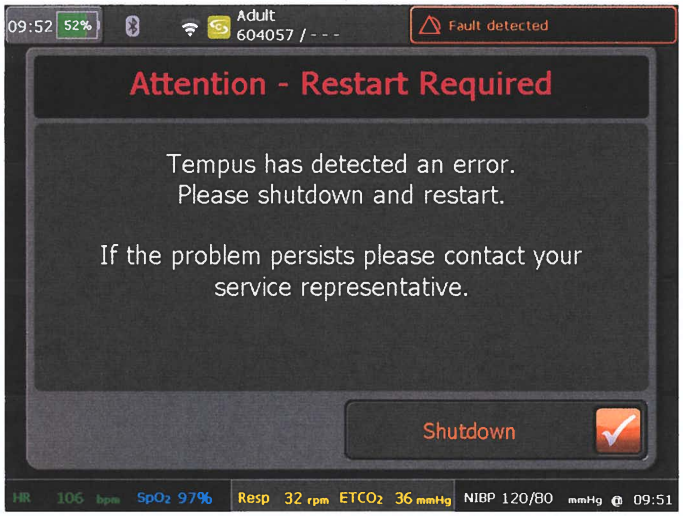
Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Dear Valued Customer,

Philips has identified an issue with the Tempus Pro Monitor where an error may occur with the Tempus Pro USB C-MAC S Imager Video Laryngoscope (Tempus Pro Video Laryngoscope). This URGENT Field Safety Notification is intended to inform you about:

**1. What the problem is and under what circumstances it can occur**

An issue has been identified with the Tempus Pro Monitor where an error may occur during video laryngoscope use with the Tempus Pro Video Laryngoscope or immediately after the Tempus Pro Video Laryngoscope has been unplugged from the Tempus Pro Monitor. If this error occurs, the user is presented with an unexpected full screen message informing the user an error has occurred, requiring shutdown and restart of the Tempus Pro Monitor. This full screen message prevents the user from viewing any graphical representation of patient vital signs; however, text and numerical values are still visible on the device's display screen. A visual of the message is shown below:




If this error occurs, the pulse tone (audio) that reflects the patient's level of oxygen saturation is no longer sounded. Additionally, the user will no longer be able to visualize the airway requiring the user to either intubate the patient without video imaging or use an alternative laryngoscope not connected to the Tempus Pro Monitor. This message cannot be cleared from the Tempus Pro Monitor's screen, and

most of the monitoring functions are not available, until the user initiates a complete shut down and restart of the device, which may take 60-100 seconds.

The issue was identified via customer complaints. There have been no reports of patient harm.

**Tempus Pro Monitor Intended Use**
The Tempus Pro is a portable Vital Signs Monitor intended to be used by clinicians and medically qualified personnel for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications.

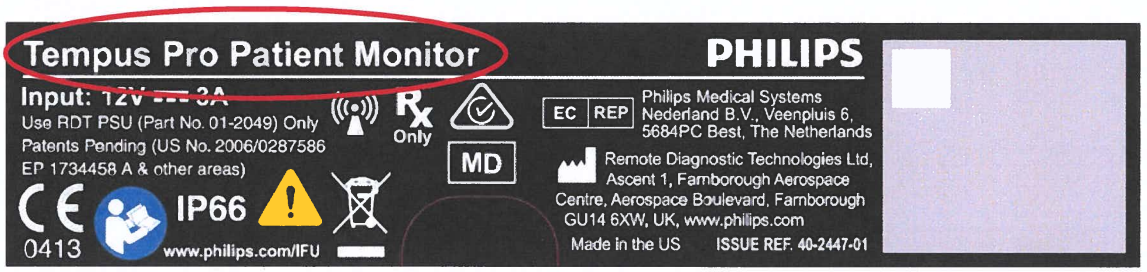
**USB C-MAC S Imager Video Laryngoscope (Tempus Pro Video Laryngoscope) Intended Use**
C-MAC pocket monitors are used for visualizing anatomy and for storing videos and images during an endoscopic intervention. C-MAC pocket monitors are non-invasive and are designed for transient use in invasive interventions through a body orifice.

**2. Describe the hazard/harm associated with the issue**

There is a possibility of delay in diagnosis that may lead to a subsequent delay in treatment or hypoxia as a result of the unexpected loss of video laryngoscopy and loss of all Tempus Pro clinical measurements while the user restarts the system.

**3. Affected products and how to identify them**

This correction affects Tempus Pro Monitors with Part Numbers 00-1004-R, 00-1007-R, 00-1024-R, and 00-1026-R with Trizeps-7 hardware, while using the Tempus Pro Video Laryngoscope with Part Number 01-2044. Tempus Pro Monitors are identified by a label placed on the rear of the device. An example is shown below:




The product number (REF) and Serial Number (SN) are printed in the gray box.

**4. Describe the actions that should be taken by the customer / user to prevent risks for patients or users**

- Check the 'About Tempus Pro' screen on the Tempus Pro monitor(s) to determine which Hardware version is present by following these steps:

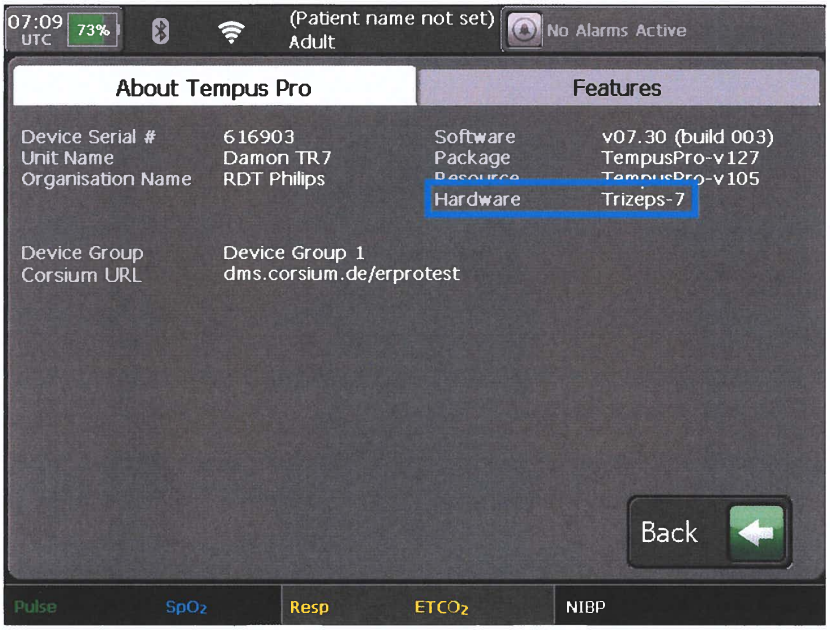
<u>To access the 'About Tempus Pro' screen:</u>

1. Press the blue 'Menu' button on the Tempus Pro monitor keypad

2. Scroll down to the last page of the menu (page 4 of 4)

3. Press 'About Tempus Pro'


4. Identify the Hardware Version (Trizeps-7 or Trizeps-6)




- If the Tempus Pro Monitor has **Trizeps-7** Hardware, remove the Tempus Pro Video Laryngoscope from service with this monitor. Users must use an alternative laryngoscope not connected to the Tempus Pro Monitor to manage the patient's airway to avoid interruption in patient care. The Tempus Pro Monitor can remain in service if the Tempus Pro Video Laryngoscope is not connected to the monitor.
- If the Tempus Pro Monitor has **Trizeps-6** Hardware, the Tempus Pro Video Laryngoscope can continue to be used with the monitor.
- Post this Urgent Field Safety Notification letter on or near your Tempus Pro device.
- Complete and return the Urgent Field Safety Notification response form included, no later than 30 days from receipt.

Please pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred (if appropriate).

**5. Describe the actions planned by Remote Diagnostic Technologies Ltd. (GB-MF-000002127), part of Philips Emergency Care, to correct the problem**

Philips has developed a software update to resolve this issue that is expected to be available in Q3 2023. When it is available, Philips will provide the updated software and installation instructions (via a downloadable link) for customer installation. Upon customer request, Philips can also provide a USB

Flash Drive with the updated version of software. If you need any further information or support concerning this issue, please contact your local Philips representative. < Key Markets insert contact information here >

This notice has been reported to the appropriate Regulatory Agencies. Be sure to report any occurrence of this issue to Philips, your Philips representative, or to your local Regulatory authority.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Tanya Deschmidt
Director of Quality

## URGENT FIELD SAFETY NOTIFICATION RESPONSE FORM

**Reference:** Tempus Pro Unexpected Device Error When Used With Video Laryngoscope

**Instructions:** Please complete and return this form to Philips promptly upon receipt and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notification, understanding of the issue, and required actions to be taken.

Customer / Consignee / Facility Name: _____

Street Address: _____

City / State / Zip / Country: _____

**Customer Actions:**

- Check the 'About Tempus Pro' screen on the Tempus Pro monitor(s) to determine which Hardware version is present by following the steps described in the letter.
- If the Tempus Pro Monitor has **Trizeps-7** Hardware, remove the Tempus Pro Video Laryngoscope from service with this monitor. Users must use an alternative laryngoscope not connected to the Tempus Pro Monitor to manage the patient's airway to avoid interruption in patient care. The Tempus Pro Monitor can remain in service if the Tempus Pro Video Laryngoscope is not connected to the monitor.
- If the Tempus Pro Monitor has **Trizeps-6** Hardware, the Tempus Pro Video Laryngoscope can continue to be used with the monitor.
- Post this Urgent Field Safety Notification letter on or near your Tempus Pro device.
- Complete and return the Urgent Field Safety Notification response form included, no later than 30 days from receipt.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notification and confirm that the information from this Notification has been properly distributed to all users that handle the Tempus Pro Monitor.

**Name of person completing this form:**

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Date (DD-MMM-YYYY): _____

**Email Address of recipient for software download link (Mandatory):**

_____

Please return this form to Philips by email or fax < Key Market Insert reply information >