PHILIPS

URGENT Field Safety Notification

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

06-NOV-2023

Dear Valued Distributor,

Philips has updated the attached notification, C&R 2023-CC-EC-005 for the Tempus Pro Monitor, to Revision B to provide further information and clarification. This includes:

- Clarification regarding alarms while the error message is displayed;
- Update to include adverse events;
- Update to the Intended Use statement for the Video Laryngoscope;
- Update to include software revisions as well as clarification of part numbers directly and not directly affected;
- Update to include what to do when you receive the updated software solution from Philips.

If you have already completed the response form with Revision A of this letter, you do not need to complete it again. If you have not completed the response form, please complete the form to receive the updated software. The updated software solution is now available, and customers have or will be contacted by Philips accordingly.

Sincerely,

Tanya Deschmidt
Director of Quality

PHILIPS

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06-NOV-2023

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

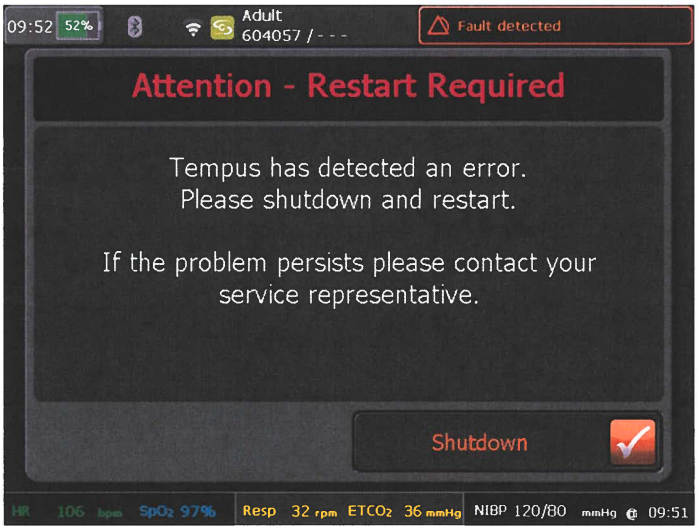
Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

Dear Valued Distributor,

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 patient pulse tone (audio) that reflects the patient's level of oxygen saturation is no longer sounded and there will be no additional patient or device alarm LEDs or audio alarms while the error message is displayed. 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. Philips has received two reports of patient harm associated with this issue.

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
The Tempus Pro can be used to obtain, save and transmit video laryngoscope images through the use of a plug-in USB Imager with a range of disposable blades. Video Laryngoscopy provides the ability to perform video assisted intubations. The device is indicated for displaying images from a Karl Storz C-MAC S Imager video laryngoscope. The video laryngoscope may be used on all patients monitored by a Tempus Pro. It can only be used with the Tempus Pro.

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 directly affects Tempus Pro Monitors with Part Numbers 00-1004-R, 00-1007-R, 00-1024-R, and 00-1026-R with Trizeps-7 hardware, software v07.26 through v07.30, while using the Tempus Pro Video Laryngoscope with Part Number 01-2044. While Tempus Pro Monitors with Part Numbers 00-1004 and 00-1007 are not directly affected, these devices may have their hardware updated to Trizeps-7 hardware so are being included in this correction as a precaution. 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:

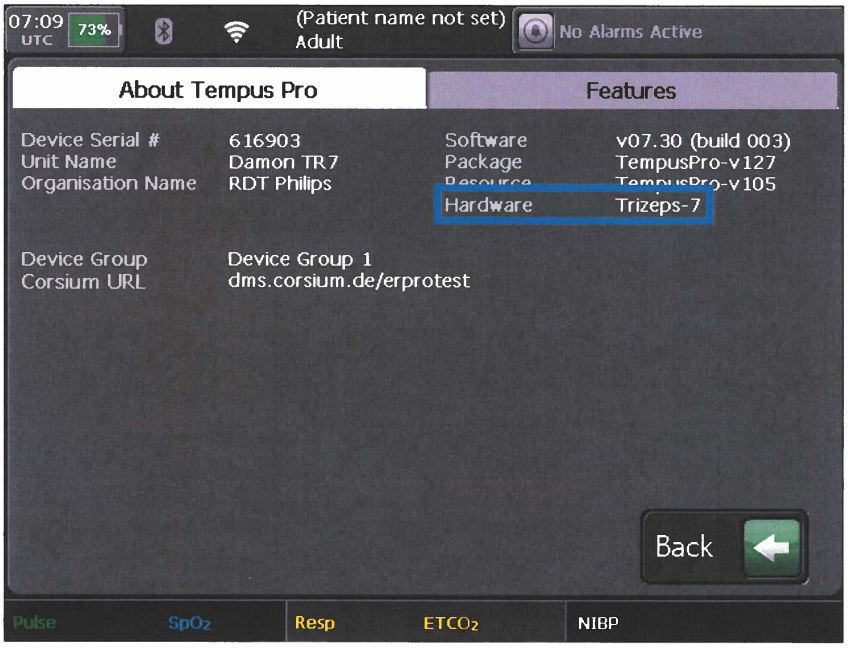
  <u>To access the 'About Tempus Pro' screen:</u>

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. If you have already completed the response form with Rev A of this letter, you do not need to complete it again.
- When you receive the updated software solution from Philips, please install the software (V07.34) on your Tempus Pro Monitor according to the installation instructions provided. Once updated, you may resume use of the Tempus Pro Video Laryngoscope if you had removed it from service.

- If you have any previous revisions of software saved on a computer or Flash Drive (including the 4G USB dongle included in part number 01-2298), please delete them. Do not revert back to any previous revisions of software.

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 that should be taken by the Distributors

- If you have any Tempus Pro Video Laryngoscopes in stock that have not been distributed, do not distribute them. As a reminder from Urgent Field Safety Notification letter 2022-CC-EC-017, if you have any Tempus Pro Monitors in stock that have not been distributed, do not distribute them and please contact your Philips sales partner for return.
- Please modify the URGENT FIELD SAFETY NOTIFICATION RESPONSE FORM found on the last page of the URGENT Field Safety Notification letter (Document Identification: FSN-2023-CC-EC-005 Rev B) to substitute your firm's own email and fax information (an electronic copy will be provided.)
- Please send a copy of the URGENT Field Safety Notification letter (Document Identification: FSN-2023-CC-EC-005 Rev B) with modified response form to each customer with Tempus Pro Monitors as soon as practical and not more than 30 days from receipt of this letter.
- If you have already completed the response form with Revision A of this letter, you do not need to complete it again. If you have not, please complete and send to Philips the DISTRIBUTOR URGENT FIELD SAFETY NOTIFICATION RESPONSE FORM found on the last page of this letter (Document Identification: DISTRIBUTOR-FSN-2023-CC-EC-005 Rev B) no later than 30 days from receipt.

After the letters have been sent to customers with Tempus Pro Monitors, please take steps to ensure customers received the letters. 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). Please transfer this notice to other organizations on which this action has an impact.

6. 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 now 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

DISTRIBUTOR 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: _____

Distributor Actions:

- If you have any Tempus Pro Video Laryngoscopes in stock that have not been distributed, do not distribute them. As a reminder from Urgent Field Safety Notification letter 2022-CC-EC-017, if you have any Tempus Pro Monitors in stock that have not been distributed, do not distribute them and please contact your Philips sales partner for return.
- Please modify the URGENT FIELD SAFETY NOTIFICATION RESPONSE FORM found on the last page of the URGENT Field Safety Notification letter (Document Identification: FSN-2023-CC-EC-005 Rev B) to substitute your firm's own email and fax information (an electronic copy will be provided.)
- Please send a copy of the URGENT Field Safety Notification letter (Document Identification: FSN-2023-CC-EC-005 Rev B) with modified response form to each customer with Tempus Pro Monitors as soon as practical and not more than 30 days from receipt of this letter.
- If you have already completed the response form with Revision A of this letter, you do not need to complete it again. If you have not, please complete and send to Philips the DISTRIBUTOR URGENT FIELD SAFETY NOTIFICATION RESPONSE FORM found on the last page of this letter (Document Identification: DISTRIBUTOR-FSN-2023-CC-EC-005 Rev B) no later than 30 days from receipt.

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

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD-MMM-YYYY): _____

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