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URGENT Field Safety Notification

Tempus Pro Monitor
Software Issues

28-APR-2025

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

This notice must be shared with all relevant personnel within your organization and with any organization where the potentially affected devices have been transferred. It is important to understand the implications of this communication.

Please retain this letter for your records.

Dear Valued Customer/Distributor,

Philips identified potential safety issues with the Tempus Pro Monitor software. This URGENT Field Safety Notice is intended to inform you about:

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

I. The device may fail to startup normally, freeze, or reboot. Error messages may be displayed, resulting in the device becoming inoperable. These issues could occur during startup or clinical use in the following ways:

- The Tempus Pro Monitor may freeze at the startup screen, display an "MPM Application" software error message, or may show an "Attention – Restart Required'' message.
- The Tempus Pro Monitor may freeze and automatically reboot either when the user starts the process of recording a 12-lead ECG (by pressing the 'Start Record' button) or after the 12-lead has been recorded when the user presses another button in the 12-lead interface, such as 'Print' or 'View interpretation'.
- The Tempus Pro Monitor may automatically reboot during an intermittent connection with the Tempus Pro Smart Mount.

II. 12-lead ECG measurements of the Tempus Pro Monitor, generated by the standard (Louvain) algorithm, could produce inaccurate ECG Rhythm and Morphology statements. This issue impacts SW versions before vx.36.

These issues were identified via customer complaints and Philips internal investigation. Philips has not received any reports of patient harm related to these issues.

Intended use of affected product
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.

2. Hazard/harm associated with the issue

I. A failure to start up, freezing during use, or failure to record 12-Lead ECG can lead to the absence of or delayed treatment or diagnosis to the patient. Device reboot takes approximately two minutes during which time the device is inoperable.

II. Inaccurate 12-lead ECG interpretations by the standard (Louvain) algorithm can lead to misdiagnosis or delayed diagnosis to the patient for devices with SW versions before vx.36. Devices that have been upgraded to SW versions starting at vx.36 without installing the new ECG analysis algorithm could lose ECG interpretation functionality.

3. Affected products and how to identify them

I. The failure to startup normally, freeze, or reboot can affect all Tempus Pro Monitors using SW versions prior to vx.40.

Product Description	Part Number
Tempus Pro Monitors	01-1007
	01-1004-R
	00-1007-R
	00-1024-R
	00-1026-R

Tempus Pro Monitors are identified by a product label on the rear of the device, as well as a UDI label with the part number.

II. Inaccurate 12-lead ECG interpretations affects only devices with SW version before vx.36 and the standard (Louvain) algorithm.

- See Appendix A for instruction on how to identify if your device has the standard (Louvain) algorithm.

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

You may continue to use your Tempus Pro Monitor. Philips advises you take the following precautions:

I. The User/Operator Manual provides precautions and warnings on maintaining appropriate power or battery supply, which may reduce the risk of occurrence of an "MPM Application" software error message:

- Warning (in Chapter 2, Getting started): Ensure the latches on both sides of the battery are fully engaged prior to using the Tempus – an incorrectly fitted battery could result in the Tempus losing power during use.
- Note: Before removing the battery, you must switch off the Tempus Pro by pressing the power button. Do not remove the battery when the Tempus is on (unless there is a power supply attached to the device).

II. If you have confirmed that your Tempus Pro has the standard (Louvain) algorithm, continue to follow the User/Operator Manual, which warns users to not make evaluations based solely on interpretation statements from the algorithm:

- Warning (in Chapter 6, Taking medical readings): ECG interpretation performed by software is not a substitute for review and evaluation of ECG recordings by a qualified clinician.

- Keep a copy of this Urgent Field Safety Notification letter with your device until you receive the correction.
- Complete and return the Urgent Field Safety Notification Response Form included with this letter within 30 days of receipt of this notice.

5. The actions that should be taken by distributors

- Modify the Urgent Field Safety Notice Response Form to substitute your firm's email and fax information.
- Send a copy of this Urgent Field Safety Notice (with modified response form) to each customer to whom you distributed the affected product as soon as possible and no later than 30 days from receipt of this notice.
- Complete and return the Urgent Field Safety Notice Response Form included with this letter within 30 days of receipt of this notice.

After the letters have been sent to customers with affected product(s), please ensure customers received the letter.

This notice must be shared with all relevant personnel within your organization and with any organization where the potentially affected devices have been transferred. Please forward this notification if the affected products were distributed outside of your facility.

6. 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 these issues that is expected to be available in Q3 2025 via FCO86700012. Customers will be contacted by Philips to implement the software update

If you need any further information or support concerning this issue, please contact your local Philips representative:
Telephone 80 30 30 35
Email philips.service@philips.com

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Sharunyan Thavarajan
Director of Quality

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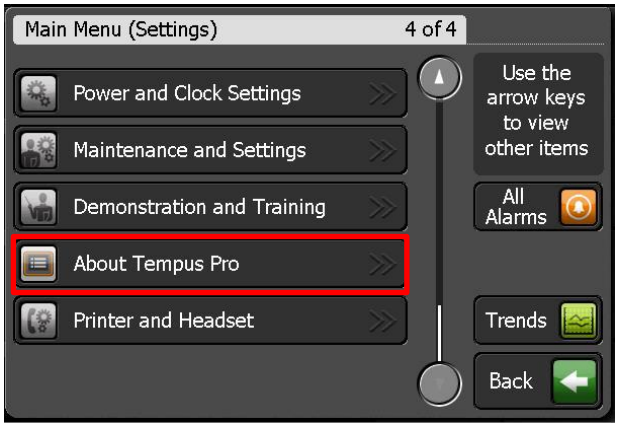
Appendix A

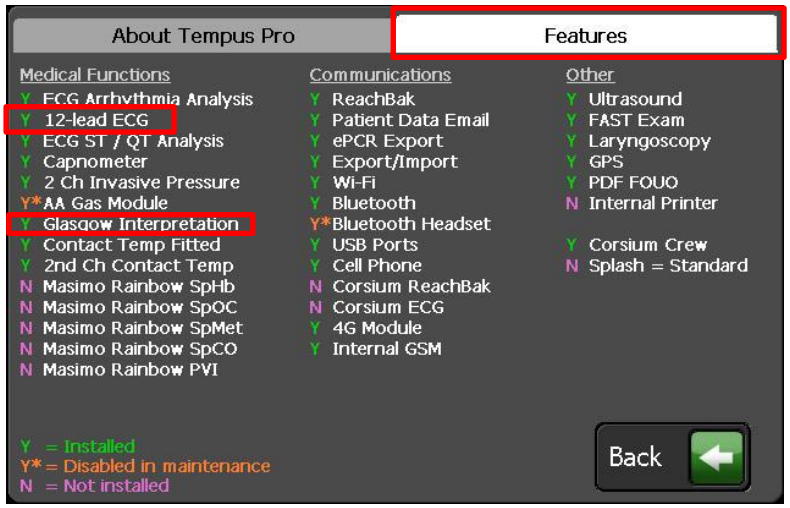
How to identify the Tempus Pro ECG Algorithm

Press Main Menu button and scroll until “About Tempus Pro” is shown.

1. Select “About Tempus Pro” from main menu.



2. Select “Features” tab.



3. If “Glasgow Interpretation” is “**Y**” and “12-lead ECG” is “**Y**”, then device has Glasgow license (not Louvain).
4. If “Glasgow Interpretation” is “**N**” and “12-lead ECG” is “**Y**”, then device has Louvain license (not Glasgow).

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URGENT FIELD SAFETY NOTIFICATION RESPONSE FORM

Reference: FSN-2024-CC-EC-023 Tempus Pro Monitor Software Issues
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 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:

I. The User/Operator Manual provides precautions and warnings on maintaining appropriate power or battery supply, which may reduce the risk of occurrence of an "MPM Application" software error message:
  - Warning (in Chapter 2, Getting started): Ensure the latches on both sides of the battery are fully engaged prior to using the Tempus – an incorrectly fitted battery could result in the Tempus losing power during use.
  - Note: Before removing the battery, you must switch off the Tempus Pro by pressing the power button. Do not remove the battery when the Tempus is on (unless there is a power supply attached to the device).

II. If you have confirmed that your Tempus Pro has the standard (Louvain) license, continue to follow the User/Operator Manual, which provides warning not to make evaluations based solely on interpretation statements from the algorithm:
  - Warning (in Chapter 6, Taking medical readings): ECG interpretation performed by software is not a substitute for review and evaluation of ECG recordings by a qualified clinician.

- Keep a copy of this Urgent Field Safety Notification letter with your device until you receive the correction.
- Complete and return the Urgent Field Safety Notification Response Form included with this letter within 30 days of receipt of this notice.

Distributor Actions:

- Modify the Urgent Field Safety Notice Response Form to substitute your firm's email and fax information.
- Send a copy of this Urgent Field Safety Notice (with modified response form) to each customer to whom you distributed the affected product as soon as possible and no later than 30 days from receipt of this notice.
- Complete and return the Urgent Field Safety Notice Response Form included with this letter within 30 days of receipt of this notice.

We acknowledge receipt and understanding of the accompanying Field Safety 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 to FCO.Nordic@philips.com