URGENT Field Safety Notification

Tempus Pro Monitor
Ingress and Basic Safety Issues

15-FEB-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 Regulatory Compliance issues with the Tempus Pro Monitor. This URGENT Field Safety Notification letter is intended to inform you about:

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

During internal testing, Regulatory Compliance issues regarding Fluid Ingress and Basic Safety Issues have been identified with the Tempus Pro Monitor, AC Mains Power Supply, and the Vehicle Adaptor. Philips has not received any complaints associated with these issues since introducing the device into the market in 2013.

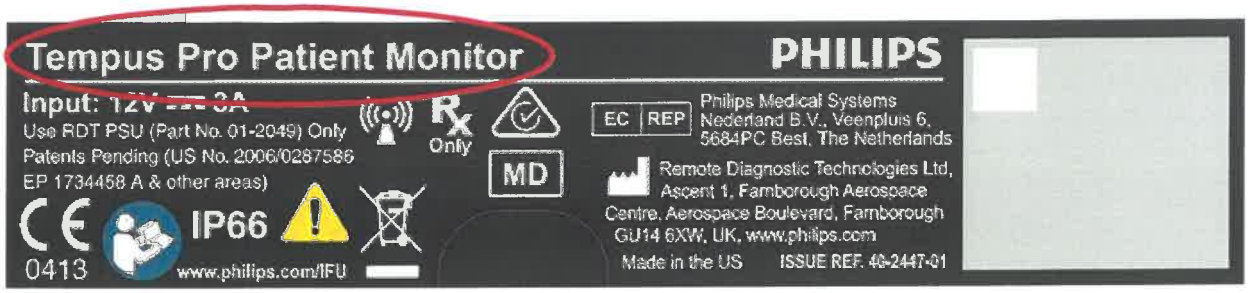
Intended use of affected product:
The Tempus Pro is a portable Vital Signs Monitor intended to be used by clinicians and medically qualified personnel, for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications.

2. Describe the hazard/harm associated with the issue

The Tempus Pro device's labeling indicates that the device is water and sand resistant to IP66 (dust and water ingress under pressure). However, testing revealed that the device does not meet the standards for Fluid and Particulate Ingress. Additionally, there is a possibility of component overheating or unanticipated voltage emitted from device electrical components. Because of the multiple levels of protection and isolation built into the product, Philips has received no reports of harm because of this issue in normal use environments. .

3. Affected products and how to identify them

This Correction affects all Tempus Pro Monitor devices. The Part Numbers for Tempus Pro are as follows: 00-1004, 00-1004-R, 00-1007, 00-1007-R, 00-1024-R, and 00-1026-R. 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

- As there is currently no indication that any of the issues have resulted in a degradation in product performance, Philips advises that the Tempus Pro devices should remain in service.
- Continue to follow the User/Operator Manual, including:
  - Take care to ensure that water or liquids are not spilt over the device or into its ventilation holes in the side corners.
  - Check connector covers, particularly the capnometer door cover, to ensure they close and latch acceptably.
- 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 Philips Emergency Care (GB-MF-000002127) to correct the problem

Philips will be providing a new and compliant AC Mains Power Supply to all affected customers. A new and compliant Vehicle Adaptor will also be provided to affected customers with devices that include that option. Philips anticipates providing this solution to customers in the second half of 2023.

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,

15 FEB 2023

Jon Yard
Director of Quality

URGENT FIELD SAFETY NOTIFICATION RESPONSE FORM

Reference: Tempus Pro Ingress and Basic Safety 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: _____

Tempus Pro Device Serial Numbers: _____

Customer Actions:

- As there is currently no indication that any of the issues have resulted in a degradation in product performance, Philips advises that the Tempus Pro devices should remain in service.
- Continue to follow the User/Operator Manual, including:
  - Take care to ensure that water or liquids are not spilt over the device or into its ventilation holes in the side corners.
  - Check connector covers, particularly the capnometer door cover, to ensure they close and latch acceptably.
- 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 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 or fax< Key Market Insert reply information >