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URGENT Field Safety Notice

Tempus Pro Monitor

Intracranial Pressure (ICP) and Bladder Pressure (BDR) Pressures May be Inaccurate

25-NOV-2025

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.

Please retain this letter for your records.

Dear Valued Customer/Distributor,

Philips is issuing this Field Safety Notice due to a regulatory compliance issue related to the Tempus Pro Monitor. The User/Operator Manual references the term 'Invasive Pressure', which includes Intracranial Pressure (ICP) and Bladder Pressure (BDR) as selectable channel labels. However, these measurements on the Tempus Pro Monitor have not been tested or validated for accuracy. The device is only cleared for Invasive Blood Pressure (IBP) measurements.

This Field Safety Notice applies to Tempus Pro Monitors that use Invasive Blood Pressure, either with IBP enabled on the device or with an external USB 2-Channel IBP Module. Please refer to Appendix A for guidance on how to identify if your Tempus Pro Monitor has IBP enabled.

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

- The Tempus Pro Monitor User/Operator Manual uses the term 'Invasive Pressure', and the device software allows users to label pressure channels as 'ICP' or 'BDR'.
- ICP and BDR measurements on the Tempus Pro Monitor have not been tested or validated for accuracy.
- The device is only cleared for Invasive Blood Pressure (IBP) monitoring.

There have been no complaints or reports of patient harm associated with this issue. The issue was identified internally.

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.

2. Hazard/harm associated with the issue

The ICP and BDR measurements have not been tested or validated for accuracy on the Tempus Pro Monitor and may be inaccurate. As a result, healthcare providers may base clinical judgment on unvalidated measurements, which could potentially lead to incorrect clinical decisions. There is no new or elevated risk associated with using the Tempus Pro for measuring ICP and BDR.

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3. Affected products and how to identify them

This Field Safety Notice applies to Tempus Pro Monitors that have IBP enabled or use an external USB 2-Channel IBP Module. See Appendix A for guidance on how to identify if your Tempus Pro Monitor has IBP enabled. Philips is sharing this notification with all Tempus Pro Monitor customers a s a precautionary measure until verification and validation testing is complete.

Product Description	Part Number
Tempus Pro Monitors	00-1007
	00-1004-R
	00-1007-R
	00-1024-R
	00-1026-R
USB 2-Channel IBP Module	01-2017

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

A picture of the external USB 2-Channel IBP Module is below; this module is identified by a label with the part number.

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

- You may continue to use your Tempus Pro Monitor including the Intracranial Pressure and Bladder Pressure measurements. Continued use of Tempus Pro for ICP/BDR measurement is preferable to not having these measurements at all, as real-time data may guide urgent clinical decisions.
- Routine comparison with reference values of most ICP/BDR readings serves to reduce potential risk inherent with ICP/BDR use.
- Complete and return the Urgent Field Safety Notification Response Form included with this letter within 30 days of receipt.

Share this notice with all relevant personnel within your organization and with any organization where affected devices have been transferred.

5. 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 a 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.

Please ensure customers receive the letters that you send to customers with affected product(s). This notice must be shared with all relevant personnel within your organization and with any organization where the affected devices have been transferred.

6. Actions planned by Remote Diagnostic Technologies Ltd. (GB-MF-000002127), part of Philips Emergency Care, to correct the problem

Philips is currently investigating this and will send a follow-up communication regarding further actions.

If you need any further information or support concerning this issue, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market>*

This notice has been reported to the appropriate Regulatory Agencies. Philips regrets any inconvenience caused by this problem.

Sincerely,

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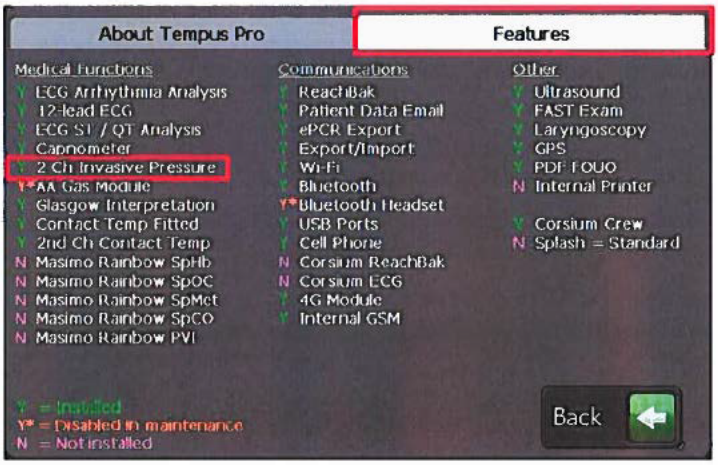
Appendix A

How to identify if your Tempus Pro Monitor has IBP enabled

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 "2 Ch Invasive Pressure" is "Y" then your device has IBP enabled.
4. If "2 Ch Invasive Pressure is "N" then your device does not have IBP enabled.

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URGENT Field Safety Notice Response Form

Reference: FSN-2025-CC-EC-008, Intracranial (ICP) and Bladder (BDR) Pressures May be Inaccurate
Instructions: Please complete and return this form to Philips promptly and no later than 30 days from receipt. Completing this form confirms receipt of the Urgent Field Safety Notice and understanding of the issue and required actions to be taken.

Customer/Consignee/ Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- You may continue to use your Tempus Pro Monitor including the ICP and BDR measurements. Continued use of Tempus Pro for ICP/BDR measurement is preferable to not having these measurements at all, as real-time data may guide urgent clinical decisions.
- Routine cross-verification of most ICP/BDR readings serves to reduce potential risk inherent with ICP/BDR use.
- Complete and return the Urgent Field Safety Notification Response Form included with this letter within 30 days of receipt.

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 a 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 Urgent Field Safety Notice and confirm that the information from this Letter 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: _____

Email Address: _____

Date (DD/MM/YYYY): _____

Please return this form to Philips by email or fax: *<Reply information to be completed by the Market or Distributor>*