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URGENT Field Safety Notice

Philips Hemodynamic Application (PHA) with software version R1.2 and R1.3 and continuous patient monitoring license.

22 – March – 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.

Please retain this letter for your records.

Dear Customer,

Philips has become aware of a potential safety issue with the Philips Hemodynamic Application (PHA) with software version R1.2 and R1.3 and an active continuous patient monitoring license, where the Invasive Blood Pressure (IBP) channel of the Philips IntelliVue X3 monitor may be switched off or may flip between arterial and venous without warning to the user. This URGENT Field Safety Notice is intended to inform you about:

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

Philips has identified that if the Philips IntelliVue X3 monitor has an internal blood pressure channel active when it is connected to the Philips Hemodynamic Application, with software version: R1.2 or R1.3 and an active continuous patient monitoring license, during the connection the following issues may occur:

- The internal blood pressure channel that was active before connecting the Philips IntelliVue X3 to the Philips Hemodynamic Application may be switched off, or
- If the pressure channel is not switched off, the pressure label on the internal blood pressure channel that was active before connecting the Philips IntelliVue X3 to the Philips Hemodynamic Application may be changed from arterial to venous or vice versa.

When any of these issues occur, there will not be any audio or visual notification to the user.

To date, Philips has not received any adverse events related to this issue.

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2. Hazard/harm associated with the issue

The following hazardous situations are identified:

If the Invasive Blood Pressure (IBP) channel is switched off while the IntelliVue X3 is connected to the Philips Hemodynamic Application (PHA), and this situation is not noticed, there could be a delayed response to physiologic deterioration of the patient, potentially resulting in patient harm.

If an arterial Invasive Blood Pressure (IBP) channel label is switched to a venous Invasive Blood Pressure IBP label or vice versa, the alarm setting will not correspond to the actual IBP being measured. A physiologic deterioration of the patient could be unnoticed, potentially resulting in patient harm.

3. Affected products and how to identify them

Affected product is the Philips Hemodynamic Application version R1.2 or R1.3 and with an active continuous patient monitoring license, that enables invasive investigation of cardiac and vascular diseases.

To identify the software version of the Philips Hemodynamic Application (PHA), the following steps can be followed:

Click on "System" and subsequently on "About" as shown in Figure 1.

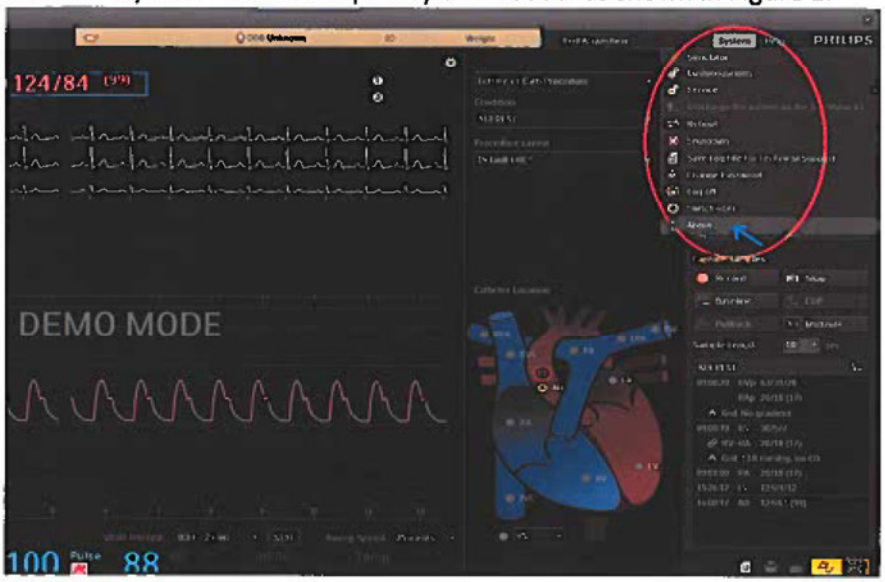

Figure 1.

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On the next screen, on the left side, the Release version is shown. Figure 2

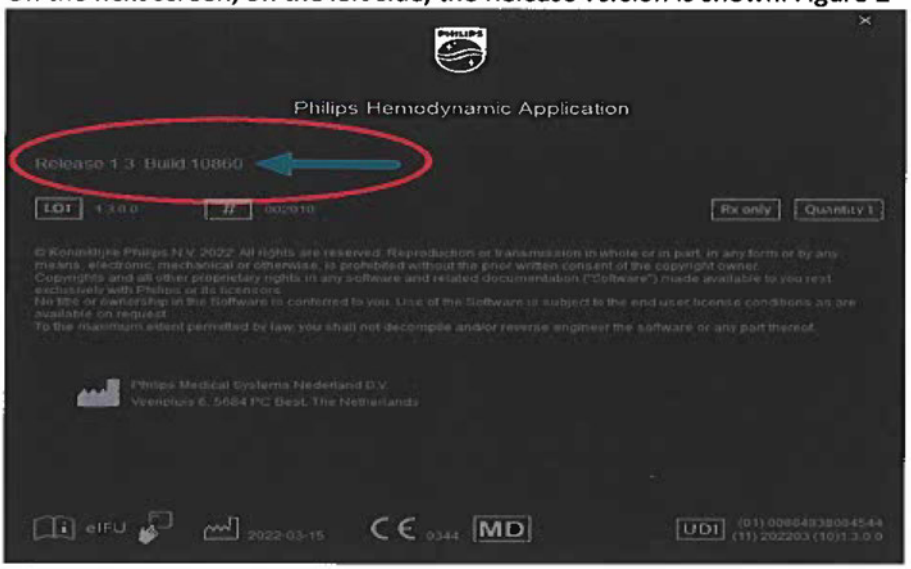

Figure 2.

There are four Philips Hemodynamic Application systems affected by this issue.
Details of these products are shown in the following table:

Model Number	Model Description	System Serial Number	System Equipment Number
722467	Philips Hemo system with IntelliVue X3	17	87727027
722467	Philips Hemo system with IntelliVue X3	24	88034655
722467	Philips Hemo system with IntelliVue X3	25	88034656
722467	Philips Hemo system with IntelliVue X3	814	96257635

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

- If the Internal Blood Pressure (IBP) channel is active when connecting the Philips InvelliVue X3 to the Philips Hemodynamic Application:
  - Ensure that the channel continues to be switched on after the connection.
  - Ensure that the channel that was active before the connection is the same one active after the connection.
- Ensure the clinical staff is always present during the patients stay and that the patient is not left unattended while being monitored.
- If a patient with an arterial line can be expected in the Cath Lab, ensure that in all layouts of the corresponding Internal Blood Pressure IBP channel are switched on and labeled as arterial pressure.
- Keep this Field Safety Notice with the documentation of the systems until Philips corrects your system.
- Circulate this Urgent Field Safety Notice to all users so that they are aware of the product issue.
- Return the attached response form to Philips to confirm that the users of the systems have reviewed and understood this Field Safety Notice.

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5. Actions planned by Philips IGT-s Hemo to correct the problem.
This problem will be resolved by a software update (reference to FCO72200513). You will be contacted by your local Philips representative to schedule the software update of your system.

This letter has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this matter.

Sincerely,

[redacted]

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URGENT Field Safety Notice Response Form

Reference: 2022-IGT-BST-003
IGT-S FCO72200513
Philips Hemodynamic Application (PHA) on software Versions R1.2 and R1.3 with an activated continuous patient monitoring license.

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 Letter, understanding of the issue, and required actions to be taken.

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- If the Internal Blood Pressure (IBP) channel is active when connecting the Philips InvelliVue X3 to the Philips Hemodynamic Application:
  - Ensure that the channel continues to be switched on after the connection.
  - Ensure that the channel that was active before the connection is the same one active after the connection.
- Ensure the clinical staff is always present during the patients stay and that the patient is not left unattended while being monitored.
- If patients with an arterial line can be expected in the Cath Lab, ensure that in all layouts the corresponding Internal Blood Pressure IBP channel is switched on and is labeled as an arterial pressure.
- Circulate this Urgent Field Safety Notice Letter to all users so that they are aware of the product issue.
- To acknowledge receipt of this notification, please complete, sign, and return the Customer Reply Form within 30 days upon receipt of this notice.

We acknowledge receipt and understanding of the accompanying Urgent Field Safety Notice Letter and confirm that the information from this Letter has been properly distributed to all users that handle the Philips Hemodynamic Application (PHA) on software Versions R1.2 and R1.3 with an activated continuous patient monitoring license.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

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Email Address: _____

Date (DD / MMM / YYYY): _____

It is important that your organization acknowledges receipt of this letter. Your organization's reply is the evidence required to monitor the progress of this Field Safety Corrective Action.

<provide instructions here for the customer regarding returning the form to Philips, e.g. fax #, email address. For example, "Please fax this completed form to Philips at (xxx)xxx-xxxx>