PHILIPS

URGENT Field Safety Notice

Philips **Interventional Hemodynamic Application** R1.2.X, R1.3.0 and R1.3.1
Potential incorrect functional measurement

30-APR-2024

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 issue with Philips Interventional Hemodynamic Application R1.2.X, R1.3.0 and R1.3.1, where synchronization of pressure wave data received from two devices – the IntelliVue X3 and Functional Measurement Patient Interface Module (FM-PIM) – may not be correct. There might be a delay of the FM-PIM data with respect to the IntelliVue X3 data which is not constant in time. When this occurs, the calculation of measurements will be affected, specifically the iFR (instantaneous wave-free ratio) and FFR (fractional flow reserve) values. This URGENT Field Safety Notice is intended to inform you about:

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

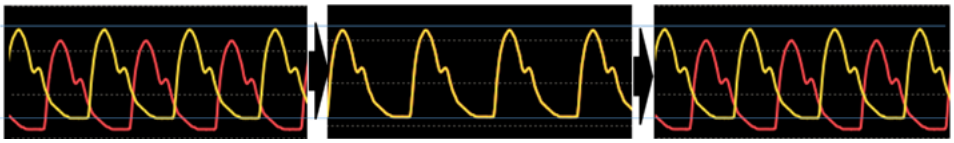
Philips Hemodynamic Application provides the functionality of hemodynamic calculations, including physiological measurements (iFR and FFR). For an iFR/FFR measurement, the Philips Hemodynamic Application has to synchronize pressure wave data received from two devices, the IntelliVue X3 and the FM-PIM, in order to compare those data.

The aorta blood pressure (Pa or AO) is measured via a catheter connected to the IntelliVue X3 patient monitor, while the internal blood pressure (Pd) is measured with a pressure wire connected to a separate transducer (FM-PIM). Both the IntelliVue X3 and FM-PIM send the pressure measurements to the Philips Hemodynamic Application.

Before an iFR/FFR measurement is performed, the waveforms of the Pa and Pd pressures need to be normalized (see Section 6.9 of the Instruction for Use). After normalization, the waveforms of the Pa and Pd pressures as acquired by the IntelliVue X3 and FM-PIM should overlap, meaning that the diastolic and systolic points ('waveform peaks and valleys') should be at the same time position and the average pressures of both measurements should be identical.

Philips has become aware that this synchronization may not be correct, which causes the wave data from one device to be delayed with respect to the wave data from the other device. This time shift can occur in two different forms, being:

- A delay of the Pd wave with respect to the Pa wave that is increasing over time ('drift'). The drift decreases in time towards zero eventually leading to a constant shift between the Pa wave and Pd wave (see Figure 1 below).



Starting point:
Pa (AO) wave (red) and Pd wave (yellow) before normalization.

- *The Pd wave shows a difference in the mean pressure (vertical position),*
- *The peaks of the Pd wave are late with respect to the Pa (AO) wave*

Expected behavior:
Normalization applies an offset in the pressure as well as in the time direction to make the waves overlap.

- *The Pd wave (yellow) overlaps the Pa (AO) wave*

The issue:
Temporal drift results in shifted curves.

Figure 1 – Pa (AO) wave (red) and Pd wave (yellow) normalization issue

- A constant delay of the Pd wave with respect to the Pa wave of exactly one (or more) cardiac cycles without any drift.

Note that the issue is in certain cases corrected by the system. If the cumulative delay of the Pd wave with respect to the Pa wave becomes larger than two seconds, the Philips Hemodynamic Application will reset all calculations. From that moment on, the initial error is not present anymore and the drift will not occur anymore.

2. Hazard/harm associated with the issue

A delay of the Pd wave with respect to the Pa wave can result in incorrect functional measurements, which may lead to misdiagnosis (under or over treatment due to the drift going unnoticed).

In extreme cases, misdiagnosis might lead to moderate illness or injury requiring professional medical intervention or hospitalization (initial or prolonged) to preclude temporary impairment.

To date, Philips has not received any reports of patient or user harm due to this issue.

3. Affected products and how to identify them

The software version of Philips Hemodynamic Application can be identified in the "About" box of the Philips Hemodynamic Application. The "About" box is shown when the application is opened, and the release version is displayed at the upper left section of the screen as shown in Figure 2 below.

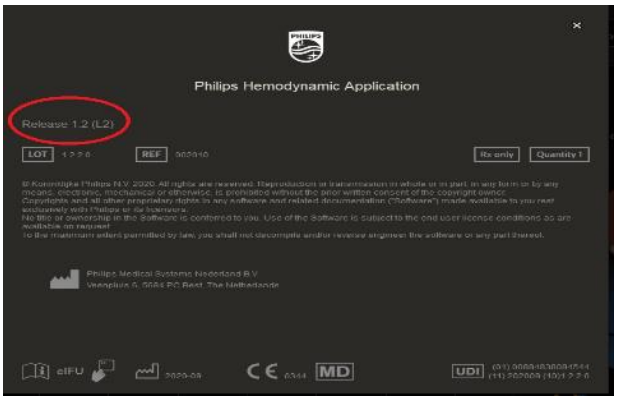


Figure 2 – "About" box indicating release version

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

- Keep this Urgent Field Safety Notice with the documentation of the system until Philips implements the correction in your system. Ensure the letter is in a place likely to be seen/viewed.
- To prevent the issue from happening, follow the below steps when connecting the pressure wire to the FM-PIM. Also refer to FM Patient Interface Module (FM-PIM) to Option Manual, Chapters 3 and 5. (Note: there are 2 types of wires that can be used with FM-PIM – OmniWire or Verrata wire):
  - Step 1: Connect the cable of the OmniWire or Verrata wire to the FM-PIM. The Philips Interventional Hemodynamic System will start "auto-zeroing" the pressure wire and the PHA display in the exam room during this process will automatically show the message "Auto-zeroing the FM-PIM pressure wire".
  - Step 2: Disconnect the cable from the FM-PIM and wait for the Philips Interventional Hemodynamic System to show the message "Connect the plug of the FM-PIM" on the display in the exam room.
  - Step 3: Reconnect the cable again with the FM-PIM. Use the cable connector indicated with the yellow boxes in the Figure 3 below.

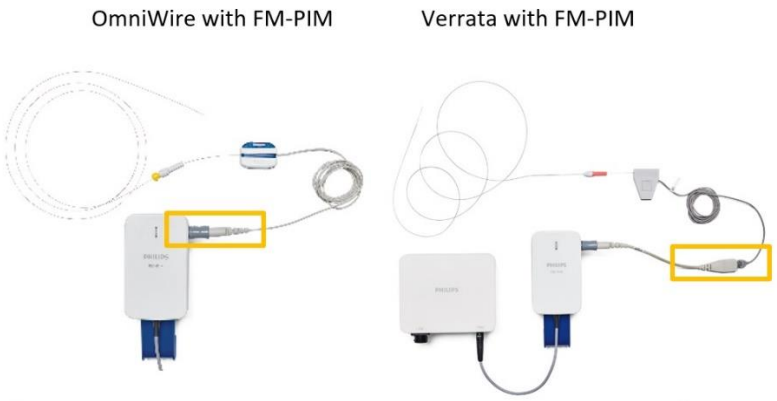


Figure 3 – Connection points of two types of cables (OmniWire and Verrata) to the FM-PIM to be used

  - Step 4: Allow the wire to "auto-zero" again (see Step 1) and continue with the iFR or FFR measurement.

- In case the steps described above are not executed and/or the described issue is observed, perform the normalization procedure in accordance with Section 6.9 of the Instruction for Use

for the Philips Hemodynamic Application: in order to normalize the Pa and Pd pressures, click Normalize: 
More details about normalization can be found in Section 6.9 of the Instruction for Use.

- Circulate this letter to all users of the system so that they are aware of the issue.
- Please complete and return the attached response form (on page 5) 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.

5. Actions planned by Philips IGT-S to correct the problem

Philips will install a software update to correct this issue. A Philips representative will contact you to schedule an onsite visit to perform the upgrade (reference FCO72200542).

If you need any further information or support concerning this issue, please contact your local Philips representative.

This notice has been reported to the appropriate Regulatory Agencies.

Please be assured that maintaining a high level of safety and quality is our highest priority. Philips regrets any inconvenience caused by this issue.

Sincerely,

Marjan Vos
Head of Quality – IGT Systems

PHILIPS

URGENT Field Safety Notice Response Form

Reference: Philips Hemodynamic Application R1.2.X, R1.3.0 and R1.3.1, Potential incorrect functional measurement, Philips C&R reference number 2023-IGT-BST-009.

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

Customer/Consignee/Facility Name: _____

Street Address: _____

City/State/ZIP/Country: _____

Customer Actions:

- Keep this Urgent Field Safety Notice with the documentation of the system until Philips implements the correction in your system. Ensure the letter is in a place likely to be seen/viewed.
- To prevent the issue, follow the steps described in Section 4 "Actions that should be taken by the customer / user in order to prevent risks for patients or users" of the Field Safety Notice (page3).
- Circulate this Notice to all users of the system so that they are aware of the issue.

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 Philips Interventional Hemodynamic Application.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

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 Urgent Field Safety Corrective Action.