PHILIPS

URGENT Field Safety Notice

Philips Interventional Hemodynamic System – IntelliVue X3, software version P.0, Invasive Blood Pressure Calibration Setting for Reusable Transducers

DDMMMYY,

Dear Distributor,

Philips is initiating an URGENT Field Safety Notice because we became aware of a potential safety issue related to disabled Invasive Blood Pressure calibration setting for reusable transducers with IntelliVue X3, software version P.0, as included in the Philips Interventional Hemodynamic System.

It is imperative that all customers with affected products receive the attached URGENT Field Safety Notice that informs about:

- The problem and under what circumstances it can occur
- Affected products and how to identify them
- The actions that the customer/user should take to prevent risk for patients
- The actions taken by Philips in order to prevent risks for patients or users

Philips is requesting customers to return a Response Form to acknowledge receipt and understanding of the URGENT Field Safety Notice and confirm that the information from this Letter has been properly distributed to all users that handle the affected product.

Together with this letter we are providing a list of affected products that Philips has sold to your organization. As distributor of the affected products, we kindly request that you:

- Add in the Response Form attached your contact information.
- Send the attached URGENT Field Safety Notice to each customer to whom you have distributed any affected product as soon as possible and no later than three days, together with the Reply Card.
- Perform a good faith effort to get the Reply Form by following up with the customer with a minimum of three attempts, and if possible, using multiple contact methods. Inform Philips about the responses received.

Please be assured that maintaining a high level of safety and quality is our highest priority. 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>*

Sincerely,

Deborah Currlin
Head of Quality

PHILIPS

URGENT Field Safety Notice

Philips Interventional Hemodynamic System – IntelliVue X3, Software Version P.0, Invasive Blood Pressure Calibration Setting for Reusable Transducers

<Date of letter deployment,>
<date format: DD-MMM-YYYY, e.g. 02-JAN-2021>

<To: Name / Title / Customer Name
Street Address
City, State, Zip Code
<modify title block format as needed>

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,

NOTE: If using disposable transducers, **no action is needed** as changing calibration factor and performing calibration is not required.

Philips has become aware of a potential safety issue related to disabled Invasive Blood Pressure calibration setting for reusable transducers with IntelliVue X3, software version P.0, as included in the Philips Interventional Hemodynamic System.
This notification is intended to inform you about:

1. The problem and under what circumstances it can occur

The Philips IntelliVue X3 Multi-Measurement Module acquires multiple physiological patient signals, displays measurement values, waves, trends, generates physiological and technical alarms, provides data recording, and supports patient data management. The device offers a monitoring solution optimized for the surgical, cardiac, medical, and neonatal care environments. IntelliVue X3 devices can be located in the patient's vicinity at the bedside or can be used in mobile applications during patient transport inside hospitals.

The IntelliVue Multi-Measurement Module X3 with Option C99 has a "hemo" specific profile, which is used when IntelliVue X3 is connected to Philips Hemodynamic Application. One of the settings in "hemo" profile is the calibration setting of Invasive Blood Pressure.
This calibration setting has been inadvertently switched to "OFF" in the "hemo" profile with software version P.0, preventing the user of the Philips Interventional Hemodynamic Application to be able to change the calibration factor of the reusable Invasive Blood Pressure transducer, or to initiate a calibration procedure.

PHILIPS

2. Hazard/harm associated with the issue

If this situation occurs, there is the potential that this may lead to under- or over-treatment due to the user expecting a calibrated Invasive Blood Pressure value, while the value is not calibrated. Although unlikely, this could potentially result in patient harm.

3. Affected products and how to identify them

Product Name	Product Number
IntelliVue Multi-Measurement Module X3 (only affects devices shipped with software version P.01.01 or P.01.02, and ordered with Option C99)	867030

The software version and installed option, can be identified during bootup of the IntelliVue X3 or while the X3 is in standby mode:

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

If you use reusable transducers, the maximum measurement error can be ±10% without calibration. Please take this into consideration when using Invasive Blood Pressure measurement for treatment options or make use of disposable transducers.

Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.

5. Actions planned by Philips to correct the problem

A Philips representative will contact you to schedule a visit from a Philips Field Service Engineer who will update the configuration profile on your IntelliVue X3 to correct this issue.

If you need any further information, please contact your local Philips representative: *<Philips representative contact details to be completed by the Market/Business>*

Philips regrets any inconvenience caused by this problem.

Sincerely,

Deborah Currlin,
Head of Quality

PHILIPS

URGENT Field Safety Notice Response Form

Reference: CR # 2023-CC-HPM-045, Philips Interventional Hemodynamic System – IntelliVue X3, software version P.0 Invasive Blood Pressure Calibration Setting for Reusable Transducers

Instructions: Please complete and return this form to Philips Healthcare promptly upon receipt and no later than 30 days from receipt by email: **recall.response@philips.com**. 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:

If you use reusable transducers, the maximum measurement error can be ±10% without calibration. Please take this into consideration when using Invasive Blood Pressure measurement for treatment options or make use of disposable transducers.

Pass this notice to all those who need to be aware within your organization or to any organization where affected devices have been potentially transferred.

We acknowledge receipt and understanding of the accompanying Product Notice and confirm that the information from this Notification has been properly distributed to all users that handle affected devices.

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____