

URGENT Field Safety Notice

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

DDMMYY,

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 Currin
Head of Quality