PHILIPS

URGENT Field Safety Notice

EarlyVue VS30 Vital Signs Monitor and EarlyVue VS30 Vitals monitor
Missing Calibration Alarm

21-Feb-2023,

Dear Distributor,

Philips is initiating a URGENT Field Safety Notice due to a problem identified in the Philips EarlyVue VS30 Vital Signs Monitor with Microstream™ sidestream etCO2 method to measure carbon dioxide (CO2) option, that could pose a risk for patients.

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
- The actions that the customer/user should take to prevent risk for patients
- The actions planned by Philips to correct the problem

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,

Avani Pandya
Head of Quality
Hospital Patient Monitoring
Philips Healthcare

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