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URGENT Field Safety Notice

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

21-Feb-2023,

To: Name / Title / Customer Name
Street Address
City, State, Zip Code

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 EarlyVue VS30 Vital Signs Monitor with Microstream™ sidestream etCO2 method to measure carbon dioxide (CO2) option where the user is not notified about the required first year calibration technical alarm.

VS30 is intended to measure, display, alarm and, record physiological information of adult, pediatric and neonatal patients in hospitals and in out-of-hospital patient care settings in which care is administered by a healthcare professional (such as clinics, outpatient surgery facilities, long-term care facilities, and physician offices).

This URGENT Field Safety Notice is intended to inform you about:

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

After initial calibration in the factory, the CO_2 OEM module used in VS30 requires calibration based on either the number of operating hours used or the number of calendar days that have passed. The calibration should be performed at the one-year mark after factory calibration or after 1,200 use hours, whichever comes first. The problem identified is that the VS30 issues a CO_2 calibration required alarm per operating hours used only, instead of issuing an alarm either based on operating hours used or calendar days passed, whichever comes first. There have been no complaints received regarding this issue. The sequence of events in which this potential safety risk can occur are as follows:

1. VS30's CO_2 module, when calibrated upon production, will accurately monitor the CO_2 measurement for up to one year or 1200 hours of use, whichever comes first.

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2. One year after the factory calibration in production, the VS30 fails to trigger a calibration required alarm. Depending on the hours of use, you may not receive a calibration alarm within the first two years of use.
3. The lack of timely calibration could result in inaccurate CO_2 measurements.

Potential Outcome:

If the CO_2 module calibration is not performed when required, there is the possibility of an inaccurate CO_2 measurement which may lead to a failure to recognize a change in patient condition.This may present a potential safety risk to the patient.

Hazard/harm associated with lack of calibration alarm after 1 year of use

The hazard associated with the lack of calibration of the alarm of the CO_2 module is the potential for delayed or incorrect treatment. The CO_2 module requires the first calibration at one year or after 1,200 use hours, which ever comes first. If this calibration is not performed when required this can result in inaccurate CO_2 measurements. Inaccurate CO2 measures may results in the Health Care Provider (HCP) failing to recognize a change in the patient's condition. The risk of harm is remote and there were no observed complaints for this issue.

2. Affected products and how to identify them

Product Number	Product Name	Software Version	Device Identifier
863359	EarlyVue VS30 Vital Signs Monitor	A.00.02 and A.00.01	(01)00884838075900
863380	EarlyVue VS30 Vitals monitor	A.00.02 and A.00.01	(01)00884838091412

To locate the Software Version of the device, refer to Images 1 through 3 below:

Image 1 - Select the Settings Icon

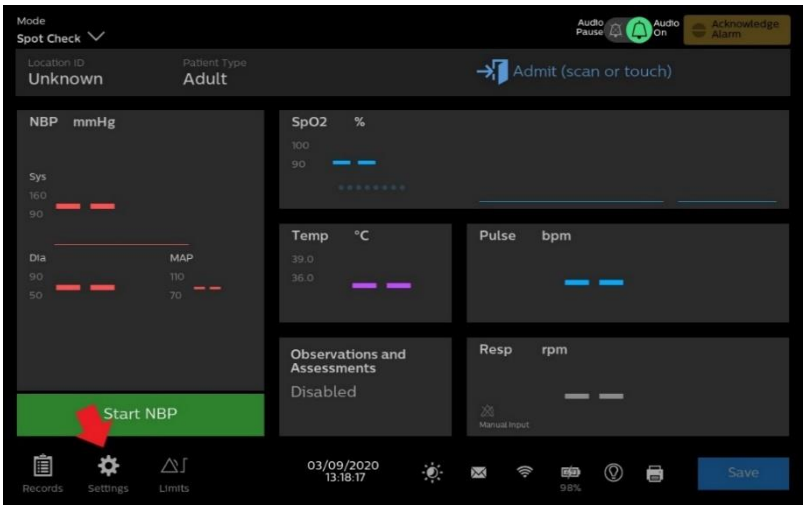


Image 2 - Select Device Info Tab

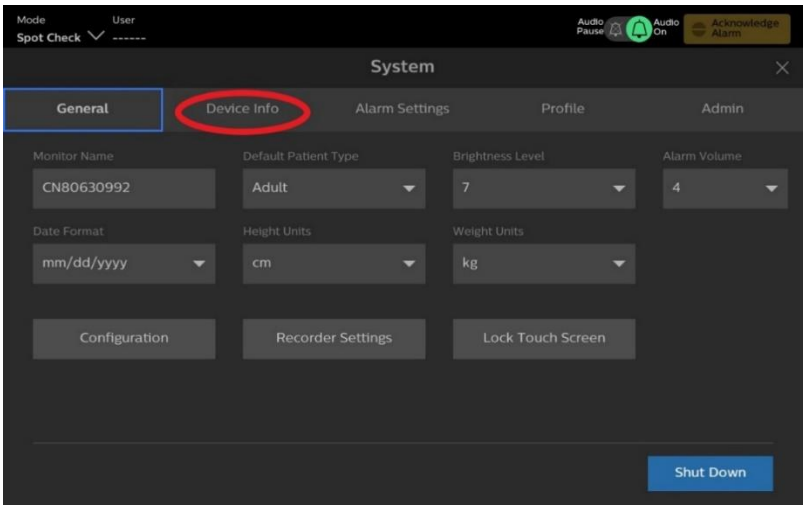
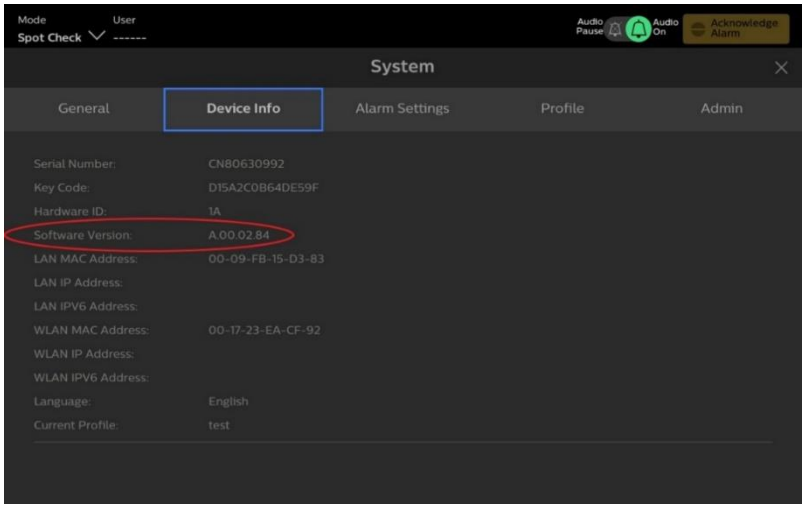


Image 3 - Software Version is display in the Device Info Tab

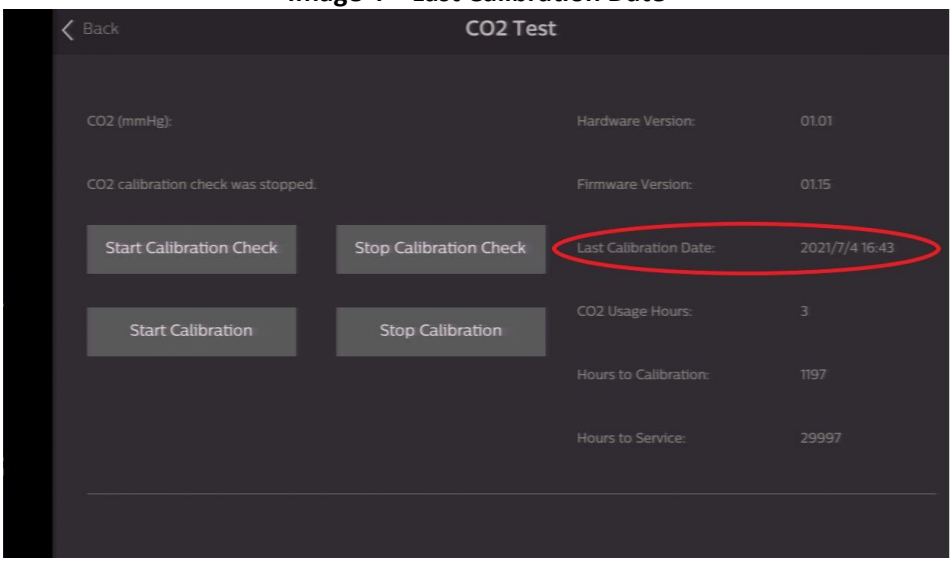


All software versions equal to or lower than A.00.02.84 must be updated.

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

1. Identify the last calibration date of the device and review your hospital maintenance plan. Determine if your device has E01 End Tidal CO2 and has not been calibrated within one year of the production calibration. If needed adjust the maintenance plan and incorporate the calibration of your affected device.
    a. The device should not be used until the calibration or maintenance plan has been reviewed.
    b. The calibration date can be accessed via the following steps on the device: Settings > Admin > Diagnostics > Page 2 of Diagnostics > Maintenance > 129 > CO2 Test. The image below shows the example of the screen to see the last calibration date of your device:

Image 4 – Last Calibration Date



2. Review this URGENT Field Safety Notice in its entirety and pass this notice to all those who need to be aware within your organization or to any organizations where the potentially affected devices have been transferred. (If appropriate).
3. Complete and return attached form to Philips promptly to confirm receipt of the URGENT Field Safety Notice Letter, understanding of the issue, and required actions to be taken.

4. Actions planned by Philips Hospital Patient Monitoring to correct the problem

A Philips representative will reach out to you to arrange a software upgrade to your monitor(s). Philips will start to schedule the upgrade upon formal release of the field action, which is planned for a six month implementation timeline.

If you experience difficulties in carrying out the instructions in this communication, please contact your local Ireland Philips Customer Care Service Centre on +353 1 7640229.

This notice has been reported to the appropriate Regulatory Agencies.

Philips regrets any inconvenience caused by this problem.

Sincerely,

Avani Pandya
Head of Quality
Hospital Patient Monitoring
Philips Healthcare

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URGENT Field Safety Notice Response Form

Reference: EarlyVue VS30 Vital Signs Monitor and EarlyVue VS30 Vitals monitor Missing Calibration Alarm, 2022-CC-HPM-056/FCO86000283A

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:

- Review your hospital maintenance plan and determine if your device has not been calibrated within one year of installation. If needed adjust the maintenance plan and incorporate the calibration of your affected device.
- Distribution of this notice to all those who need to be aware within your organization or to any organizations where the potentially affected devices have been transferred. (If appropriate).

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 EarlyVue VS30 Vital Signs Monitor and EarlyVue VS30 Vitals monitor(s).

Name of person completing this form:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD / MMM / YYYY): _____

Please return the completed and signed reply form to **safetynoticeuki@philips.com**