

To our customers of
Vista 120 and Central Monitoring Station (CMS) using CMS SW 1.64

August 2021

Important Safety Notice

Software Patch for Vista CMS required

Only the following products are affected:

Vista 120 patient monitor (Non-Nellcor version) with SW 3.14
in combination with
Vista Central Monitoring Station CMS with SW 1.64

Dear Sir or Madam,

During the course of our global market surveillance activities, we have become aware of a case in which an exceeding of SpO2 alarm thresholds triggered an alarm at the bedside monitor Vista 120 as expected but did not lead to visual or audible alarming at the Central Monitoring Station (CMS). Numeric values were displayed correctly but a delayed recognition of critical patient situations cannot be excluded in case of recurrence and thus, belated interventions may be the consequence.

Actions to be taken:

Dräger would like to emphasize the importance of usual clinical practice to use more than one vital parameter for monitoring of patients and not to solely rely on one single source of measurement. The exceeding of thresholds for other vital parameter like heart rate or blood pressure will generate respective alarms at the CMS.

Please ensure that all users of the above-mentioned products and other persons within your organization are made aware of this Important Safety Notice. If you have provided the products to third parties, please forward a copy of this information.

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Seite 2 / 2

An improved SW for the CMS has been developed, tested and released already. All CMS units in the field that have been shipped with SW 1.64 installed as well as those units that have been updated/ upgraded to SW 1.64 later in the facilities will be subject to an update with the improved SW version.

Please keep this information at least until the measure has been completed.

The responsible authorities have been notified of this action.

Identification of the affected medical devices:

According to our records, you have received systems manufactured by Drägerwerk AG & Co. KGaA (European Single Registration Number: G10105780037 Rev. 01) that may be affected by this issue.

A combination of CMS with SW 1.64 and patient monitors having SW 3.13 or older installed is not affected; central monitoring stations with other SW versions than 1.64 will also not exhibit the issue. If Nellcor SpO2 evaluation technology is embedded in a Vista 120 patient monitor, SpO2 alarm generation at the CMS works as expected.

The installed SW version for CMS can be derived from the menu point System Setup > User Maintain > About. The SW version for the monitor can be derived from User Maintain > Common Functions > About – please consult the IfU for getting access.

Contact:

If you have any questions, please do not hesitate to contact your Dräger representative.

We apologize for any inconvenience caused by this measure.

We thank you for your support.

With kind regards

Steffen Protsch

President

Business Unit Patient Monitoring

Drägerwerk AG & Co. KGaA