

**To customers and users of the
Dräger ventilators Evita V800, Evita V600,
Babylog VN800 and Babylog VN600**

May 2021

Amendment to Important Safety Notice!

Restarts, incorrect alarms about FiO₂ concentration, suspension of SmartCare/PS (SC/PS)

Affected products: Evita V800, Evita V600, Babylog VN800 and Babylog VN600 with SW1.05.00 and lower

Dear Madam/Sir,

In April 2021 we informed you about three software errors in our ventilators Evita V800, Evita V600, Babylog VN800 and Babylog VN600 with an important safety notice.

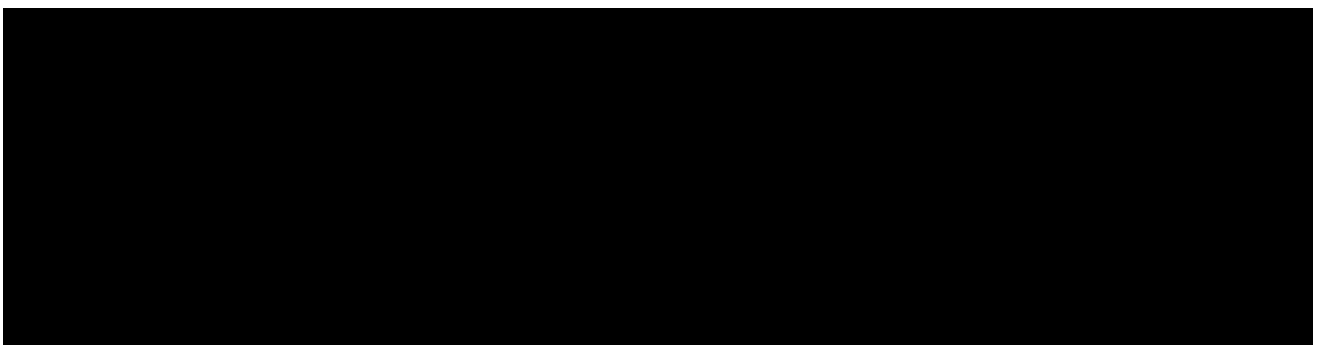
In that Safety Notice we reported that the problems happened only occasionally. We had not, however, provided any further information about the number of such events. We underlined that the devices can still be used while paying special attention to the described situations.

With this letter, we would like to share additional information on why according to Draeger's assessment the devices are safe for use until the software update to resolve the three software problems is available. We further would like to provide an update on our investigation and the timeline until the availability of the updated software.

Restart of the Ventilation Unit

Until the safety notice was published, 13 complaints for Evita V800 and Evita V600 had been reported to Dräger in relation to the restart problem (which is a rate* of 4 within one year of operation of 1000 ventilators). Meanwhile, we were able to confirm a correlation between the use of etCO₂ measurement and the observed restarts.

Babylog VN800 and Babylog VN600 ventilators operated in neonatal patient category are not affected as no CO₂ measurement can be used. In all Evita V800, Evita V600, Babylog VN800 and Babylog VN600 ventilators, restarts caused by the identified root cause cannot happen without activation of the CO₂ monitoring.



Incorrect FiO2 High and FiO2 Low alarms

Until the safety notice was published, 9 complaints had been reported to Dräger in relation to the incorrect "FiO2 high" and "FiO2 low" alarms (which is a rate* of 3 within one year of operation of 1000 ventilators). The occurrence is influenced by changes of FiO2 setting during Standby prior to setting the device to operation. The described behaviour can only happen directly after the start of ventilation and is therefore always visible to the user. The set FiO2 concentrations are properly applied and the monitored and displayed FiO2 value is correctly displayed in this situation.

SmartCare/PS (SC/PS) weaning (only relevant to Evita V800 and Evita V600)

Until the safety notice was published, 4 complaints had been reported to Dräger in relation to the suspended weaning in SmartCare/PS (which is a rate* of 5 within one year of operation of 1000 ventilators). In this situation all ventilation functions are maintained, and related alarms are given correctly. Without the activation of SmartCare/PS, the described problem cannot occur. Babylog VN800 and Babylog VN600 ventilators are not affected as SmartCare/PS functionality is not available with these devices.

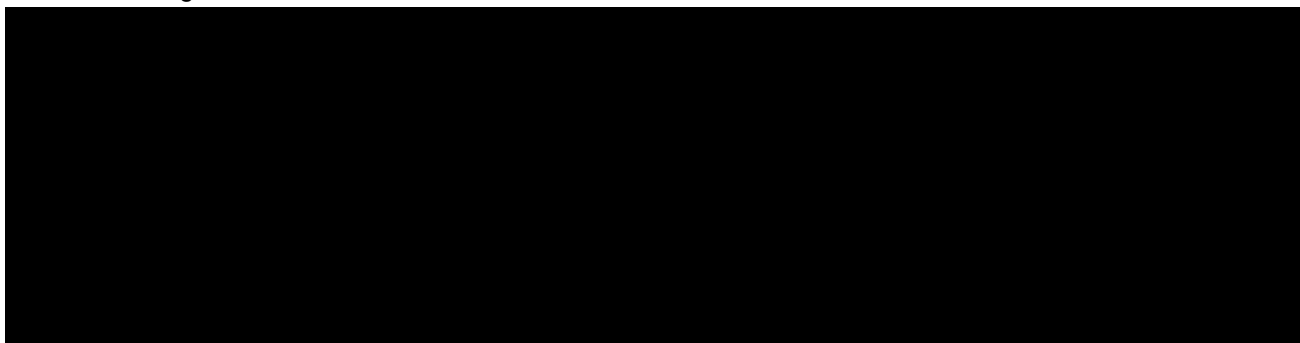
Availability of corrected software version

We were able to identify all three root causes and are currently preparing a software solution. The release is expected to be available in early Q3 of 2021.

Once the software is available, your local Dräger Service representative or our service partner will contact you to arrange a date for the software update to be performed free of charge.

We apologize again for any inconvenience but believe this to be an essential preventive measure to increase patient and user safety.

With kind regards



*: rate calculation is based on number of reported events, installed base of devices and duration of operation, at the time of assessment