

**To customers of the
Dräger ventilators
Infinity Acute Care System - Workstation Critical Care (Evita V500),
Infinity Acute Care System – Workstation Neonatal Care (Babylog VN500)
and Evita V300**

August 2021

Important Safety Notice!

Occasional restarts of the device

Only the following products are affected:

Infinity Acute Care System - Workstation Critical Care (Evita V500) with SW2.60 and lower with installed CO2 measurement option.

Infinity Acute Care System – Workstation Neonatal Care (Babylog VN500) with SW2.60 and lower with installed CO2 measurement option.

Evita V300 with SW2.60 and lower with installed CO2 measurement option.

Dear Madam or Sir,

In the course of our global market surveillance activities, we have become aware of sporadic cases in which the above-mentioned products restarted.

A restart is a designed system recovery function to restore the proper function of the ventilator. In the rare reported cases, however, an error in the data processing of the activated CO2 measurement caused the restart of the ventilation unit. Devices without integrated or with disabled CO2 measurement function are not affected. The behavior can be effectively prevented by not activating the integrated CO2 measurement. If necessary, external CO2 monitoring can be used. If the information from this safety notice is considered, the devices can remain in operation.

As of the date of this letter, 23 complaints for Evita V500 and Evita V300 had been reported worldwide to Dräger in relation to this behavior (which is a rate* of 3 within one year of operation of 1000 ventilators). There were no reports of any adverse impact on the health of the patients in question.

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Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7903 HL
Komplementär: Drägerwerk Verwaltungs AG
Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 7395 HL

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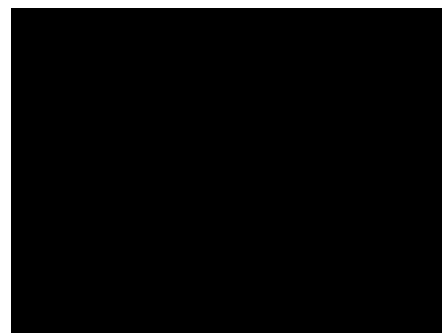
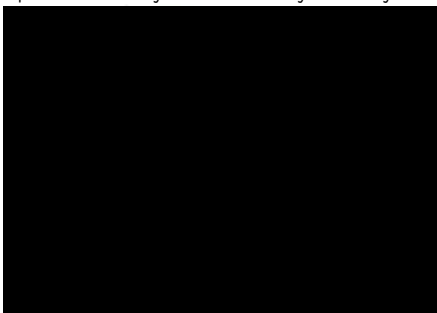
During the restart, the ventilation is temporarily interrupted, and an audible alarm is activated by the auxiliary acoustic alarm system. The breathing system is opened to the ambient air during the restart to potentially allow the patient to breathe spontaneously. Opening the breathing system to ambient causes a loss of ventilation support from the ventilator including PEEP. The ventilation unit is restarted and after approximately 8 seconds automatically resumes ventilation at the identical settings prior to the restart. Once the restart process has been completed, the user is alerted to the fact by the alarm notification "Ventilation unit restarted" visually on the display unit, together with a sequence of audible alarm tones. Thereafter, the audible auxiliary acoustic alarm of the ventilation unit stops. Please refer to the Instructions for Use of the devices for further information about this alarm notification.

The release of a corrected software is expected to be available in Q4 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.

Please ensure that all users of the above-mentioned products and other concerned 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. Please keep this information at least until the corrective measure has been completed.

The responsible authorities have been notified of this action.

We apologize for any inconvenience but believe this to be an essential preventive measure to increase patient safety. We thank you for your support.



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