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

April 2021

## 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**

Dear Madam/Sir,

Within the framework of our global product surveillance activities, cases have come to our attention in which technical errors have occurred in connection with the aforementioned products.
These are three separate and unrelated problems that are attributable to the software used in the above products and may occur occasionally. In none of the reported cases was there any risk to the patient as a result of the errors.

We are writing to you today to provide you with some information about these problems and to tell you about the steps we will be taking next.

### 1. Restart of ventilation unit

Due to an error in the device software (incorrect time-out in the data processing of the microprocessor system), the ventilator (ventilation unit and the display unit) may sporadically restart.

The restart is not an error in itself but in fact restores the proper function of the ventilator. However, ventilation is temporarily interrupted during the restarting process, and an alarm is sounded by the secondary acoustic alarm system (intermittent beeping).

The breathing system is opened to the ambient air during the restart so that the patient is able to breathe spontaneously. Opening the breathing system to ambient causes a loss of PEEP. After approx. 8 seconds, the ventilation unit is restarted and automatically resumes ventilation with the same settings as before.

The restart of the display unit is complete after approx. one minute. Meanwhile, the already resumed ventilation can be seen on the OLED display of the ventilation unit, with

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key parameters such as FiO2 concentration, minute volume and airway pressure being displayed there.

Once the restart is complete, the user is alerted to the fact by the alarm notification “Ventilation unit restarted” on the display unit, together with a sequence of audible alarm tones, and the audible secondary acoustic alarm of the ventilation unit stops. Please refer to the Instructions for Use of the devices for further information about this alarm notification.

## 2. Incorrect *“FiO2 high”* and *“FiO2 low”* alarms

Due to a software error, “*FiO2 high*” and "*FiO2 low*“ alarms may be given simultaneously, or there may be a discrepancy between the FiO2 alarm and the measured oxygen concentration that is displayed.

Also in this error condition, the measured value displayed in the FiO2 parameter field and on the OLED display of the ventilation unit corresponds to the measured and applied oxygen concentration.

The problem can only occur if FiO2 is adjusted when the device is in Standby mode. This could happen for example when the device is to be prepared for another patient and the “New patient” key is tapped.

In this case, the aforementioned alarms may occur under certain circumstances once ventilation has started. It is not possible to determine in advance how long it will take for the problem to be solved and alarms to disappear of their own accord. This will depend among other things on how long the device was operated in Standby. If a genuine deviation from the alarm limit were to occur, no additional alarm could be given due to the ongoing alarm.

If this problem occurs, please check the patient’s condition.

The problem can be avoided by operating the devices for only a short period of time in Standby mode, or by switching them on directly before using them for ventilation. We recommend this until an updated software is made available and installed.

**3. SmartCare/PS (SC/PS) suspends weaning (only relevant to Evita V800, EvitaV600)**

Due to an error in the device software weaning may be suspended and not restored.

The problem is triggered and can be identified as follows:

1. SC/PS indicates correct function with  the symbol
2. If for example a disconnection or a leakage is detected, the patient session is temporarily suspended as specified.
3. A suspended patient session is indicated by  the symbol.
4. Due to a software error, the system does not correctly identify that the cause has been resolved, e.g. reconnection or leakage no longer present.
5. As a result, no further automatic adjustment of the pressure support is made in this case.
   The condition is permanently indicated  by the symbol, though no alarm

   is given to indicate the continuous interruption or the suspension of the SC/PS application.

The problem can be caused for example by the consecutive occurrence of different reasons for the suspension of a patient session (see Instructions for Use SC/PS Section 7.1 *Alarms and related actions*) or by the repeated occurrence of one reason.

If an SC/PS patient session is permanently suspended, it is possible that not matching messages such as “SC: SBT successful” or “SC: Reduce PEEP if possible” will continue to be displayed. In cases in which these messages are displayed, please check whether possible next steps related to these messages are clinically indicated or whether the SC/PS patient session is permanently suspended.

If the SC/PS patient session is permanently suspended no further automatic adjustment of the pressure support is made. The patient will continue to receive the most recently active form of pressure support. Changes to the pressure support or to other settings can still be made manually. All ventilation functions are maintained, and related alarms are given correctly.  Potentially content relevant to SC/PS will be displayed on the graphical user interface.

In order to restore the proper function of SC/PS, the ventilator has to be disconnected from the patient, shut down completely and then restarted. You can continue to use the function, but please observe the symbol described above.

We are currently in the process of investigating the aforementioned errors and preparing a software solution. This is expected to be available in the second half of 2021. Your local Dräger Service representative or our service partner will contact you to arrange a date for your software update to be performed free of charge.

In the meantime, you can still use the devices by paying special attention to the above described situations.

Please notify all affected users in your facility about the problems. The competent authorities will also be informed about this action.

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

With kind regards

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