Supplement to instructions for use

– Infinity Acute Care System Workstation Critical Care and Neonatal Care
– Infinity Acute Care System Evita Infinity V500
– Infinity Acute Care System Babylog VN500
– Evita V300

WARNING
To properly use this medical device, read and comply with the instructions for use and this supplement.
Supplement to instructions for use

This supplement applies only to the listed medical devices and updates the information of the respective instructions for use. Each chapter indicates the medical devices to which the information applies.

<table>
<thead>
<tr>
<th>Medical device</th>
<th>Part number of instructions for use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infinity Acute Care System Workstation Critical Care and Neonatal Care</td>
<td>9052077</td>
</tr>
<tr>
<td>Infinity Acute Care System Evita Infinity V500</td>
<td>9052161</td>
</tr>
<tr>
<td>Infinity Acute Care System Babylog VN500</td>
<td>9038982</td>
</tr>
<tr>
<td>Evita V300</td>
<td>9052995</td>
</tr>
</tbody>
</table>

Keep this supplement with the current instructions for use of the respective medical device.

Where changes to screen content affect all of the medical devices, the screen is displayed which shows the maximum number of functions.

Devices delivered as of July 22, 2014 meet the requirements of the 3rd edition of the IEC 60601-1 standard.

Typographical conventions

Applies to:
– Workstation Critical Care and Neonatal Care
– Evita Infinity V500
– Babylog VN500
– Evita V300

Use of terms

Dräger uses the term "Accessory" not only for accessories in the sense of IEC 60601-1, but also for consumable parts, removable parts, and attached parts.

The designation "Infinity Acute Care System" is omitted hereafter in this document.
For your safety and that of your patients

General safety information

Applies to:
- Workstation Critical Care and Neonatal Care
- Evita Infinity V500
- Babylog VN500
- Evita V300

Device combinations

This device can be operated in combination with other Dräger devices or with devices from other manufacturers. Observe the accompanying documents of the individual devices.

If a device combination is not approved by Dräger, the safety and the functional state of the individual devices can be compromised. The operating organization must ensure that the device combination complies with the applicable editions of the relevant standards for medical devices.

Device combinations approved by Dräger meet the requirements of the following standards:
- IEC 60601-1, 3rd edition (general requirements for safety, device combinations, software-controlled functions)
  - IEC 60601-1-2 (electromagnetic compatibility)
  - IEC 60601-1-8 (alarm systems)

Or:
- IEC 60601-1, 2nd edition (general requirements for safety)
  - IEC 60601-1-1 (device combinations)
  - IEC 60601-1-2 (electromagnetic compatibility)
  - IEC 60601-1-4 (software-controlled functions)
  - IEC 60601-1-8 (alarm systems)

Training

Training for users is available via the Dräger organization responsible (see www.draeger.com).
For your safety and that of your patients

Product-specific safety information

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

WARNING
Risk of malfunction
Unauthorized modifications to the medical device lead to malfunctions.
This medical device must not be modified unless authorized by the manufacturer.

WARNING
Risk of fire
The use of unapproved O2 pressure reducers can lead to excess pressure which can cause a fire.
When supplying the ventilator with oxygen from a compressed gas cylinder, only use pressure reducers compliant with ISO 10524. Slowly open the pressure reducer manually. Do not use tools.

WARNING
Risk of unnoticed change in inspiratory O2 concentration
If an additional flow is delivered by an external flow source, the actual O2 concentration delivered may deviate from the displayed values.
Use additional monitoring, e.g., external SpO2 monitoring, if necessary.

WARNING
Risk of patient injury
If leakages are present, e.g., with non-invasive ventilation, the actual tidal volume may deviate from the measured values for VTe and VTi.
Activate leakage compensation and monitor the measured value for VT. Minimize or remedy all leakages.

CAUTION
Risk of malfunction
The touch screen has a sensitive surface. Damage to the surface may cause the touch-sensitive controls not to work properly.
Do not operate the screen with sharp objects.

CAUTION
Risk of patient injury
An additional flow delivered by an external flow source can affect the measured values for airway pressure and flow.
Application

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Environment of use

Do not operate the device with helium or helium mixtures.
Overview

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

Range of functions

Connecting accessories
Accessories can be attached to the following holders:
- Universal holder with standard rail (G93140)
- Humidifier holder, can be swiveled (G93111)
- Humidifier holder, side rail (8416325)

Observe the permitted maximum distance to the trolley and the permitted maximum load, see "Maximum loads of holders" on page 8.

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>BTPS</td>
<td>Body Temperature Pressure Saturated, measured values based on the condition of the patient's lungs, body temperature 37 °C (98.6 °F), water vapor-saturated gas, ambient pressure and airway pressure</td>
</tr>
<tr>
<td>Vds</td>
<td>Serial dead space, volume up to CO2 cuvette</td>
</tr>
<tr>
<td>Symbol</td>
<td>Explanation</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td><img src="image1.png" alt="Symbol" /></td>
<td>Attention!</td>
</tr>
<tr>
<td><img src="image2.png" alt="Symbol" /></td>
<td>Warning! Strictly follow these instructions for use. Label with notice: “Transport within the hospital”</td>
</tr>
<tr>
<td><img src="image3.png" alt="Symbol" /> nom. 58 kg (128 lbs) max. 133 kg (293 lbs)</td>
<td>Nominal weight and maximum weight (for information, see chapter &quot;Technical data&quot;)</td>
</tr>
<tr>
<td><img src="image4.png" alt="Symbol" /></td>
<td>Temperature limitation during storage</td>
</tr>
<tr>
<td><img src="image5.png" alt="Symbol" /></td>
<td>Ambient pressure</td>
</tr>
<tr>
<td><img src="image6.png" alt="Symbol" /></td>
<td>Relative humidity</td>
</tr>
<tr>
<td><img src="image7.png" alt="Symbol" /></td>
<td>Use by</td>
</tr>
<tr>
<td><img src="image8.png" alt="Symbol" /></td>
<td>Keep dry</td>
</tr>
</tbody>
</table>
Assembly and preparation

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

Safety information

**WARNING**
Risk of tipping over
Do not tilt the device by more than 5°.

Prepare trolley 2 – 90 cm

Securing accessories to the standard rail

**Maximum loads of holders**

The following information applies to the holders:

<table>
<thead>
<tr>
<th>Holder</th>
<th>Position of the holder</th>
<th>Maximum load</th>
<th>Possible accessories</th>
<th>Maximum distance to side rail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal holder with standard rail (G93140)</td>
<td>On the front of the trolley</td>
<td>10 kg (22 lbs)</td>
<td>Breathing gas humidifier, medication nebulizer</td>
<td>–</td>
</tr>
<tr>
<td>Humidifier holder, can be swiveled (G93111)</td>
<td>On the side of the trolley</td>
<td>5 kg (11 lbs)</td>
<td>Breathing gas humidifier</td>
<td>–</td>
</tr>
<tr>
<td>Humidifier holder, side rail (8416325)</td>
<td>On the side rails of the ventilation unit&lt;sup&gt;1)&lt;/sup&gt;</td>
<td>5 kg&lt;sup&gt;2)&lt;/sup&gt; (11 lbs)</td>
<td>Breathing gas humidifier</td>
<td>10 cm (3.9 in)</td>
</tr>
<tr>
<td>IACS hinged arm (MP00690)</td>
<td>On the side rails of the ventilation unit&lt;sup&gt;1)&lt;/sup&gt;</td>
<td>1 kg (2.2 lbs)</td>
<td>Breathing hoses</td>
<td>100 cm (39.4 in)</td>
</tr>
</tbody>
</table>

<sup>1)</sup> Maximum load on the side rails of the ventilation unit: 5 kg (11 lbs) per side rail

<sup>2)</sup> If a hinged arm is attached to the side rails of the ventilation unit in addition to the humidifier holder (8416325), the maximum load of 5 kg (11 lbs) per side rail must be observed. The humidifier holder can then only support 4 kg (8.8 lbs).
Preparing the Medical Cockpit

Using the MEDIBUS or the MEDIBUS.X protocol

**WARNING**
Risk of patient injury
All data transferred via the MEDIBUS interface are for information only and must not be used as the sole basis for diagnostic or therapeutic decisions. The MEDIBUS interface is not intended for use with a distributed alarm system according to IEC 60601-1-8:2012.

Preparing the ventilation unit

Safety information for the use of HMEs, bacterial filters, and breathing circuits

**CAUTION**
Additional components in the breathing circuit such as bacterial filters, HME or CO2 cuvettes may increase the dead space, compressible volume, and resistance.

Particular care and monitoring are required when using additional components.

Before checking the breathing circuit (see instructions for use, chapter "Getting started"), attach all necessary additional components up to the patient connection.

**WARNING**
Increased resistance
Medication nebulization and active humidification may increase the resistance of additional components.

Check the breathing circuit regularly for signs of increased resistance and replace additional components if necessary.

Installing a neonatal flow sensor

If a neonatal flow sensor and HME are used in the patient categories **Neo.** or **Ped. pat.**, the HME must be installed between the neonatal flow sensor and the patient connection.
Assembly and preparation

Connecting the mains power supply

**WARNING**
Risk of electric shock and of device failure
If the device is connected to a power socket with incorrect mains voltage or without a protective ground, the user can be injured and the device damaged.

Only connect the power cable to power sockets with a protective ground and the correct mains voltage. Observe the technical data.

**NOTE**
The mains power socket in use must be freely accessible during operation.

Connecting the nurse call

**WARNING**
Risk of patient injury
All data transferred via the nurse call are for information only and must not be used as the sole basis for diagnostic or therapeutic decisions. The nurse call is not intended for use with a distributed alarm system according to IEC 60601-1-8:2012.

Transportation of patients within the hospital

When transporting the patient within the hospital, grasp the trolley handle firmly and push the device in longitudinal direction.
Assembly and preparation

Transport within the hospital

Transport refers to any movement of the medical device without the patient that does not serve to position the medical device.

Increasing the tipping stability

- Swivel the control and display unit (Medical Cockpit) until it is centrally aligned with the ventilation unit.
- Set the hinged arms to minimum extension.
- Drain the water container of the breathing gas humidifier.
- Secure the breathing gas humidifier to the trolley, not to the side rails of the ventilation unit.
- Do not attach any additional parts to the side rails of the ventilation unit.
- If fitted, slide the bed coupling into its retracted position.
- Grasp the trolley handle firmly and push the device in longitudinal direction.

Safety information for patient transport within the hospital also applies, see instructions for use.
Getting started

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

The Start/Standby > Start/Standby page is organized as follows:
- The text on the combined button (A) changes depending on the mode in use:
  - Standby
  - Start ventilation
- The results of the last system check are displayed (B).

The Start/Standby dialog window cannot be closed with the X button (C).

Checking readiness for operation

Performing the breathing circuit check

Starting the breathing circuit check
Prerequisite: The page System check (A) > Breathing circ. check (B) is open. The check has been started.

4 When requested by the device in the instruction field (E): Seal the patient connection port, e.g., with a sterile glove. Confirm with OK (F).
5 When requested, open the patient connection port. Confirm with OK (F).
Display of results of the breathing circuit check

Prerequisite: The System check page (A) is opened.

- Touch the Check results tab (B).

The detailed results of the check are displayed.

C  Compliance [mL/mbar]
D  Flow [L/min]
E  Inspiratory resistance [mbar/L/s]
F  Expiratory resistance [mbar/L/s]

Checking the switch to battery operation

- Unplug the mains plug.

The device switches to battery operation without interruption. The Battery activated alarm is displayed.

- Plug the power cable back in.

The device switches back to mains operation. The Battery activated alarm message goes out.

Checking the alarm signaling

When the system check has been successfully completed, the device is ready for operation. The alarm signaling can also be checked. The description of alarm signaling can be found in the instructions for use in chapter "Alarms." Additional information on alarm criteria can be found in the instructions for use in chapter "Alarm – Cause – Remedy."

High-priority alarm message

1  Start ventilation.
2  After 2 minutes set the upper alarm limit for \( MVe \) to a value below the measured value \( MVe \).

The \( MV_{high} \) alarm is triggered.

Medium-priority alarm message

For Evita Infinity V500 and Evita V300:
1  Start ventilation.
2  Set the upper alarm limit for \( VT \) to a value below the measured value \( VT \).

The \( VT_{high} \) alarm is triggered.

For Babylog VN500:
1  Start ventilation.
2  Switch on the additional setting Volume Guarantee.
3  Reduce the upper alarm limit for \( Paw \) until the \( VT\) not reached, Pmax active alarm is triggered.

Low-priority alarm message

1  Start ventilation.
2  In the Special maneuvers > Maneuvers dialog window, press and hold the Man. insp./hold button until the Inspiratory hold interrupted alarm is triggered.
Checking alarm limits

The alarm limits for a settable alarm can be checked by setting the alarm limits appropriately. When the alarm limit is exceeded, the corresponding alarm is triggered. Additional information on setting alarm limits can be found in the instructions for use, chapter “Setting alarm limits.”

Test of the acoustic alarm system

The acoustic alarm system need not be tested by the user. The device tests the functions of the acoustic alarm system automatically during the device check.
Operation

Setting ventilation

Applies to: Babylog VN500

Additional settings for ventilation

Ventilation parameters for the additional settings

**CAUTION**
Undetected worsening of the patient's condition

During high-frequency ventilation with Volume Guarantee, the ventilator automatically compensates for changes in lung mechanics. As a result, a gradual worsening of patient condition may only be detected after a delay.

Observe patient condition. Check ventilation pressure regularly and set the alarm limits accordingly.
### Operation

#### Special maneuvers

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

**Oxygen enrichment for suction maneuver**

**Closed suction**

**WARNING**

Risk of patient injury during suction in a closed breathing circuit

Using closed suction systems produces negative pressure in the patient's airways. This leads to impaired ventilation and therefore to impaired gas exchange.

Observe patient condition.
Medication nebulization

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Continuous medication nebulization

Prerequisite: The Special maneuvers > Nebulization page is open.

Press the (A) button.
Continuous medication nebulization is started. The message Continuous nebulization in progress is displayed.

Medication nebulization is interrupted every 30 minutes and the flow sensor is calibrated. After the flow sensor has been calibrated, medication nebulization is continued.

When medication nebulization is used in the patient category Neo. or Ped. pat. and the neonatal flow sensor has thus been removed, medication nebulization is not interrupted.

If the parameter field for continuous nebulization Cont. neb. has been configured for display, the duration of medication nebulization is displayed.

Safety information on medication nebulization

CAUTION
Ventilation impaired
If unapproved pneumatic medication nebulizers are used, the actually delivered tidal volume and O2 concentration may deviate from the displayed values.
Only use the medication nebulizers listed in the current list of accessories.

CAUTION
Ventilation impaired
Aerosols can impair the proper functioning of the expiratory valve.
When using medication nebulization, shorten the reprocessing cycles for the expiratory valve.

Mains power supply / DC power supply

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Battery charging

The battery charge display applies to both charging and discharging.
Flow monitoring

Calibrating Infinity ID flow sensors

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

Starting the calibration of the Infinity ID flow sensor

1 Touch the Sensors/Parameters... button in the main menu bar.

The device opens the Sensors/Parameters dialog window.

2 Touch the Flow sensor tab (A).

3 Touch the Start button (B).

4 The device displays information about the calibration in field (D). Button (E) is preselected. Confirm with the rotary knob.

The device uses the next inspiratory phase for calibration of the Infinity ID flow sensor. Short inspiratory times are extended to approximately 1 second.

The device displays information about the calibration in the message field (C).

At the completion of calibration, the Start button (B) turns pale green.

WARNING
Risk of fire
Residual vapors of easily flammable disinfectants (e.g., alcohols) and deposits that were not removed during reprocessing can ignite when the flow sensor is in use.
- Ensure particle-free cleaning and disinfection.
- After disinfection, allow the flow sensor to air for at least 30 minutes.
- Before inserting the flow sensor check for visible damage and soiling, such as residual mucus, medication aerosols, and particles.
- Replace flow sensors when damaged, soiled, or not particlefree.
Alarms

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Displaying information on alarms

Acknowledging alarm messages

Alarm messages that can be acknowledged are listed in the instructions for use in chapter "Alarm – Cause – Remedy." For alarm messages that can be acknowledged the "Remedy" column in the table contains the information that the alarm message can be acknowledged by pressing the ALARM RESET button and confirming with the rotary knob.

The following alarm messages that can be acknowledged are not listed:
– Suction maneuver overused?
– PEEP high (!)
– Flow sensor? Ventilation impaired
  (Evita Infinity V500, Evita V300)
– Low Flow PV Loop maneuver overused?
  (Evita Infinity V500)

Alarm history

The alarm history is part of the logbook. The length of the alarm history depends on the number of logbook entries.

When the logbook reaches its maximum size, the oldest entry in the logbook is deleted as each new entry is logged.

Switching the device off and on are not recorded in the logbook.

Setting the volume of the alarm tone

The lower value for the volume of the alarm tone is limited by the configured minimum volume of the alarm tone. The minimum volume is configured on page System setup > Alarms > Alarm vol./tone, see chapter "Setting the alarm tone" on page 20.

WARNING

Missing alarms in loud environments

Alarm situations are not detected.

Set the volume of the alarm tone so that alarms can be heard.
Configuration

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Information on configuration

The Exchange intervals page has been renamed to System status. Information on the exchange intervals can be found at System setup > System status > Exchange intervals. Additional information regarding the System status page can be found on page 22.

The System status page is password-protected.

Configuring alarm settings

Setting the alarm tone

**WARNING**
Missing alarms in loud environments
Alarm situations are not detected.
Set the volume of the alarm tone so that alarms can be heard.

Setting the minimum alarm volume

Configuring the minimum alarm volume sets the lower limit of the factory setting for the volume of the alarm tone (10 % to 100 %). This allows the setting range to be adjusted to the acoustical situation at operation site.

Prerequisite: The System setup > Alarms > Alarm vol./tone page is opened.

1. Touch the (A) button.
2. Set the value for the minimum volume by turning the rotary knob and push to confirm.
Setting the priority of the battery alarm

The device offers the following priorities for battery alarms:

B  **IEC/CEI**  Priority of the battery alarm in accordance with IEC 60601-2-12

C  **Dräger ventilation**  Priority of the battery alarm according to Dräger

The **Battery activated** alarm message indicating the changeover to battery operation can be configured as a high- or medium-priority alarm when **Dräger ventilation** is selected.

- Touch the **Medium** (D) or **High** (E) button and confirm.

Depending on the setting (IEC/CEI or Dräger ventilation), alarm messages have the following priority:

<table>
<thead>
<tr>
<th>Alarm message</th>
<th>Priority IEC/CEI</th>
<th>Priority Dräger ventilation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Battery activated</strong></td>
<td>Low-priority alarm message</td>
<td>High-priority or medium-priority alarm message</td>
</tr>
<tr>
<td><strong>Battery low</strong></td>
<td>Medium-priority alarm message</td>
<td>High-priority alarm message</td>
</tr>
<tr>
<td><strong>Battery discharged</strong></td>
<td>High-priority alarm message</td>
<td>High-priority alarm message</td>
</tr>
</tbody>
</table>
System status

The **System status** page contains the following information:

- General status information on maintenance and operating hours
- Exchange intervals

1. Touch the **System setup...** button in the main menu bar.
2. Touch the **System status tab** (A).
3. Enter password and confirm with **Enter**.

---

**Displaying general status information**

- Touch the **General status** tab (B).

The following information is displayed:

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>Next service due</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>Cockpit</td>
<td>Operating hours: Standby Operating hours: Running</td>
</tr>
<tr>
<td>E</td>
<td>Ventilation unit</td>
<td>Operating hours: Standby Operating hours: Running Battery installation date</td>
</tr>
<tr>
<td>F</td>
<td>Gas supply unit (GS500)</td>
<td>Operating hours: Blower Installation date</td>
</tr>
<tr>
<td>G</td>
<td>Power supply unit (PS500)</td>
<td>Installation date</td>
</tr>
</tbody>
</table>
## Alarm – Cause – Remedy

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

<table>
<thead>
<tr>
<th>Alarm priority</th>
<th>Alarm message</th>
<th>Cause</th>
<th>Remedy</th>
</tr>
</thead>
</table>
| ! 100          | Air supply low, GS500 active | Air supply insufficient to deliver the required flow and pressure.  
Air is supplied by the gas supply unit GS500.  
Air supply is not required when FiO2 = 100 Vol.%.
| Central Air supply insufficient.  
Gas delivery system is supplied with Air delivered by GS500. | Check connection to Air supply.  
Make sure supply pressure is greater than 3 bar (43.5 psi).  
Consider readjusting ventilation settings.  
Remove connection to Air supply if alarm condition persists (to avoid reverse flow into the Air supply). |
| !! 140         | Airway pressure negative (averaged)  
Applies only to Babylog VN500. | Average airway pressure has fallen below –2 mbar (–2 cmH₂O). | Disconnect tube for suctioning.  
Check patient condition.  
Check ventilation settings. |
| ! 200          | Alarm limit not confirmed | One or more alarm limits have been changed but not confirmed. | If necessary, change these alarm limits and confirm the change with the rotary knob. |
## Alarm – Cause – Remedy

<table>
<thead>
<tr>
<th>Alarm priority</th>
<th>Alarm message</th>
<th>Cause</th>
<th>Remedy</th>
</tr>
</thead>
</table>
| ! 201          | Battery activated                      | The ventilation unit is powered by the battery as there is no mains power supply.  
                  |                                        | - If PS500 is not connected, the maximum operating time is 30 minutes.  
                  |                                        | - If PS500 is connected, the maximum operating time is 360 minutes.    | Connect device to the mains power supply. |
| ! 127          | Battery charging deferred              | Battery charging is deferred to prevent battery overheating. The device can be used normally.   | Battery charging continues automatically and is indicated by a flashing segment in the battery symbol. |
| !!! 254        | Battery discharged                     | The remaining operating time of the battery is less than 5 minutes.    | Connect device immediately to the mains power supply.                 |
| !!! 250        | Battery low                            | The battery is almost discharged.                                      | Connect device to the mains power supply.                              |
| !! 251         | Battery low                            | The battery is almost discharged.                                      | Connect device to the mains power supply.                              |
| ! 100          | Continuous nebulization activated      | Continuous nebulization was activated by the user.                    | To end continuous nebulization, press the “Cancel” button if required. |
| !!! 253        | Device failure                         | A system failure was detected.                                         | Disconnect patient from the device and continue ventilation without delay using another independent ventilator.  
                  |                                        |                                                                      | Call DrägerService.                                                  |
| !!! 253        | Device failure (10)                    | A failure was detected by the safety software system.                 | Disconnect patient from the device and continue ventilation without delay using another independent ventilator.  
<pre><code>              |                                        |                                                                      | Call DrägerService.                                                  |
</code></pre>
<table>
<thead>
<tr>
<th>Alarm priority</th>
<th>Alarm message</th>
<th>Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>!!! 253</td>
<td>Device failure (11)</td>
<td>A failure was detected during the start-up phase.</td>
<td>Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Call DrägerService.</td>
</tr>
<tr>
<td>!!! 253</td>
<td>Device failure (12)</td>
<td>A system failure was detected.</td>
<td>Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Call DrägerService.</td>
</tr>
<tr>
<td>!! 090</td>
<td>Device failure (13)</td>
<td>The broken wire detection for the flow sensor is faulty.</td>
<td>Ventilation functions are not affected. Call DrägerService.</td>
</tr>
<tr>
<td>!!! 237</td>
<td>Device failure (2)</td>
<td>Internal safety system failure.</td>
<td>Do not use this device for ventilation therapy. Call DrägerService.</td>
</tr>
<tr>
<td>!! 140</td>
<td>PEEP high</td>
<td>Expiratory valve or breathing circuit obstructed.</td>
<td>Check breathing circuit and expiratory valve. Check for condensate.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Expiratory resistance increased.</td>
<td>Check viral/bacterial filter. Replace it if necessary.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Device failure.</td>
<td>Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Call DrägerService.</td>
</tr>
<tr>
<td>!!! 140</td>
<td>PEEP low</td>
<td>Applies only to Babylog VN500. Measured PEEP is 3 mbar (3 cmH2O) less than set PEEP.</td>
<td>Check breathing circuit for tight connections. Check whether the expiratory valve is properly engaged. Make sure that the tube or mask is connected correctly.</td>
</tr>
</tbody>
</table>
### Alarm – Cause – Remedy

<table>
<thead>
<tr>
<th>Alarm priority</th>
<th>Alarm message</th>
<th>Cause</th>
<th>Remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>! 200</td>
<td>Setting not confirmed</td>
<td>One or more settings have been changed but not confirmed.</td>
<td>If necessary, change these settings and confirm the change with the rotary knob.</td>
</tr>
<tr>
<td>!!! 255</td>
<td>Standby mode activated</td>
<td>Device has been switched to standby mode.</td>
<td>Acknowledge standby mode by touching &quot;ALARM RESET&quot; button and confirm with rotary knob.</td>
</tr>
<tr>
<td>! 200</td>
<td>Ventilation mode not confirmed</td>
<td>The ventilation mode has been changed but not confirmed.</td>
<td>If necessary, change the ventilation mode and confirm the change with the rotary knob.</td>
</tr>
<tr>
<td>!! 140</td>
<td>VThf not reached</td>
<td>Tidal volume could not be reached due to increased resistance.</td>
<td>Check patient condition. Check ventilation settings.</td>
</tr>
<tr>
<td></td>
<td>Applies only to Babylog VN500.</td>
<td>Tidal volume could not be reached due to pressure limitation of the device.</td>
<td>Reduce ff or increase I:Ehf to 1:1.</td>
</tr>
</tbody>
</table>
Cleaning, disinfection and sterilization

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Safety information on reprocessing

The components filled with contaminated gas during normal operation and in the event of a fault must be reprocessed.

During normal operation the expiratory valve, along with the ejector and muffler, are filled with contaminated gas.

In the event of a fault, the inspiratory unit may be contaminated.

Additional information on reprocessing can be found in the instructions for use.

Reprocessing list

Semi-critical medical devices

<table>
<thead>
<tr>
<th>Items which can be reprocessed</th>
<th>Recommended reprocessing intervals</th>
<th>Pre-cleaning</th>
<th>Machine cleaning and disinfection</th>
<th>Manual Cleaning</th>
<th>Manual Disinfection</th>
<th>Sterilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breathing hoses</td>
<td>Per patient/weekly</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

According to the corresponding instructions for use

Safety information concerning the reprocessing of the neonatal flow sensor:

**NOTE**
– Do not use brushes for reprocessing the sensor insert and do not use a syringe on the sensor insert.
– For reprocessing the housing use lint-free brushes only.
Maintenance

Appplies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

Overview

**WARNING**
Risk of patient injury
Performing maintenance work during ventilation endangers the patient.
Only perform maintenance work when no patient is connected to the device.
Technical data

Ambient conditions

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

During operation
Altitude Up to 3000 m (9842 ft)

Set values

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

The desired parameters can be set without loss of accuracy using the therapy controls. The controlled parameters – pressure, flow, volume, and O2 concentration – can only be applied with the accuracy of the associated measured values.

The accuracies indicated apply only under the following conditions:
– The device is ready for operation, see chapter "Getting started."
– Any accessories being used are approved for the device, see the list of accessories.
– The type of humidification is selected correctly in the Start/Standy > Br. circuit/ Humidifier dialog window.

The tolerances do not include the measurement uncertainty of external test equipment. This information is available on request.

O2 concentration

<table>
<thead>
<tr>
<th>T0 ... 90</th>
<th>Test conditions as per ISO 80601-2-12:2011, Sec. 201.12.1.104</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>&lt;35 s</td>
</tr>
</tbody>
</table>

(Evita Infinity V500, Evita V300)
**Technical data**

**Set values (cont.)**

<table>
<thead>
<tr>
<th>Patient Category</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pediatric patients</td>
<td>&lt;35 s</td>
</tr>
<tr>
<td>Neonates</td>
<td>&lt;15 s</td>
</tr>
</tbody>
</table>

**Performance characteristics**

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

Medication nebulization: For 5, 10, 15, 30 minutes, continuously (∞)

Accuracy of measured values:
Depending on the patient category, the accuracies indicated for the measured values apply to the following performance characteristics of the breathing circuit.

Breathing circuit for adults including additional components (Evita Infinity V500, Evita V300)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance</td>
<td>≤3 mL/mbar (or mL/hPa or mL/cmH₂O)</td>
</tr>
<tr>
<td>Inspiratory resistance</td>
<td>≤10 mbar/L/s at 30 L/min</td>
</tr>
<tr>
<td></td>
<td>≤10 hPa/L/s at 30 L/min</td>
</tr>
<tr>
<td></td>
<td>≤10 cmH₂O/L/s at 30 L/min</td>
</tr>
<tr>
<td>Expiratory resistance</td>
<td>≤10 mbar/L/s at 30 L/min</td>
</tr>
<tr>
<td></td>
<td>≤10 hPa/L/s at 30 L/min</td>
</tr>
<tr>
<td></td>
<td>≤10 cmH₂O/L/s at 30 L/min</td>
</tr>
</tbody>
</table>

Breathing circuit for pediatric patients including additional components

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance</td>
<td>≤1.5 mL/mbar (or mL/hPa or mL/cmH₂O)</td>
</tr>
<tr>
<td>Inspiratory resistance</td>
<td>≤44 mbar/L/s at 15 L/min</td>
</tr>
<tr>
<td></td>
<td>≤44 hPa/L/s at 15 L/min</td>
</tr>
<tr>
<td></td>
<td>≤44 cmH₂O/L/s at 15 L/min</td>
</tr>
<tr>
<td>Expiratory resistance</td>
<td>≤44 mbar/L/s at 15 L/min</td>
</tr>
<tr>
<td></td>
<td>≤44 hPa/L/s at 15 L/min</td>
</tr>
<tr>
<td></td>
<td>≤44 cmH₂O/L/s at 15 L/min</td>
</tr>
</tbody>
</table>
### Technical data

#### Performance characteristics (cont.)

Breathing circuit for neonates including additional components

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance</td>
<td>( \leq 1.5 \text{ mL/mbar} )</td>
</tr>
<tr>
<td>Inspiratory resistance</td>
<td>( \leq 44 \text{ mbar/L/s at 15 L/min} )</td>
</tr>
<tr>
<td>Expiratory resistance</td>
<td>( \leq 44 \text{ mbar/L/s at 15 L/min} )</td>
</tr>
</tbody>
</table>

**Displayed measured values**

- **Applies to:**
  - Evita Infinity V500
  - Babylog VN500
  - Evita V300

**O2 measurement (inspiratory side)**

- Inspiratory O2 concentration (in dry air)
- Drift of measurement accuracy
  - \( \text{FiO2} \text{ (in accordance with ISO 21647, ISO 80601-2-55)} \)
  - Measured values are barometrically pressure compensated.

**CO2 measurement in mainstream**

- End-expiratory CO2 concentration
- Measurement conditions
  - Respiratory rate (adults): 6 to 40/min
  - Respiratory rate (pediatric patients): 40 to 100/min
  - Inspiratory time: >250 ms
  - Expiratory time: >250 ms

**Flow measurement (expiratory)**

- Tidal volume measurement
  - Volume trapped in the lungs (determined by the PEEPi maneuver)
    - \( \text{Vtrap (BTPS)} \)
    - Range: 0 to 1500 mL

---

*Note: The text contains technical specifications and measurement conditions for medical devices.*
Displayed measured values (cont.)

Accuracy

±12 % of the measured value or ±12 mL, whichever is greater, under calibration conditions (1013 mbar (1013 cmH₂O), dry gas, 20 °C (68 °F)), 5 % CO₂, flow sensor flap closed and no leakage

Exhaled CO₂ per breath

<table>
<thead>
<tr>
<th>Range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTCO₂</td>
<td>±12 %</td>
</tr>
</tbody>
</table>

Applies to:
- Babylog VN500

Device flow (inspiratory, only with HFO)

<table>
<thead>
<tr>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>±10 %</td>
</tr>
</tbody>
</table>

Displayed calculated values

Applies to:
- Evita Infinity V500
- Babylog VN500

Static compliance (determined by Low Flow PV loop maneuver) Cstat

<table>
<thead>
<tr>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 to 500 mL/mbar (or mL/hPa or mL/cmH₂O)</td>
</tr>
</tbody>
</table>

Monitoring

Applies to:
- Evita Infinity V500
- Babylog VN500

Sound pressure level LPA of alarm signals measured in accordance with IEC 60601-1-8 and A1:2012 (3rd edition)

Alarm tone sequence IEC/CEI

<table>
<thead>
<tr>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-priority alarms according to volume setting</td>
</tr>
<tr>
<td>Approx. 55 dB(A) to 72 dB(A)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium-priority alarms according to volume setting</td>
</tr>
<tr>
<td>Approx. 52 dB(A) to 69 dB(A)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-priority alarms according to volume setting</td>
</tr>
<tr>
<td>Approx. 49 dB(A) to 67 dB(A)</td>
</tr>
</tbody>
</table>
## Technical data

### Monitoring (cont.)

<table>
<thead>
<tr>
<th>Alarm tone sequence</th>
<th>Dräger ventilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range for high-priority alarms according to volume setting</td>
<td>Approx. 55 dB(A) to 72 dB(A)</td>
</tr>
<tr>
<td>Range for medium-priority alarms according to volume setting</td>
<td>Approx. 53 dB(A) to 70 dB(A)</td>
</tr>
<tr>
<td>Range for low-priority alarms according to volume setting</td>
<td>Approx. 45 dB(A) to 62 dB(A)</td>
</tr>
<tr>
<td>Range for power supply failure alarm and auxiliary alarm</td>
<td>Approx. 70 dB(A) to 75 dB(A)</td>
</tr>
</tbody>
</table>

Applies to:
- Evita V300

Sound pressure level LPA of alarm signals measured in accordance with IEC 60601-1-8 and A1:2012 (3rd edition)

<table>
<thead>
<tr>
<th>Alarm tone sequence</th>
<th>IEC/CEI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range for high-priority alarms according to volume setting</td>
<td>Approx. 56 dB(A) to 74 dB(A)</td>
</tr>
<tr>
<td>Range for medium-priority alarms according to volume setting</td>
<td>Approx. 48 dB(A) to 65 dB(A)</td>
</tr>
<tr>
<td>Range for low-priority alarms according to volume setting</td>
<td>Approx. 53 dB(A) to 71 dB(A)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Alarm tone sequence</th>
<th>Dräger ventilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range for high-priority alarms according to volume setting</td>
<td>Approx. 54 dB(A) to 72 dB(A)</td>
</tr>
<tr>
<td>Range for medium-priority alarms according to volume setting</td>
<td>Approx. 51 dB(A) to 69 dB(A)</td>
</tr>
<tr>
<td>Range for low-priority alarms according to volume setting</td>
<td>Approx. 45 dB(A) to 64 dB(A)</td>
</tr>
<tr>
<td>Range for power supply failure alarm and auxiliary alarm</td>
<td>Approx. 70 dB(A) to 75 dB(A)</td>
</tr>
</tbody>
</table>
## Operating data

**Applies to:**
- Evita Infinity V500
- Babylog VN500
- Evita V300

### Mains power supply

**Inrush current**
- Approx. 8 to 24 A peak
- Approx. 6 to 17 A quasi-RMS

**Degree of protection against ingress of liquids and particles**
- IP21
  - Protection against particles with a diameter of more than 12.5 mm (0.47 in)
  - Protection against vertically dripping water

### Noise emission in accordance with
**ISO 80601-2-12:2011** under consideration of
**ISO 4871:2009 and ISO 3744:2010**

- **A-class mean surface sound pressure level (LPA)** with a radius of 2 m (79 in)
  - Approx. 33 dB
  - Approx. 43.5 dB with GS500
  - Approx. 50 with HFO (Babylog VN500)
  - Uncertainty (k) 3.5 dB
- **A-class surface sound pressure level (LWA)**
  - Approx. 46 dB
  - Approx. 57.5 dB with GS500
  - Approx. 63.5 dB with HFO (Babylog VN500)
  - Uncertainty (k) 3.5 dB

### Weight

- **Ventilation unit**
  - Approx. 17 kg (37.5 lbs)
- **Medical Cockpit with holder**
  - Approx. 8 kg (17.6 lbs)
- **Trolley**
  - Approx. 33 kg (72.8 lbs)
- **PS500**
  - Approx. 27 kg (59.5 lbs)
- **GS500**
  - Approx. 10.5 kg (23 lbs)
- **Nominal weight (weight of ventilation unit and Medical Cockpit on trolley)**
  - Nom. 58 kg (128 lbs)
- **Maximum weight (permitted maximum total weight)**
  - Max. 133 kg (293 lbs)
**Technical data**

### Operating data (cont.)

<table>
<thead>
<tr>
<th>Maximum load</th>
<th>kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Universal holder with standard rail (G93140)</td>
<td>10</td>
</tr>
<tr>
<td>Humidifier holder, can be swiveled (G93111)</td>
<td>5</td>
</tr>
<tr>
<td>Humidifier holder, side rail (8416325)</td>
<td>5</td>
</tr>
</tbody>
</table>

If a hinged arm is attached to the side rails of the ventilation unit in addition to the humidifier holder (8416325), the maximum load of 5 kg (11 lbs) per side rail must be observed. The humidifier holder can then only support 4 kg (8.8 lbs).

### Essential performance characteristics

**Applies to:**
- Evita Infinity V500
- Babylog VN500
- Evita V300

The essential performance consists in a controlled and monitored patient ventilation with user-defined settings for the monitoring functions:
- minimum and maximum tidal volume,
- maximum airway pressure,
- minimum and maximum O2 concentration in the breathing gas,

or, if a set limit is exceeded, an appropriate alarm.

Additionally, the integrated monitoring alarms in the following situations:
- Failure of the external power supply
- Battery discharge
- Failure of the gas supply
Automatic alarm limits

Pressure monitoring
Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

<table>
<thead>
<tr>
<th>Alarm message</th>
<th>Description/Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PEEP high / Plow high (!!!)</strong></td>
<td>The alarm limit is 8 mbar (8 cmH2O) above the set PEEP or Plow level. The alarm triggers a pressure release to ambient pressure. The alarm is not triggered below 11 mbar (11 cmH2O). An alarm is triggered if this condition applies for 2 breaths or after a maximum of 15 seconds. To avoid false alarms, it is monitored whether the lower pressure level has been reached if APRV and the Tiow value were set to less than 1 s or if AutoRelease is activated.</td>
</tr>
<tr>
<td><strong>PEEP high / Plow high (!!)</strong></td>
<td>The alarm limit is 4 mbar (4 cmH2O) above the set PEEP value. An alarm is triggered if this condition applies for 2 breaths or after a maximum of 15 seconds.</td>
</tr>
<tr>
<td><strong>PEEP low / Plow low (only for Evita Infinity V500 and Evita V300)</strong></td>
<td>A too low PEEP or Plow value during ventilation is monitored. The alarm limit depends on the set value of the PEEP or Plow level. The alarm limit is 5 mbar (5 cmH2O) below the set value. An alarm is triggered if this condition applies for 10 breaths.</td>
</tr>
<tr>
<td><strong>PEEP low / Plow low (only for Babylog VN500)</strong></td>
<td>A too low PEEP or Plow value during ventilation is monitored. The alarm limit depends on the set value of the PEEP or Plow level. The alarm limit is 3 mbar (3 cmH2O) below the set value. An alarm is triggered if this condition applies for 10 breaths.</td>
</tr>
</tbody>
</table>
Volume monitoring

Applies to:
– Evita Infinity V500
– Evita V300

The expiratory minute volume $MV_e$ is monitored within the set alarm limits.

The inspiratory tidal volume $VT_i$ or, when leakage compensation is switched on, the leakage-compensated tidal volume $VT$ is monitored within the set alarm limits.

Because the device ensures the minimum inspiratory tidal volume when volume-controlled ventilation modes or pressure-controlled ventilation modes with Volume Guarantee are selected, it is not possible to set the lower alarm limit for $VT_i$ or $VT$ manually.

Applies to:
– Babylog VN500

The expiratory minute volume $MV_e$ is monitored in the patient category Ped. pat. and in the case of invasive ventilation in the patient category Neo. within the set alarm limits.

The minimum tidal volume is monitored only when Volume Guarantee is activated. To accomplish this, with leakage compensation switched off the value $VT_i$ is monitored in the patient category Ped. pat., and the value $VTe$ is monitored in the patient category Neo.. When leakage compensation is activated, $VT$ is generally used and the automatically set alarm limit $VT\ low$ is monitored, whereby the limit $VT\ low$ corresponds to 90 % of the selected $VT$.

Electromagnetic compatibility

Applies to:
– Workstation Critical Care and Neonatal Care

The references for the tables have been updated:

– Electromagnetic environment:
  Information regarding electromagnetic emissions (IEC 60601-1-2, table 1)

– Electromagnetic immunity:
  Information regarding electromagnetic immunity (IEC 60601-1-2, tables 2, 3, and 4)

– Recommended separation distances to portable and mobile RF telecommunication devices:
  Information regarding separation distances (IEC 60601-1-2, tables 5 and 6)
Connections to IT networks

 Applies to:
 – Evita Infinity V500
 – Babylog VN500
 – Evita V300

 Data can be exchanged in an IT network using wired and wireless technologies. IT networks include all data interfaces (e.g., RS232, LAN, USB, printer interface) described in standards and conventions.

 During operation, this device can exchange information with other devices by means of IT networks and supports the following functions:
 – Display of waveforms and parameter data
 – Signaling of alarms
 – Transfer of device settings and patient data
 – Service mode, access to logbooks

 Connecting this device to a network that incorporates other devices or making subsequent changes to that network can lead to new risks for patients, users, and third parties. Before the device is connected to the network or the network is changed, these risks must be identified, analyzed, and evaluated, and appropriate measures taken.

 Examples of subsequent changes to the network:
 – Changing the network configuration
 – Removing devices from the network
 – Adding new devices to the network
 – Performing upgrades or updates on devices that are connected to the network

 Information on connecting to the network

 Prerequisites

 This device must only be connected to the network by service personnel. The IT representative of the hospital must be consulted in advance.

 The following documents must be observed:
 – Accompanying documents of this device
 – Description of the network interface
 – Description of the network-based alarm systems

 Dräger recommends complying with IEC 80001-1 (risk management for IT networks with medical devices).

 Serial interfaces

 The following interfaces are supported:
 – RS232 interfaces complying with EIA RS-232 (CCITT V.24/V.28) for the following applications:
   – MEDIBUS, MEDIBUS.X
   – Connection to medical devices from other manufacturers
Consequences of using an unsuitable network

If the network does not meet the requirements, dangerous situations can result. The following situations can occur with this device:

– Due to an insecure decentralized alarm system:
  – Alarms or data are transmitted at the wrong time.
  – Alarms are not transmitted.

– During an interruption of the network connection:
  – Suppressed alarms or alarm tones are not reactivated, but remain suppressed.
  – Alarms are not transmitted.

– Without firewall and antivirus software:
  – Data are not protected.
  – Device settings are changed.
  – The device generates false alarms or no alarms.

– Data are sent incomplete, sent to the wrong device, or not sent at all.

– Patient data are intercepted, falsified, or damaged.

– Data have incorrect time stamps.

Electrical requirements of connected devices and networks

The analog and digital ports are only appropriate for connecting devices or networks that have a nominal voltage on the network side of max. 24 V DC and meet the requirements of one of the following standards:

– IEC 60950-1: Ungrounded SELV circuits
– IEC 60601-1 (as of 2nd edition): Touchable secondary circuits
Principles of operation

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

Pneumatic functional description

An active breathing gas humidifier and an pneumatic medication nebulizer can also be installed. Additional information can be found in the instructions for use in the chapters "Assembly and preparation" and "Operation."

Flow reduction Anti Air Shower

When the Anti Air Shower function is activated and a disconnection is detected during ventilation, the flow is reduced until reconnection is detected. Simultaneously, the Disconnection? alarm is displayed. With non-invasive ventilation, the time before the alarm is triggered can be delayed with Tdisconnect. The minute ventilation can be reduced due to the already reduced flow.
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