Evita V series / Babylog VN series

Reprocessing instructions

WARNING
To properly reprocess the products, read and comply with this document.

*Dräger. Technology for Life*
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1 Information about this document

1.1 Scope of application

These reprocessing instructions apply to all ventilators in the Evita V series and in the Babylog VN series.

These reprocessing instructions replace the "Reprocessing" chapter in the instructions for use for the ventilators Evita Infinity V500, Evita V300, and Babylog VN500.

1.2 Typographical conventions

**Text**

- Bold, italicized texts indicate labels on the device and screen texts.
- Numbers followed by a period indicate individual action steps in a sequence of actions. Numbering begins with the number 1 for each new sequence of actions.
- Lowercase letters followed by a period indicate subordinate action steps. Numbering begins anew with the letter a. for each new subordinate action step.
- This bullet point indicates individual process steps with no specific sequence.
- This triangle in safety instructions and precautionary statements indicates ways to avoid danger.

(1) Numbers in parentheses refer to elements in figures.
- Numbers in figures indicate elements referred to in the text.
- The greater-than symbol indicates the navigation path in a dialog.
- This symbol indicates information that makes it easier to use the product.
- This arrow indicates the result of an action step.
- This check mark indicates the result of a sequence of actions.

1.3 Illustrations

Illustrations of products and screen content in this document may differ from the actual products depending on configuration and design.

1.4 Use of terms

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

Ventilators in the Evita V series are also referred to as "Evita".

Ventilators in the Babylog VN series are also referred to as "Babylog".
### 1.5 Trademarks

#### 1.5.1 Trademarks owned by Dräger

<table>
<thead>
<tr>
<th>Trademark</th>
<th>Trademark owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evita®</td>
<td></td>
</tr>
<tr>
<td>Babylog®</td>
<td></td>
</tr>
<tr>
<td>Infinity®</td>
<td></td>
</tr>
</tbody>
</table>

The following web page provides a list of the countries in which the trademarks are registered: [www.draeger.com/trademarks](http://www.draeger.com/trademarks)

#### 1.5.2 Trademarks owned by third-party manufacturers

<table>
<thead>
<tr>
<th>Trademark</th>
<th>Trademark owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dismozon®</td>
<td>BODE Chemie</td>
</tr>
<tr>
<td>Korsolex®</td>
<td></td>
</tr>
<tr>
<td>neodisher mediclean®</td>
<td>Dr. Weigert</td>
</tr>
<tr>
<td>acryl-des®</td>
<td></td>
</tr>
<tr>
<td>Mikrozid®</td>
<td>Schülke &amp; Mayr</td>
</tr>
<tr>
<td>Perform®</td>
<td></td>
</tr>
<tr>
<td>Actichlor®</td>
<td>Ecolab</td>
</tr>
<tr>
<td>Incidin®</td>
<td></td>
</tr>
<tr>
<td>Oxyclide®</td>
<td>Ecolab USA</td>
</tr>
<tr>
<td>Sekusept®</td>
<td></td>
</tr>
<tr>
<td>Dispatch®</td>
<td>Clorox</td>
</tr>
<tr>
<td>Descogen®</td>
<td>Antiseptica</td>
</tr>
<tr>
<td>Oxygenon®</td>
<td></td>
</tr>
<tr>
<td>SteriMax®</td>
<td>Aseptix</td>
</tr>
<tr>
<td>Cleanisept®</td>
<td>Dr. Schumacher</td>
</tr>
</tbody>
</table>
2 Safety-related information

2.1 Information on safety instructions and precautionary statements

Safety instructions and precautionary statements warn of risks and give instructions for the safe use of the product. Failure to observe them may lead to personal injury or property damage.

2.1.1 Safety instructions

This document contains sections with safety instructions which warn of risks. The type of risk and the consequences of non-compliance are described in each safety instruction.

2.1.2 Precautionary statements

Precautionary statements relate to action steps and warn of risks that may arise when performing the action steps. Precautionary statements precede the action steps.

The following warning signs and signal words indicate precautionary statements and differentiate the possible consequences of non-compliance.

<table>
<thead>
<tr>
<th>Warning sign</th>
<th>Signal word</th>
<th>Consequences of non-compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>WARNING</td>
<td>May result in death or serious injury.</td>
</tr>
<tr>
<td>!</td>
<td>CAUTION</td>
<td>May result in moderate or minor injury.</td>
</tr>
<tr>
<td></td>
<td>NOTICE</td>
<td>May result in property damage.</td>
</tr>
</tbody>
</table>

2.2 Safety instructions

Reusable products

Reusable products must be reprocessed, otherwise there is an increased risk of infection.

- Follow the infection prevention policies and reprocessing regulations, including the reprocessing intervals, of the health-care facility.
- Follow the national infection prevention policies and reprocessing regulations.
- Use validated procedures for reprocessing.
- Reprocessing is performed by reprocessing personnel who have specialist knowledge in the reprocessing of medical devices and who have read and understood this document.
- Follow the manufacturer's instructions for cleaning agents, disinfectants, and reprocessing devices.

Signs of wear, e.g., cracks, deformation, discoloration, or peeling, may occur with reprocessed products.

- Check products for signs of wear and replace them if necessary.


2.2.1 Inspiratory valve

For spontaneously breathing patients, patient gas can flow through the inspiratory valve in the following situations:

- Overpressure in the system caused by a kink in the expiratory hose
- Failure of both supply gases
- Complete failure of the power supply (failure of mains power supply and discharged or faulty batteries)

If the inspiratory valve is not reprocessed after situations like these, there is a risk of infection.

► Reprocess the inspiratory valve.

3 Reprocessing

3.1 Information on reprocessing

Follow the national infection prevention policies and reprocessing regulations.

Follow the infection prevention policies and reprocessing regulations of the healthcare facility (e.g., concerning the reprocessing cycles).

Reusable components through which contaminated breathing gas passes during normal operation and in the event of a fault must be reprocessed. In normal operation, contaminated breathing gas passes through the expiratory valve and other accessories in the expiratory path. In the event of a fault, the inspiratory valve and other accessories in the inspiratory path may become contaminated.

3.2 Classifications for reprocessing

3.2.1 Classification of medical devices

The classification depends on the intended use of the medical device. The risk of infection transmission through the application of the product to the patient without proper reprocessing is the basis of the Spaulding classification.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-critical</td>
<td>Components that come into contact only with skin that is intact</td>
</tr>
<tr>
<td>Semi-critical</td>
<td>Components that carry breathing gas or come into contact with mucous membranes or pathologically altered skin</td>
</tr>
<tr>
<td>Critical</td>
<td>Components that penetrate skin or mucous membranes or come into contact with blood</td>
</tr>
</tbody>
</table>
3.2.2 Classification of device-specific components

The following classification is a recommendation from Dräger.

Non-critical
- Device surface, incl. display unit
- Trolley and holders
- Removable parts of the main device
- GS500 gas supply unit
- PS500 power supply unit

Semi-critical
- Expiratory valve
- Neonatal expiratory valve
- Inspiratory valve

3.3 Before reprocessing

Observe before disassembly
1. Switch off the device and all devices connected to it.
2. Disconnect all power plugs.
3. Drain the water traps and the breathing hoses.
4. Drain the water reservoir of the breathing gas humidifier.

3.3.1 Patient-specific accessories and consumables

The patient-specific accessories and consumables must be removed from the device and, if necessary, disassembled.

Reusable products:
- If the reusable product has its own instructions for use, perform reprocessing in accordance with the separate instructions for use. Information on compatible reusable products can be found in the list of accessories.

Disposable products:
- Dispose of the disposable products.

Removing the breathing circuit
- Remove the breathing hoses from the inspiratory port and the expiratory port.
Removing the expiratory flow sensor from the ventilator Evita
1. Open the flap.
2. Push the flow sensor as far as possible to the left.
3. Remove the flow sensor (1) from the socket (2).

Disassembling the neonatal flow sensor
Prerequisites:
– The sensor plug was removed from the rear of the device.
Procedure for the ISO 15 neonatal flow sensor:
1. Remove the flow sensor housing (4) from the Y-piece.
2. Disconnect the plug of the flow sensor cable (1) from the flow sensor.
3. Gently press the knobs (2) on both sides while removing the insert (3) from the sensor housing (4).
Procedure for the neonatal flow sensor Y-piece:
1. Remove the breathing hoses from the flow sensor Y-piece (4).
2. Disconnect the plug of the flow sensor cable (1) from the flow sensor.
3. Gently press the knobs (2) on both sides while removing the sensor insert (3) from the flow sensor Y-piece (4).
Removing the CO₂ sensor

Prerequisites:
- The sensor plug was removed from the rear of the device.

Procedure:
1. Remove the CO₂ sensor (1) from the cuvette.
2. Remove the cuvette (2) from the patient port of the Y-piece.

Removing the pneumatic medication nebulizer (white, 8412935)

After use in the Adult patient category:
1. Remove the nebulizer hose (1) from the medication nebulizer (2) and from the nebulizer port on the device.
2. Remove the medication nebulizer (2) from the breathing hoses.
3. Disassemble the medication nebulizer in accordance with the corresponding instructions for use.

After use in the Pediatric patient and Neonate patient categories:
1. Remove the nebulizer hose (7) from the medication nebulizer (5) and from the nebulizer port on the device.
2. Remove the medication nebulizer (5) from the breathing hoses.
3. Remove the soft connector (6) from the inlet port.
4. Remove the adapter (4) from the outlet port.
5. Remove the corrugated hose (3) from the adapter (4).
6. Disassemble the medication nebulizer in accordance with the corresponding instructions for use.

**Removing the pneumatic medication nebulizer (black, 8411030)**

1. Remove the nebulizer hose (1) from the medication nebulizer (2) and from the nebulizer port on the device.

2. Remove the medication nebulizer (2) from the breathing hoses.

3. Remove the corrugated hose for the breathing circuit (3) from the inlet port.

4. Remove the corrugated hose (4) from the outlet port.

5. Disassemble the medication nebulizer in accordance with the corresponding instructions for use.
3.3.2 Device-specific components

The device-specific components must be removed from the device and, if necessary, disassembled.

Removing the expiratory valve or the neonatal expiratory valve from the ventilator

This section addresses how to remove the expiratory valve from the ventilator Evita. The neonatal expiratory valve is removed from the Evita and Babylog ventilators in the same manner.

Prerequisites:
- The flap on the front of the ventilator is open.
- The expiratory flow sensor is removed from the ventilator Evita.

Procedure:
1. Turn the locking ring (1) as far as possible to the left.
2. Remove the expiratory valve from the fitting.
Disassembling the expiratory valve or the neonatal expiratory valve

No. | Expiratory valve     | Neonatal expiratory valve |
-----|----------------------|----------------------------|
1    | Flow sensor sleeve   | -                          |
2    | Diaphragm            | Diaphragm                  |
3    | -                    | Muffler                    |
4    | Water trap container | Water trap container       |

Procedure:
1. Remove the flow sensor sleeve (1) from the expiratory valve or remove the muffler (3) from the neonatal expiratory valve.
2. Remove the diaphragm (2) and do not disassemble it further.
3. Remove the water trap container (4).
4. Drain the water trap container.
Removing the inspiratory valve from the ventilator
This section addresses how to remove the inspiratory valve from the ventilator Evita. The neonatal inspiratory valve is removed from the ventilator Babylog in the same manner.

Prerequisites:
- The inspiratory valve is removed and disassembled only if patient gas has flowed through the inspiratory valve.
- The device is switched off.

Procedure:
1. Press and hold the locking lever (2) on the underside of the inspiratory valve (1).
2. Simultaneously turn the inspiratory valve approx. 20° counterclockwise.
3. Remove the inspiratory valve from the fitting.

Disassembling the inspiratory valve
This section addresses how to disassemble the inspiratory valve for the ventilator Evita. The neonatal inspiratory valve is disassembled from the ventilator Babylog in the same manner.
1. Remove the diaphragm with adapter (1) from the fitting of the inspiratory valve.
2. Remove the seal (2).
3.4 Validated reprocessing procedures

3.4.1 Overview of the reprocessing procedures for the device and device-specific components

<table>
<thead>
<tr>
<th>Device and components</th>
<th>Surface disinfection with cleaning</th>
<th>Machine cleaning with thermal disinfection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device surface, trolley, and additional non-critical components</td>
<td>Yes (see &quot;Surface disinfection with cleaning&quot;, page 14)</td>
<td>No</td>
</tr>
<tr>
<td>Expiratory valve</td>
<td>No</td>
<td>Yes (see &quot;Machine cleaning with thermal disinfection&quot;, page 15)</td>
</tr>
<tr>
<td>Neonatal expiratory valve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inspiratory valve</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.4.2 Surface disinfection with cleaning

Components:
- Device surface, trolley, and additional non-critical components

<table>
<thead>
<tr>
<th>Surface disinfectant</th>
<th>Manufacturer</th>
<th>Concentration</th>
<th>Contact time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dismozon pur/plus</td>
<td>BODE Chemie</td>
<td>1.6 %</td>
<td>15 min</td>
</tr>
</tbody>
</table>

Prerequisites:
- The surface disinfectant has been prepared in accordance with the manufacturer's instructions.
- The manufacturer's instructions, e.g., regarding shelf life or application conditions, are observed.
- An uncontaminated, lint-free cloth soaked in surface disinfectant is used for the cleaning surface disinfection.

⚠️ WARNING
Risk due to penetrating liquid
Penetrating liquid may cause the following:
- Damage to the device
- Electric shock
- Device malfunctions
  ▶ Ensure that no liquid penetrates the device.

Cleaning
1. Wipe off obvious soiling with a disposable cloth soaked in surface disinfectant. Dispose of the cloth.
2. Wipe all surfaces. After that, there must no longer be any soiling visible.

Surface disinfection
3. Wipe cleaned surfaces again to visibly wet all surfaces to be disinfected with surface disinfectant.
4. Wait for the surface disinfectant contact time.
5. At the end of the contact time, moisten a new, uncontaminated and lint-free cloth with water (at least drinking water quality).
6. Wipe all surfaces until no remains of the surface disinfectant, such as foam residues or streaks, are visible.
7. Wait until the surfaces are dry.
8. Check the surfaces for visible damage and, if necessary, replace the product.

### 3.4.3 Machine cleaning with thermal disinfection

Use a washer-disinfector that meets the requirements of the standard ISO 15883. Dräger recommends the use of a load carrier for anesthesia accessories and ventilation accessories. Follow the manufacturer's instructions for the washer-disinfector.

**Components:**
- Expiratory valve
- Neonatal expiratory valve
- Inspiratory valve

<table>
<thead>
<tr>
<th>Step</th>
<th>Agent</th>
<th>Manufacturer</th>
<th>Concentration</th>
<th>Temperature</th>
<th>Contact time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary cleaning</td>
<td>Tap water</td>
<td>–</td>
<td>–</td>
<td>Tap water temperature</td>
<td>Min. 2 min</td>
</tr>
<tr>
<td>Cleaning</td>
<td>neodisher Medi- Clean forte</td>
<td>Dr. Weigert</td>
<td>Min. 0.3 %</td>
<td>Min. 55 °C (131 °F)</td>
<td>Min. 5 min</td>
</tr>
<tr>
<td>Neutralizing</td>
<td>neodisher Z</td>
<td>Dr. Weigert</td>
<td>Min. 0.1 %</td>
<td>Tap water temperature</td>
<td>Min. 1 min</td>
</tr>
<tr>
<td>Flushing</td>
<td>Demineralized water</td>
<td>–</td>
<td>–</td>
<td>Tap water temperature</td>
<td>Min. 1 min</td>
</tr>
<tr>
<td>Disinfecting</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>Min. 90 °C (194 °F)</td>
<td>Min. 5 min</td>
</tr>
<tr>
<td>Drying</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>Drying time depends on the load</td>
</tr>
</tbody>
</table>

**Prerequisites:**
- The washer-disinfector has been prepared in accordance with the manufacturer's instructions.
Positioning the expiratory valve in the load carrier

Procedure:
1. Position the expiratory valve as shown.

2. Position the components (flow sensor sleeve, diaphragm, water trap container) to be stable.

3. Ensure the following:
   – All surfaces and interior spaces can be completely rinsed.
   – The water can drain off freely.

Positioning the neonatal expiratory valve in the load carrier

Required aids:
– Hose (diameter: 12 mm (0.47 in), length: max. 50 cm (19.7 in)) to connect the neonatal expiratory valve

Procedure:
1. Connect the hose to the nozzle of the neonatal expiratory valve.

2. Connect the other end of the hose to a suitable nozzle on the load carrier.

3. Position the components (muffler, diaphragm, water trap container) to be stable.
4. Ensure the following:
   – All surfaces and interior spaces can be completely rinsed.
   – The water can drain off freely.

**Positioning the inspiratory valve in the load carrier**
The following section addresses the inspiratory valve for the ventilator Evita. The inspiratory valve for the ventilator Babylog is positioned in the same manner.

**Procedure:**
1. Position the inspiratory valve as shown.
   Example: Inspiratory valve for Evita:

2. Position the components (diaphragm with adapter, seal) to be stable.
3. Ensure the following:
   – All surfaces and interior spaces can be completely rinsed.
   – The water can drain off freely.

**Performing reprocessing**
1. Select a cycle.
2. When the cycle has ended, check the components for visible soiling and repeat the cycle if necessary.
3. Check the components for visible damage and replace if necessary.

**Supplementary information**

Dräger states that nebulization and reprocessing may result in color changes in the metal insert. Color change does not indicate that the product is not functioning correctly.

Flow sensor sleeve:
The life span of plastics is limited and depends on the way in which they are reprocessed and how frequently. If the surface is cracked, sticky, or strongly discolored or if the material has hardened, the function of the components must be checked and the component replaced, if necessary.
3.4.4 Storage and transport

After reprocessing, there are no special requirements for storage and transport of the product. However, the following must be observed:
– Store dry and free of dust
– Avoid recontamination and damage during transport

All further information on storage and transport included in the accompanying documents must be observed.

3.5 Other agents and reprocessing procedures

3.5.1 Disinfectants

Use nationally approved disinfectants suitable for the respective reprocessing procedure and field of application.

Surface disinfectants

The manufacturers of the surface disinfectants have verified at least the following spectra of activity:
– Bactericidal
– Yeasticidal
– Virucidal or virucidal against enveloped viruses

Follow the manufacturer’s instructions for surface disinfectants.

The following surface disinfectants were compatible with the material at the time of testing:

<table>
<thead>
<tr>
<th>Class of active ingredient</th>
<th>Surface disinfectant</th>
<th>Manufacturer</th>
<th>Listing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorine-releasing agents</td>
<td>Clorox Professional Disinfecting Bleach Cleaner</td>
<td>Clorox</td>
<td>EPA¹)</td>
</tr>
<tr>
<td></td>
<td>Dispatch Hospital Cleaner</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Disinfectant Towels with Bleach</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Actichlor plus</td>
<td>Ecolab</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Chlor-Clean Tablets</td>
<td>helix Solution</td>
<td>ARTG²)</td>
</tr>
<tr>
<td>Oxygen-releasing agents</td>
<td>Descogen Liquid</td>
<td>Antiseptica</td>
<td>CE</td>
</tr>
<tr>
<td></td>
<td>Descogen Liquid r.f.u.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Oxygenon Liquid r.f.u.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dismozon plus</td>
<td>BODE Chemie</td>
<td>CE</td>
</tr>
<tr>
<td></td>
<td>Oxycide</td>
<td>Ecolab USA</td>
<td>EPA</td>
</tr>
<tr>
<td></td>
<td>Perform</td>
<td>Schülke &amp; Mayr</td>
<td>CE</td>
</tr>
<tr>
<td></td>
<td>SteriMax Wipes</td>
<td>Aseptix</td>
<td>CE</td>
</tr>
<tr>
<td></td>
<td>Incidin OxyWipes</td>
<td>Ecolab USA</td>
<td>CE</td>
</tr>
<tr>
<td></td>
<td>Rubysta</td>
<td>Kyorin (Japan)</td>
<td>–</td>
</tr>
<tr>
<td></td>
<td>Rely+On Virkon</td>
<td>LANXESS Corporation</td>
<td>EPA</td>
</tr>
</tbody>
</table>
Reprocessing instructions  | Evita V series / Babylog VN series
---|---

Dräger states that oxygen-releasing agents and chlorine-releasing agents may cause color change in some materials. Color change does not indicate that the product is not functioning correctly.

Other surface disinfectants are used at one’s own risk.

### 3.5.2 Reprocessing procedures

#### 3.5.2.1 Manual cleaning followed by disinfection by immersion

Manual cleaning with subsequent disinfection by immersion can be performed for the following components:

- Expiratory valve
- Neonatal expiratory valve
- Inspiratory valve

The following disinfectants and cleaning agents were compatible with the material at the time of testing:

<table>
<thead>
<tr>
<th>Component</th>
<th>Agent</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspiratory valve, expiratory valve</td>
<td><strong>Cleaning agent:</strong> neodisher LM2</td>
<td>Dr. Weigert</td>
</tr>
<tr>
<td></td>
<td><strong>Disinfectant:</strong> Korsolex Extra</td>
<td>BODE Chemie</td>
</tr>
<tr>
<td>Neonatal expiratory valve</td>
<td><strong>Cleaning agent:</strong> Sekusept Pulver CLASSIC</td>
<td>Ecolab</td>
</tr>
<tr>
<td></td>
<td><strong>Disinfectant:</strong> Korsolex Extra</td>
<td>BODE Chemie</td>
</tr>
</tbody>
</table>

1) United States Environmental Protection Agency
2) Australian Register of Therapeutic Goods
3) Virucidal against enveloped viruses
3.5.2.2 Steam sterilization

The following components can be steam sterilized:
- Expiratory valve
- Neonatal expiratory valve
- Inspiratory valve

Procedure:
1. Sterilize the components (maximum 134 °C (273.2 °F), 5 min).
2. Check the components for visible damage and replace if necessary.

3.6 Reprocessing of patient-specific accessories

3.6.1 Categorization of accessories

<table>
<thead>
<tr>
<th>Category</th>
<th>Classification</th>
<th>Part number</th>
</tr>
</thead>
<tbody>
<tr>
<td>CO2 mainstream sensor</td>
<td>Non-critical</td>
<td>6871950 (Dräger InfinityMCable Mainstream CO2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6873570 (Dräger CO2 Mainstream Sensor)</td>
</tr>
<tr>
<td>Reusable cuvette for the CO2 sensor</td>
<td>Semi-critical</td>
<td>6870279 (for adults)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6870280 (for pediatric patients)</td>
</tr>
<tr>
<td>Expiratory flow sensor</td>
<td>Semi-critical</td>
<td>8403735 (Spirolog)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MK01900 (SpiroLife)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6871980 (Infinity ID)</td>
</tr>
<tr>
<td>Neonatal flow sensor</td>
<td>Semi-critical</td>
<td>8410185 (Y-piece)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8411130 (ISO 15)</td>
</tr>
</tbody>
</table>

Reprocessing of these reusable products is performed in accordance with the corresponding instructions for use.
3.7 After reprocessing

3.7.1 Assembling and fitting device-specific components

Prerequisites:
– All components are reprocessed and dry.

Assembling the expiratory valve or the neonatal expiratory valve

<table>
<thead>
<tr>
<th>No.</th>
<th>Expiratory valve</th>
<th>Neonatal expiratory valve</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Flow sensor sleeve</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Diaphragm</td>
<td>Diaphragm</td>
</tr>
<tr>
<td>3</td>
<td>Muffler</td>
<td>Muffler</td>
</tr>
<tr>
<td>4</td>
<td>Water trap container</td>
<td>Water trap container</td>
</tr>
</tbody>
</table>

Procedure:
1. Make sure all components are completely dry; otherwise, this may impair proper functioning.
2. Connect the flow sensor sleeve (1) to the expiratory valve or connect the muffler (3) to the neonatal expiratory valve.
3. Attach the diaphragm (2) onto the edge of the expiratory valve housing.
4. Connect the water trap container (4).
Reprocessing

Fitting the expiratory valve or the neonatal expiratory valve to the ventilator

This section addresses how to fit the expiratory valve to the ventilator Evita. The neonatal expiratory valve is fitted to the Evita and Babylog ventilators in the same manner.

Prerequisites:
- The flap on the front of the ventilator is open.

Procedure:
1. Turn the locking ring of the expiratory valve as far as possible to the left.
2. Push the expiratory valve (1) into the fitting.
3. Turn the locking ring (2) as far as possible to the right until it perceptibly clicks into place.
4. Check that it is properly secured by gently pulling on the expiratory valve.
5. Close the flap.

The expiratory valve can be reused as long as the test step in the system test is passed. Exchange the expiratory valve if signs of wear become visible, such as cracks in the plastic parts, deformation and hardening of the rubber parts. Discolorations of the metal insert do not impair its function.
Assembling the inspiratory valve
This section addresses how to assemble the inspiratory valve for the ventilator Evita. The neonatal inspiratory valve is assembled for the ventilator Babylog in the same manner.

1. Let the components (inspiratory valve, diaphragm with adapter, seal) completely dry. Otherwise, this may impair proper functioning.

2. Insert the adapter (1) of the diaphragm into the opening of the fitting (2). The adapter must be able to slightly move up and down in the opening.

3. Position the diaphragm in such a way that it is in the recesses (3) of the fitting.

4. Attach the diaphragm onto the edge of the fitting (4).

5. Attach the seal (5).
Fitting the inspiratory valve to the ventilator
This section addresses how to fit the inspiratory valve to the ventilator Evita. The neonatal inspiratory valve is fitted to the ventilator Babylog in the same manner.

1. Insert the inspiratory valve (1) into the recesses of the fitting and push it into the fitting as far as possible.

2. Turn the inspiratory valve clockwise until the lock clicks into place.

3. Check whether the inspiratory valve is properly engaged.

3.7.2 Preparation before next use of device

3.7.2.1 Assembling and fitting patient-specific accessories and consumables
- See the section "Preparing the ventilation unit" in the chapter "Assembly and preparation" in the instructions for use for the main device.

3.7.2.2 Checking the operational readiness

Prerequisites:
- The device has been assembled and prepared so that it is ready for operation.

Procedure:
1. Check the operational readiness; see the chapter "Getting started" in the instructions for use for the main device.
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