Reprocessing Guide

Expiratory valve set, autoclavable
Adult/Pediatric/Neonatal

624591/04 | 2017-03-06

REF 160245, 151972, 161175, 161188
Reprocessing guide per EN ISO 17664 (ENGLISH)

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The equipment must be operated and serviced by trained professionals only.

Definitions

- **WARNING**
  Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

- **CAUTION**
  Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

- **NOTICE**
  Emphasizes information of particular importance.
Definitions

This recommendation is valid for the following products from the Hamilton Medical accessories and consumables program. The autoclavable expiratory valve, membrane, and locking ring consist of the following materials.

<table>
<thead>
<tr>
<th>Expiratory valve set, autoclavable PN</th>
<th>Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAMILTON-C2, HAMILTON-C3, HAMILTON-C6</td>
<td></td>
</tr>
<tr>
<td>160245</td>
<td></td>
</tr>
<tr>
<td>Housing</td>
<td>Polyamide 12</td>
</tr>
<tr>
<td>Locking ring</td>
<td>Polyamide 12</td>
</tr>
<tr>
<td>Membrane</td>
<td>Silicone rubber</td>
</tr>
<tr>
<td>Cap on membrane</td>
<td>Stainless steel</td>
</tr>
<tr>
<td>HAMILTON-G5, HAMILTON-S1</td>
<td></td>
</tr>
<tr>
<td>151972</td>
<td></td>
</tr>
<tr>
<td>Housing</td>
<td>Polysulfone</td>
</tr>
<tr>
<td>Membrane</td>
<td>Silicone rubber</td>
</tr>
<tr>
<td>Cap on membrane</td>
<td>Stainless steel</td>
</tr>
<tr>
<td>HAMILTON-C1, HAMILTON-T1, HAMILTON-MR1</td>
<td></td>
</tr>
<tr>
<td>161175 (adult/pediatric)</td>
<td></td>
</tr>
<tr>
<td>161188 (neonatal)</td>
<td></td>
</tr>
<tr>
<td>Housing</td>
<td>Polycarbonate</td>
</tr>
<tr>
<td>Locking ring</td>
<td>Polyamide 12</td>
</tr>
<tr>
<td>Membrane</td>
<td>Silicone rubber</td>
</tr>
<tr>
<td>Cap on membrane</td>
<td>Stainless steel</td>
</tr>
</tbody>
</table>
Definitions

All materials used are heat resistant up to 140°C (284°F).

**WARNING**

- Clean, disinfect, and sterilize the expiratory valve set directly after use.
- Hamilton Medical cannot be held responsible for the correct functioning of expiratory valve sets that are not reprocessed and used according to these instructions.
- Ensure that only processes that have been specifically validated for the product or device are used, and that the validated parameters are used with every cycle.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Expiratory valve components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiratory valve membrane, autoclavable PN</td>
<td>HAMILTON-C2, HAMILTON-C3, HAMILTON-C4</td>
</tr>
<tr>
<td>166500 (pack of 5)</td>
<td>Membrane</td>
</tr>
<tr>
<td>Cap on membrane</td>
<td>Stainless steel</td>
</tr>
<tr>
<td>Expiratory valve membrane and housing, autoclavable PN</td>
<td>HAMILTON-C5, HAMILTON-S1</td>
</tr>
<tr>
<td>151233 (pack of 5)</td>
<td>Membrane</td>
</tr>
<tr>
<td>Cap on membrane</td>
<td>Stainless steel</td>
</tr>
<tr>
<td>151228</td>
<td>Housing</td>
</tr>
<tr>
<td>Expiratory valve membrane and locking ring, autoclavable PN</td>
<td>HAMILTON-C1, HAMILTON-T1, HAMILTON-MR1</td>
</tr>
<tr>
<td>161390 (pack of 5)</td>
<td>Membrane</td>
</tr>
<tr>
<td>Cap on membrane</td>
<td>Stainless steel</td>
</tr>
</tbody>
</table>

All materials used are heat resistant up to 140°C (284°F).
Reprocessing the autoclavable expiratory valve set in accordance with EN ISO 17664

- A used expiratory valve set must be handled as a contaminated item. Follow all local, state, and federal regulations with respect to environmental protection when disposing of used expiratory valve sets.
- Follow hospital infection control procedures, as well as local laws and regulations. This applies in particular to the various regulations regarding an effective deactivation of prions.
- Visually inspect the expiratory valve set for damage prior to use.

⚠️ CAUTION

- The autoclavable expiratory valve set has a limited life span. The expiratory valve set may be damaged due to the use of hard brushes, scouring agents, or by the exertion of too much force.
- The use of rinse aids will reduce the life span of the expiratory valve set, as it can lead to early failure and cracks in the plastic expiratory valve housing.
- The expiratory valve set must not be autoclaved if medication containing aromatic or chlorinated hydrocarbons has been applied via a nebulizer.
- (USA only): Only use EPA registered cleaning and disinfection solutions.

Reprocessing the autoclavable expiratory valve set in accordance with EN ISO 17664

Make sure that the reprocessing does not damage the steel ring and the membrane.

The steel ring is there to reinforce the membrane and to improve tightness. Make sure the ring does not get bent out of shape.

Reprocessing overview

The expiratory valve set must be cleaned, disinfected, and sterilized after each use.
After each reprocessing cycle, the expiratory valve housing must be inspected for damage. If any changes are visible, the valve must be discarded. Perform a tightness test after each reprocessing cycle. If the test fails, it may be repeated once. The expiratory valve set must be replaced if the tightness test fails the second time.

Rinse aids will cause premature damage and reduce product life span, and should not be used. Hamilton Medical does not guarantee the expiratory valve set's life span if rinse aids are used.

Figure 1  Expiratory valve components

1 Membrane  3 Expiratory valve locking ring

2 Expiratory valve housing
Disassembly

Note that expiratory valve sets for the HAMILTON-C2/C3/C6/G5/S1 comprise only two components. The locking ring is permanently attached to the housing.

Preparation and reprocessing after use

Notice

Since mechanical disinfection is more effective and consistent, manual cleaning and disinfection is only permitted when no mechanical process is available.

Reprocess the expiratory valve set immediately after use. The reprocessing cycle comprises cleaning, disinfection, and sterilization.

Remove macroscopic impurities of the expiratory valve set by rinsing or wiping. You can add an aldehyde-free disinfection agent to the rinse water. You must not use any hard tools or hard brushes to remove resilient impurities.

Prior to sterilization, the expiratory valve set must be cleaned and disinfected.

Disassembly

To disassemble the components

1. Remove the locking ring from the housing by twisting the ring counter-clockwise (1) and pulling it off of the housing (2).

   Note that expiratory valve sets for the HAMILTON-C2/C3/C6/G5/S1 comprise only two components. The locking ring is permanently attached to the housing.

2. Holding the expiratory valve housing, remove the silicone membrane by lifting it up (3).
Cleaning and disinfection

Follow the chemical concentrations and soak times as stated in the corresponding manufacturer’s Instructions for use. Only use freshly made solutions. The disinfection solution must not foam.

Use only sterile water or water with a low microorganism count for all cleaning steps. Make sure that the particulate matter concentration in the water is low.
Manual cleaning and disinfection

When in doubt, contact the manufacturer of the disinfection or cleaning agent.

Manual cleaning and disinfection

When selecting the cleaning and disinfection agent, consider whether the agents in question are suitable for the expiratory valve set. Make sure the disinfection agents’ effects are proven and the chemicals are compatible with the materials of the expiratory valve set. In addition, instructions for cleaning with the selected agents must be available.

Manual cleaning

To manually clean the components

1. Disassemble the expiratory valve set (Figure 2).
2. Submerge the expiratory valve components in the cleaning solution (for example, Neodisher Mediclean forte) and let it soak for the time defined by the manufacturer of the disinfection or cleaning agent.
   
   Make sure that all parts of the expiratory valve components are fully submerged in the solution.
3. Rinse all parts at the beginning and the end of the soak time with the cleaning agent at least five times.
4. Remove matter and larger exterior impurities by carefully scrubbing the expiratory valve components with a soft brush or soft towel.
5. Rinse the expiratory valve components at least five times intensively, or according to the validated cleaning plan, in freshly distilled or deionized water.
6. Repeat the cleaning process if the last cleaning solution was not clear or there are still visible impurities on the expiratory valve components.
Manual disinfection

**NOTICE**
Only use common disinfection agents that are recommended for use with plastics and silicone rubber.

To manually disinfect the components

1. Disassemble the expiratory valve set (Figure 2) and submerge it in the disinfection solution.
2. Let it soak for the time defined by the manufacturer of the disinfection agent (for example, CIDEX OPA). Make sure that all components of the expiratory valve set are fully submerged in the solution.
3. Rinse the expiratory valve components at the beginning and at the end of the soak time with the disinfection solution at least five times, or in accordance with the validated disinfection plan.
4. Rinse the expiratory valve components in freshly distilled or deionized water at least five times intensively, or according to the validated cleaning plan.
5. Repeat the cleaning process if the last cleaning solution was not clear or there are still visible impurities on the expiratory valve.
6. Dry the expiratory valve components with filtered, oil-free compressed air.
7. Immediately package the expiratory valve set using appropriate packaging.
Mechanical cleaning and disinfection

The expiratory valve set must be reprocessed in such a manner that hygienic and safe reuse can be assured. Cleaning / disinfection should only be carried out in a cleaning and disinfection device that complies with ISO 15883 and has been proven to be effective. Place the expiratory valve components in such a manner that it is easy to clean and the effectiveness of cleaning and disinfection is not impaired.

Figure 3 Arranging components in the device

HAMiLTON-C1/T1/MR1

HAMiLTON-C2/C3/C6
To ensure safe cleaning, the expiratory valve housing must be connected to the corresponding receptors. The expiratory valve must not disconnect from the receptor during reprocessing. Expiratory valves that disconnect during reprocessing must be processed again. After the cleaning process is complete, check that the expiratory valve is completely dry and undamaged. Damaged expiratory valve sets must be discarded.

The program parameters in Table 3 must be met for successful mechanical cleaning.

Table 3  Mechanical cleaning program parameters

<table>
<thead>
<tr>
<th>Program parameters</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-rinse</td>
<td>one cycle using cold water for 1 min</td>
</tr>
<tr>
<td>Cleaning</td>
<td>one cycle at 55°C (131°F) for 5 min</td>
</tr>
<tr>
<td>Optional neutralization</td>
<td>one cycle using cold water for 1 min</td>
</tr>
<tr>
<td>Rinsing</td>
<td>one cycle using cold water for 1 min</td>
</tr>
<tr>
<td>Thermic disinfection</td>
<td>one cycle at 83°C (181.4°F) for 10 min</td>
</tr>
<tr>
<td>Drying</td>
<td>100°C (212°F) for 10 min and 95°C (203°F) for 30 min</td>
</tr>
</tbody>
</table>
Recommended equipment and cleaning agents

**CAUTION**

Using a rinse aid will cause premature damage and reduce product life span.

Hamilton Medical recommends the DES-VAR-TD-Anaesthesia program, among others in the Miele PGB536 disinfector, together with the E436/3 injector tray.

Table 4   Supported cleaning agents

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Weigert</td>
<td>Neodisher Mediclean forte&lt;sup&gt;®&lt;/sup&gt;</td>
<td>1.00%</td>
</tr>
</tbody>
</table>

Table 5   Supported neutralizer

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Weigert</td>
<td>Neodisher Z®</td>
<td>0.10%</td>
</tr>
</tbody>
</table>

Packaging

Make sure that the expiratory valve sets are not moist during packaging.

The packaging must conform to ISO 11607 and be suitable for vapor sterilization (heat resistance up to 141.0°C (285.8°F)) and be sufficiently permeable to vapor.

Only use packaging suitable for sterilization, such as MEDIPEEL®<sup>®</sup> see-through pouches.

(USA only): For packaging, only use an FDA approved sterilization pouch.
Visual test
After each cleaning and disinfection cycle, the expiratory valve set must be macroscopically clean, that is, free of visible residual matter and other impurities. If it is not, the entire cleaning and disinfection process must be repeated.

Visually check for external damage, such as cracks, broken or deformed parts, or discoloration.

Sterilization
Sterilize the expiratory valve set after cleaning and disinfection and prior to reuse according to the following:
- 134.0°C (273.2°F) with or without prevacuum, with an exposure time of a minimum of 3 min and a maximum of 18 min

Place the expiratory valve components horizontally into the sterilizer; do not stack them. Note that Hamilton Medical is not responsible for the efficacy of any sterilization method, including but not limited to hot-air, ethylene oxide, formaldehyde, radiation, and low-temperature plasma sterilization.

Reassembly

To reassemble the components

1. Holding the expiratory valve housing, seat the silicone membrane onto the housing (1). See Figure 4.
   The metal plate must face up and be visible.
2. Align the locking ring with the bottom of the housing (2), and twist clockwise until it locks into place (3).
   Be sure not to over-tighten the expiratory valve locking ring.
Reassembly

Figure 4  Reassembling the components  
HAMILTON-C1/T1/MR1 (Adult/Ped shown)

Note that expiratory valve sets for the HAMILTON-C2/C3/C6/G5/S1 comprise only two components. The locking ring is permanently attached to the housing.
Testing before use

**WARNING**
Defective expiratory valve sets or expiratory valve sets that fail the tightness test must not be used.

Carry out a visual check and a tightness test as described in your ventilator’s Operator’s Manual. Replace defective expiratory valve sets.

**Expiratory valve life span**
As long as the expiratory valve set passes the tightness test during the preoperational check, the expiratory valve set can be used. Tests and calibrations must be carried out as specified in the ventilator’s Operator’s Manual.

It is the user’s responsibility to validate the processes used if the reprocessing procedures used differ from those in this guide.

**Autoclaved and packaged expiratory valve: life span and storage conditions**
The life span of an autoclaved and packaged expiratory valve set depends on how long the packaging can keep the expiratory valve set sterile. Follow the packaging manufacturer’s specifications. At a minimum, the expiratory valve set must be autoclaved every two years. Storage is subject to the same guidelines as the Hamilton Medical ventilator, as specified in your ventilator Operator’s Manual.

**Disposal**
A used expiratory valve set must be handled as a contaminated item. Follow all local, state, and federal regulations with respect to environmental protection when disposing of used expiratory valve sets.