# High-Level Disinfection Guide

This guide is intended for multi-patient use of a Fisher & Paykel Healthcare Mask in the hospital or other clinical setting where proper disinfection of the device must occur between patient uses. If you use the mask as a single-patient user in the home, please refer to your mask Instructions For Use for cleaning instructions.

### General Warnings and Cautions
- Do not iron the headgear as the material is heat sensitive and will be damaged.
- Do not clean the mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer.
- Do not dry or store the mask in direct sunlight.
- Do not wash the mask in a dishwasher.
- The above actions may deteriorate or damage the mask and shorten its life. If your Fisher & Paykel Healthcare Mask weakens or cracks, discontinue use and seek replacement immediately.

**Disclaimer:** It is the user’s responsibility to qualify any deviations from the recommended methods of reprocessing. Contact your local homecare provider for additional information.

### Cleaning the headgear
The headgear does not require disinfection. Thoroughly washing the headgear between patients is acceptable.

1. Hand-wash the headgear in soap. Do not soak for longer than 10 minutes.
2. Rinse well in fresh water and allow it to air-dry out of direct sunlight.

**Components that cannot be disinfected**
The following components cannot be disinfected and should be replaced between patients:
- Foam Cushion
- Diffusers
- Contoured Mask Frame

### Components that cannot be disinfected

<table>
<thead>
<tr>
<th>Component</th>
<th>Thermal Disinfection</th>
<th>Hexanios G+R®</th>
<th>CIDEX® OPA</th>
<th>Autoclave</th>
<th>Sterrad® 100S &amp; 100NX</th>
<th>Sporox® II</th>
</tr>
</thead>
<tbody>
<tr>
<td>F&amp;P Eson Nasal Mask (excluding Diffuser)</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F&amp;P Zest Q Nasal Mask (excluding Foam Cushion and Diffuser)</td>
<td>✓</td>
<td>Soak for 10 minutes (107 °F)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F&amp;P Lady Zest Nasal Mask</td>
<td>✓</td>
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</tr>
<tr>
<td>FlexiFit 405/406/407 Nasal Mask (excluding Foam Cushion and Diffuser)</td>
<td>✓</td>
<td>Soak for 30 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aclaim2 Nasal Mask (excluding Foam Cushion and Diffuser)</td>
<td>✓</td>
<td>Soak for 30 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F&amp;P Simplus Full Face Mask</td>
<td>✓</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Forma Full Face Mask (excluding Foam Cushion)</td>
<td>✓</td>
<td>Soak for 30 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FlexiFit 431 Full Face Mask (excluding Foam Cushion)</td>
<td>✓</td>
<td>Soak for 30 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F&amp;P Pilairo Q Nasal Pillows Mask</td>
<td>✓</td>
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<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Opus360 Nasal Pillows Mask (excluding Contoured Mask Frame)</td>
<td>✓</td>
<td>Soak for 30 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oracle Oral Mask</td>
<td>✓</td>
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</tbody>
</table>

See overleaf for more information.
Your Fisher & Paykel Healthcare Mask is provided patient-ready. To reuse between patients please select one of the procedures below.

All masks have been validated for 20 cycles.

## PROCEDURES

<table>
<thead>
<tr>
<th>Thermal Disinfection</th>
<th>Hexanios G+R®</th>
<th>CIDEX® OPA at 20°C (68°F)</th>
<th>Autoclave Sterrad® 100S &amp; 100NX</th>
<th>Sterrad® &amp; 100NX at 20°C (68°F)</th>
</tr>
</thead>
</table>

### Disassembly
Disassemble the mask according to the instructions shown in the relevant mask’s Instructions For Use.

### Cleaning and Drying
- Clean all surfaces of the mask and components with a soft-bristled brush and soap. Ensure all visible soil is removed.
- Rinse thoroughly under running potable water to remove soap.
- Allow the mask components to thoroughly air-dry out of direct sunlight before processing with High-Level Disinfection.

**FAILURE TO PROPERLY CLEAN THE MASK MAY RESULT IN INADEQUATE DISINFECTION.**

### High-Level Disinfection and Drying

1. **Using a certified Hot Water Disinfection System,** soak those components of the mask that can be disinfected.
   - See overleaf for appropriate mask validated temperatures and times.
2. On completion, remove the mask components from the Hot Water Disinfection System.
3. Allow the mask components to air-dry out of direct sunlight.
4. Store in clean conditions.

1. Soak those components of the mask that can be disinfected in the Hexanios G+R® Solution according to the manufacturer’s instructions.
2. Rinse the mask components thoroughly in potable water.
3. Allow the mask components to air-dry out of direct sunlight.
4. Store in clean conditions.

1. Immerse those components of the mask that can be disinfected in the CIDEX® OPA Solution according to the manufacturer’s instructions.
2. Rinse the mask components thoroughly in potable water.
3. Allow the mask components to air-dry out of direct sunlight.
4. Store in clean conditions.

1. Enclose those components of the mask that can be disinfected in the Sterrad® OPA as described in the instructions for the autoclave.
2. Place in the autoclave for the required time.
3. Rinse for appropriate mask validated times.
4. Remove the components from the autoclave.
5. Store in clean conditions.

1. Package the mask components prior to sterilization as described in the manufacturer’s instructions for the Sterrad® 100S or 100NX Sterilization System.
2. Disinfect the mask following the manufacturer’s instructions for the Sterrad® 100S or 100NX Sterilization System.
3. See overleaf for appropriate mask Sterrad® validated times.
4. Remove the components from the Sterrad® 100S or 100NX Sterilization System.
5. Store in clean conditions.

### Inspection
Before each use: Inspect the mask for deterioration. If any visible deterioration of a mask component is apparent, the mask component should be discarded and replaced. Some discoloration may occur after reprocessing and is acceptable.

### Reassembly
Reassemble the mask according to the instructions shown in the relevant mask Instructions For Use.

### Packaging and Storage
Do not store the mask in direct sunlight. Store in clean conditions.

**Storage Temperature: F&P Pilairo and F&P Eson:** -20 °C to 50 °C (-4 °F to 122 °F). All other masks: -20 °C to 60 °C (-4 °F to 140 °F).

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