














# 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.

		Thermal Disinfection	Hexanios G+R®	CIDEX® OPA	Autoclave	Sterrad® 100S & 100NX	Sporox® II
		Soak parts in hot-water bath.	Follow manufacturer's instructions.	Follow manufacturer's instructions for high-level disinfection. Immerse at 20 °C (68 °F). Rinse thoroughly in potable water.	Gravity displacement-type autoclave at 121 °C (250 °F). Enclose components in a sterilization peel pouch.	Dry thoroughly before disinfecting. Follow manufacturer's instructions for the Sterrad® 100S or 100NX Sterilization System.	Follow manufacturer's instructions for high-level disinfection. Immerse at 20 °C (68 °F). Rinse thoroughly in potable water.
See overleaf for more information.							
	<b>F&amp;P Eson™</b> Nasal Mask (excluding Diffuser)	✓ 10 minutes at 80 °C (176 °F)	✓ Soak for 30 minutes				
	<b>F&amp;P Zest™ Q</b> <b>F&amp;P Lady Zest™ Q</b> Nasal Mask (excluding Foam Cushion and Diffuser)	✓ 10 minutes at 80 °C (176 °F)	✓ Soak for 30 minutes			100S	
	<b>Zest™</b> Nasal Mask (excluding Foam Cushion)	✓ 30 minutes at 70 °C (158 °F)	✓ Soak for 30 minutes	✓ Soak for 30 minutes		100S	
	<b>FlexiFit™ 405/406/407</b> Nasal Mask (excluding Foam Cushion and Diffuser)	✓ 30 minutes at 70 °C (158 °F)		✓ Soak for 12 minutes	✓ 15-minute exposure	100S	✓ Soak for 6 hours
	<b>Aclaim®2</b> Nasal Mask (excluding Foam Cushion and Diffuser)	✓ 30 minutes at 70 °C (158 °F)		✓ Soak for 30 minutes	✓ 30-minute exposure. Note: Do not autoclave the FlexiTube	100S	✓ Soak for 6 hours
	<b>F&amp;P Simplus™</b> Full Face Mask	✓ 10 minutes at 80 °C (176 °F)					
	<b>Forma™</b> Full Face Mask (excluding Foam Cushion)	✓ 30 minutes at 70 °C (158 °F)	✓ Soak for 30 minutes	✓ Soak for 30 minutes		100S & 100NX	
	<b>FlexiFit 432</b> Full Face Mask (excluding Foam Cushion)	✓ 30 minutes at 75 °C (167 °F)		✓ Soak for 60 minutes	✓ 30-minute exposure	100S	
	<b>FlexiFit 431</b> Full Face Mask	✓ 30 minutes at 75 °C (167 °F)		✓ Soak for 3 hours	✓ 30-minute exposure	100S	
	<b>F&amp;P Pilairo™ Q</b> Nasal Pillows Mask	✓ 10 minutes at 80 °C (176 °F)					
	<b>Opus™360</b> Nasal Pillows Mask (excluding Contoured Mask Frame)	✓ 30 minutes at 75 °C (167 °F)		✓ Soak for 30 minutes		100S	
	<b>Oracle™</b> Oral Mask	✓ 10 minutes at 80 °C (176 °F)		✓ Soak for 30 minutes			✓ Soak for 30 minutes

## 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.

- Hand-wash the headgear in soap. Do not soak for longer than 10 minutes.
- 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

# Validated High-Level Disinfection Procedures

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					
	Thermal Disinfection	Hexanios G+R®	CIDEX® OPA at 20 °C (68 °F)	Autoclave Gravity displacement-type autoclave at 121 °C (250 °F)	Sterrad® 100S & 100NX	Sporox® II at 20° C (68 °F)
<b>Disassembly</b>	Disassemble the mask according to the instructions shown in the relevant mask's Instructions For Use.					
<b>Cleaning and Drying</b>	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. <b>FAILURE TO PROPERLY CLEAN THE MASK MAY RESULT IN INADEQUATE DISINFECTION.</b>					
<b>High-Level Disinfection and Drying</b>	<ol style="list-style-type: none"> <li>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.</li> <li>On completion, remove the mask components from the Hot Water Disinfection System.</li> <li>Allow the mask components to air-dry out of direct sunlight.</li> <li>Store in clean conditions.</li> </ol>	<ol style="list-style-type: none"> <li>Soak those components of the mask that can be disinfected in the Hexanios G+R® Solution according to the manufacturer's instructions. See overleaf for appropriate mask validated times.</li> <li>Rinse the mask components thoroughly in potable water.</li> <li>Allow the mask components to air-dry out of direct sunlight.</li> <li>Store in clean conditions.</li> </ol>	<ol style="list-style-type: none"> <li>Immerse those components of the mask that can be disinfected in the CIDEX® OPA Solution according to the manufacturer's instructions. See overleaf for appropriate mask validated times.</li> <li>Rinse the mask components thoroughly in potable water.</li> <li>Allow the mask components to air-dry out of direct sunlight.</li> <li>Store in clean conditions.</li> </ol>	<ol style="list-style-type: none"> <li>Enclose those components of the mask that can be disinfected in a sterilization peel pouch as described in the instructions for the autoclave.</li> <li>Place in the autoclave for the required time. See overleaf for appropriate mask validated times.</li> <li>Remove the components from the autoclave.</li> <li>Store in clean conditions.</li> </ol>	<ol style="list-style-type: none"> <li>Package the mask components prior to sterilization as described in the manufacturer's instructions for the Sterrad® 100S or 100NX Sterilization System.</li> <li>Disinfect the mask following the manufacturer's instructions for the Sterrad® 100S or 100NX Sterilization System. See overleaf for appropriate mask Sterrad® Sterilization System.</li> <li>Remove the components from the Sterrad® 100S or 100NX Sterilization System.</li> <li>Store in clean conditions.</li> </ol>	<ol style="list-style-type: none"> <li>Immerse those components of the mask that can be disinfected in the Sporox® II Solution according to the manufacturer's instructions. See overleaf for appropriate mask validated times.</li> <li>Rinse the mask components thoroughly in potable water.</li> <li>Allow the mask components to air-dry out of direct sunlight.</li> <li>Store in clean conditions.</li> </ol>
<b>Inspection</b>	<b>Before each use:</b> 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.					
<b>Reassembly</b>	Reassemble the mask according to the instructions shown in the relevant mask Instructions For Use.					
<b>Packaging and Storage</b>	Do not store the mask in direct sunlight. Store in clean conditions. <b>Storage Temperature:</b> 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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