











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	CIDEX® OPA	Autoclave	Sterrad® 100S & 100NX	Sporox® II
		Soak parts in hot-water bath.	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.						
	F&P Zest™ Q F&P Lady Zest™ Q Nasal Mask (excluding Foam Cushion and Diffuser)	✓ 10 minutes at 80 °C (176 °F)			100S	
	Zest™ Nasal Mask (excluding Foam Cushion)	✓ 30 minutes at 70 °C (158 °F)	✓ Soak for 30 minutes		100S	
	FlexiFit™ 405/406/407 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
	Aclaim®2 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
	Forma™ Full Face Mask (excluding Foam Cushion)	✓ 30 minutes at 70 °C (158 °F)	✓ Soak for 30 minutes		100S & 100NX	
	FlexiFit 432 Full Face Mask (excluding Foam Cushion)	✓ 30 minutes at 75 °C (167 °F)	✓ Soak for 60 minutes	✓ 30-minute exposure	100S	
	FlexiFit 431 Full Face Mask	✓ 30 minutes at 75 °C (167 °F)	✓ Soak for 3 hours	✓ 30-minute exposure	100S	
	Opus™360 Nasal Pillows Mask (excluding Contoured Mask Frame)	✓ 30 minutes at 75 °C (167 °F)	✓ Soak for 30 minutes		100S	
	Oracle™ 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.

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

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	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)
Disassembly	Disassemble the mask according to the instructions shown in the relevant mask's Instructions For Use.				
Cleaning and Drying	<p>Clean all surfaces of the mask and components with a soft-bristled brush and soap. Ensure all visible soil is removed.</p> <p>Rinse thoroughly under running potable water to remove soap.</p> <p>Allow the mask components to thoroughly air-dry out of direct sunlight before processing with High-Level Disinfection.</p> <p>FAILURE TO PROPERLY CLEAN THE MASK MAY RESULT IN INADEQUATE DISINFECTION.</p>				
High-Level Disinfection and Drying	<ol style="list-style-type: none"> 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. On completion, remove the mask components from the Hot Water Disinfection System. Allow the mask components to air-dry out of direct sunlight. Store in clean conditions. 	<ol style="list-style-type: none"> 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. Rinse the mask components thoroughly in potable water. Allow the mask components to air-dry out of direct sunlight. Store in clean conditions. 	<ol style="list-style-type: none"> Enclose those components of the mask that can be disinfected in a sterilization peel pouch as described in the instructions for the autoclave. Place in the autoclave for the required time. See overleaf for appropriate mask validated times. Remove the components from the autoclave. Store in clean conditions. 	<ol style="list-style-type: none"> Package the mask components prior to sterilization as described in the manufacturer's instructions for the Sterrad® 100S or 100NX Sterilization System. Disinfect the mask following the manufacturer's instructions for the Sterrad® 100S or 100NX Sterilization System. See overleaf for appropriate mask Sterrad® Sterilization System. Remove the components from the Sterrad® 100S or 100NX Sterilization System. Store in clean conditions. 	<ol style="list-style-type: none"> 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. Rinse the mask components thoroughly in potable water. Allow the mask components to air-dry out of direct sunlight. 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	<p>Do not store the mask in direct sunlight. Store in clean conditions.</p> <p>Storage Temperature: -20 °C to 60 °C (-4 °F to 140 °F).</p>				

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