

# Disinfection and Sterilization Guide

This guide is intended for multi-patient use of a Fisher & Paykel Healthcare mask in the hospital, or other clinical settings, where proper disinfection/sterilization of the device must occur between patients. If you use the mask as a single-patient user in the home, please refer to your mask user instructions under “Cleaning your mask at home”.

**Note:** Only masks listed in the table below have been validated according to these instructions for reprocessing between patients

Mask	Replace these parts with new parts between patients	High level thermal disinfection <i>In line with EN ISO 15883, the uncertainty range for disinfection temperature is -0°C and +5°C</i>			High level chemical disinfection	Sterilization	Validated number of cycles
		1min at 90 °C (194 °F)	10mins at 80 °C (176 °F)	30mins at 75 °C (167 °F)	CIDEX® OPA <sup>1</sup> , MetriCide™ OPA Plus <sup>2</sup> or Rapicide® OPA/28 <sup>3</sup> .	Sterrad® <sup>4</sup> .	

## Nasal masks

F&P Eson™ 2	Diffuser; Seal - see note under Cidex OPA	✓	✓	✓	✓ (Replace seal)	100S, 100NX, NX	20
F&P Eson™	Diffuser mats; Seal - see note under Cidex OPA	✓	✓	✓	✓ (Replace seal if discolours)	100S, 100NX, NX	20

## Full Face masks

F&P Simplus™	Seal - see note under Cidex OPA		✓		✓ (Replace seal if discolours)	100S, 100NX, NX	20
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## Nasal Pillow masks

F&P Brevida™	Diffuser	✓	✓	✓	✓ (Replace seal. Replace tube if discolours)	100S, 100NX, NX	20
F&P Pilairo™ Q	Diffuser mats		✓	✓			20

1. Product of Advanced Sterilization Products, division of Ethicon Inc., a Johnson & Johnson company.

2. Product of Metrex™ Research, LLC.

3. Product of Medivators Inc.

4. Product of Advanced Sterilization Products, division of Ethicon Inc., a Johnson & Johnson company.

## Validated disinfection and sterilization procedures

<b>Point of Use</b>	Remove any gross soiling on the mask by wiping or rinsing in potable water.		
<b>Disassembly</b>	Disassemble the mask according to the instructions shown in the relevant mask's Instructions For Use.		
<b>Cleaning</b>	Masks should always be properly cleaned before further reprocessing is undertaken, failure to do this may result in ineffective disinfection/sterilization.		
	Soak all reprocessable parts of the mask in a solution of mildly alkali, anionic detergent e.g. Alconox <sup>5</sup> according to the manufacturer's instructions (at 1% concentration and 50°C for 10mins), ensuring that no air bubbles are present on the device surface. Using a soft non-metallic brush (e.g. medium-hard toothbrush)*, vigorously brush the mask parts until visibly clean but not for less than 10 seconds. Pay close attention to crevices and cannulations, such as the join between the silicone seal and plastic housing and the socket between the elbow and frame, and elbow and tube. Rinse by submerging in 5 litres of demineralised water and agitating for at least 10 seconds. Repeat rinse. <i>*An additional thin bottle brush is required to access the inside of the Brevida Nasal Pillows Mask tube.</i>		
<b>Drying</b>	Make sure mask components are thoroughly dry before continuing, to ensure effective disinfection/sterilization. This can be done with a lint-free cloth, or by leaving to air dry out of direct sunlight.		
<b>Disinfection or Sterilization</b>	<b>High Level Thermal Disinfection</b>	<b>High Level Chemical Disinfection</b>	<b>Sterilization</b>
	<b>For all reprocessable components:</b>		
	Soak in a water bath or run a disinfection cycle in an automatic washer-disinfector using one of the time/temperature combinations shown on the front page of this guide. These time/temperature combinations are consistent with EN ISO 15883 and are equivalent in terms of known thermal inactivation kinetics of vegetative micro-organisms, meeting an A <sub>0</sub> of 600.	1. Immerse completely in an undiluted bath of CIDEX® OPA, MetriCide™ OPA Plus or Rapicide® OPA/28 at 20°C for 12 minutes, ensuring that no air bubbles are present on the device surface.  2. Rinse thoroughly following the manufacturer's rinsing instructions.	Utilize a STERRAD NX, 100S or 100NX Sterilization System according to the manufacturer's instructions, using the pouch method.
<b>Drying</b>	Allow all components to air dry out of direct sunlight.		
<b>Inspection</b>	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 discolouration may occur after reprocessing and is acceptable.		
<b>Reassembly</b>	Reassemble the mask according to the instructions shown in the relevant mask's Instructions For Use, or Use and Care Guide.		
<b>Storage</b>	Ensure the mask is completely dry before storing. Store in clean conditions out of direct sunlight. Storage temperature: -20°C to 50°C (-4°F to 122°F)		
<b>Cleaning the Headgear</b>	The headgear does not require disinfection or sterilization. Thoroughly washing the headgear between patients is acceptable. 1. Hand-wash the Headgear Assembly in soap dissolved in lukewarm water. Do not soak for more than 10 minutes. 2. Rinse thoroughly with fresh water, ensuring that all soap residue is removed. 3. Leave all parts to air dry out of direct sunlight before reassembling.		
<b>General Warnings and Cautions</b>	The instructions provided above have been validated as being capable of preparing the masks for re-use. Fisher & Paykel Healthcare does not recommend any deviations from the recommended method of reprocessing. The following actions may deteriorate or damage the mask and shorten its life: <ul style="list-style-type: none"> <li>Do not iron the headgear</li> <li>Do not clean the mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer.</li> <li>Do not wash the mask in a dishwasher.</li> </ul> <b>NB. If your Fisher &amp; Paykel Healthcare mask weakens or cracks, discontinue use and seek replacement immediately.</b>		

5. Product of Alconox Inc.

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