

This guide is intended for multi-patient use of Fisher & Paykel Evora™ Nasal 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”.

Mask Components	Thermal Disinfection <i>In line with EN ISO 15883, the uncertainty range for disinfection temperature is -0°C and +5°C</i>			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 ¹ , MetriCide™ OPA Plus ² or Rapicide® OPA/28 ³ .	Sterrad® ⁴ .	
F&P Evora Nasal mask (excluding headgear)	✔	✔	✔	✔ (Replace seal if discolours)	-	25
F&P Evora Nasal Headgear*	✔	✔	✔	-	-	25

* If contaminated with blood, please replace the contaminated component between patients.

Validated disinfection and sterilization procedures

Point of Use	Remove any gross soiling on the mask by wiping or rinsing in potable water.
Disassembly	Disassemble the mask according to the Disassembling your Mask and the Advanced Assembly/Disassembly instructions provided in the Evora Nasal Use and Care Guide.
Cleaning	<p>Masks should always be properly cleaned before further reprocessing is undertaken, failure to do this may result in ineffective disinfection/sterilization.</p> <p>Disassemble the mask according to the Disassembling Your Mask instructions and the advance instructions below. Soak all reprocessable parts of the mask and headgear assembly in a solution of mildly alkali, anionic detergent e.g. Alconox™⁵ 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 for no less than 10 seconds and headgear for no less than 30 seconds. Brush until visibly clean paying close attention to crevices, cavities and corners, such as the join between the silicone seal and plastic housing. Rinse headgear under running water for at least 30 seconds, intermittently wringing the fabric. Submerge headgear and mask parts separately in 5 litres of demineralised water each, agitating the mask parts for at least 10 seconds and agitating and squeezing headgear for at least 30 seconds. Repeat submerged rinse. Repeat as necessary to ensure that all detergent residue is removed. Ensure mask components are air-dried thoroughly before continuing.</p> <p>*An additional thin bottle brush is required to access the inside of the Evora Nasal mask tube.</p>
Drying	Make sure mask components are thoroughly dry before continuing by leaving to air dry out of direct sunlight. Failure to do this may result in ineffective chemical disinfection/sterilization.

	Thermal Disinfection	Chemical Disinfection	Sterilization
Disinfection or Sterilization	For all reprocessible components:		
	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 ₀ of 600.	<ol style="list-style-type: none"> 1. Immerse completely in an undiluted bath of CIDEX® OPA, MetriCide™ OPA Plus or Rapicide® OPA/28 at 20 °C (68 °F) for 12 minutes, ensuring that no air bubbles are present on the device surface. 2. Rinse thoroughly following the manufacturer's rinsing instructions. 	-
Drying	Allow all components to air dry out of direct sunlight.		
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 discolouration may occur after reprocessing and is acceptable.		
Reassembly	Reassemble the mask according to the Assembling your Mask and the Advanced Assembly/Disassembly instructions given in the Evora Nasal Use and Care Guide.		
Storage	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).		
General Warnings and Cautions	<p>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:</p> <ul style="list-style-type: none"> • Do not iron the headgear • Do not clean the mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer. • Do not wash the mask in a dishwasher. • Do not store or dry the mask in direct sunlight. <p>NB. If your Fisher & Paykel Healthcare mask weakens or cracks, discontinue use and seek replacement immediately.</p>		

1. Cidex is a registered trademark of Advanced Sterilization Products, a division of Ethicon Inc., a Johnson & Johnson Company. Product of Metrex™ Research, LLC.
2. MetriCide is a registered trademark of Metrex Research
3. Rapicide is a registered trademark of Medivators Inc.
4. Sterrad is a registered trademark of Advanced Sterilization Products, a division of Ethicon Inc., a Johnson & Johnson Company
5. Alconox is a trademark of Alconox, Inc.

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