



This guide is intended for multi-patient use of the F&P Evora™ Full Face mask in the hospital, or other clinical settings, where proper disinfection or sterilization of the device must occur between patients. When using the mask for single-patient use in the home, please refer to your Evora Full Use and Care Guide 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  CIDEX® OPA <sup>1</sup> , MetriCide™ OPA Plus <sup>2</sup> or Rapicide® OPA/28 <sup>3</sup>	Sterilization  Sterrad® <sup>4</sup>
	1 min at 90 °C (194 °F)	10 mins at 80 °C (176 °F)	30 mins at 75 °C (167 °F)		
F&P Evora Full Face Mask • Frame	Replace these parts with new parts between patients				
• Seal* • Tube • Swivel	15 cycles	-	-	25 cycles	-
F&P Evora Full Face Headgear • Headgear** • Headgear clips** • Frame clip**	25 cycles	-	-	-	-

\*Replace seal if it discolors.

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



Each cycle is limited to one day of use.

### General Warnings and Cautions

The instructions provided in this guide 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.

<b>Warning</b>	Deviations from the recommended methods of reprocessing may result in inadequate disinfection/sterilization and adverse health effects.
<b>Warning</b>	Frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified in the accompanying documents or exceeding the number of processing cycles, can have an adverse effect on the mask and consequently the safety or the quality of the therapy.
<b>Caution</b>	Only clean the mask with cleaning products specified in the cleaning instructions of this guide, as any other products may result in an adverse reaction if cleaning residue is left behind.
<b>Caution</b>	Do not clean the mask with products containing alcohol, antibacterial agents, antiseptic, bleach, chlorine or moisturizer as these may compromise the function of the mask.
<b>Caution</b>	Do not clean the mask in a dishwasher as this may compromise the function of the mask.

## 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 Disassembling your Mask and the Advanced Disassembly instructions provided in the Evora Full Use and Care Guide.  <b>Caution:</b> Failure to fully disassemble the mask may compromise the effectiveness of cleaning and the subsequent disinfection/sterilization steps which may result in a range of harms, some of which are severe.			
<b>Cleaning</b>	Masks should always be properly cleaned before further reprocessing.  <b>Warning:</b> Failure to properly clean this device may result in ineffective disinfection/sterilization and adverse health effects.			
	<i>Cleaning the mask</i>	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 10 mins), ensuring that no air bubbles are present on the device surface.		
	<i>Seal, Tube, Swivel</i>	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. An additional narrow bottle brush is required to access the Tube. Pay close attention to crevices and cannulations, such as the join between the silicone seal and plastic housing. Rinse by submerging in 5 liters of demineralised water and agitating for at least 10 seconds. Repeat rinse.		
	<i>Headgear, Headgear Clips, Frame Clip</i>	Using a soft non-metallic brush, e.g. medium-hard toothbrush, scrub the headgear and clips until visibly clean but not for less than 30 seconds. Pay close attention to crevices, cavities and corners. Rinse under running water for at least 30 seconds, intermittently wringing the fabric. Submerge in 5 liters of demineralised water while agitating and squeezing for at least 30 seconds. Repeat submerged rinse. Ensure that all detergent residue is removed by repeating submerged rinse as many times as necessary.		
	Ensure the mask is visually clean before continuing. If not, repeat the cleaning step above.			
<b>Drying</b>	Make sure mask components are thoroughly dry before continuing by leaving them to air dry out of direct sunlight. Failure to do this may result in ineffective chemical disinfection/sterilization.			
<b>Disinfection or Sterilization</b>		<b>Thermal Disinfection</b>	<b>Chemical Disinfection</b>	
		<b>For all reprocessable components:</b>		
	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 microorganisms, meeting an A <sub>0</sub> of 600.	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. Rinse thoroughly following the manufacturer's rinsing instructions.	Run a standard cycle in a STERRAD NX, 100S or 100NX Sterilization System according to the manufacturer's instructions.	
<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.			
<b>Reassembly</b>	Reassemble the mask according to the Assembling your Mask and the Advanced Assembly instructions given in the Evora Full 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).			

1. Cidex is a registered trademark of Advanced Sterilization Products, a division of Ethicon Inc., a Johnson & Johnson Company.
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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