

This guide is intended for multi-patient use of Fisher & Paykel Vitera™ Full Face 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 Vitera mask components listed in the table below have been validated according to these instructions for reprocessing between patients

Mask Components	Replace these parts with new parts between patients	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 ¹ , MetriCide™ OPA Plus ² or Rapicide® OPA/28 ³ .	Sterilization Sterrad® ⁴ .	Validated number of cycles
		1min at 90 °C (194 °F)	10mins at 80 °C (176 °F)	30mins at 75 °C (167 °F)			
F&P Vitera Full Face mask • Seal* • Frame • Swivel	Elbow	✓	✓	✓	✓	✓	20
F&P Vitera Headgear • Headgear** • Headgear clips** • Forehead clips**		✓	✓	✓	-	-	20

*Replace seal if it discolours.

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

Validated disinfection and sterilization procedures

Point of Use (optional)	Any gross soiling on the mask may be removed by wiping or rinsing with potable water.	
Disassembly	Disassemble the mask according to the Disassembly for Cleaning and the Advanced Assembly/Disassembly instructions given in the Vitera Use and Care Guide.	
Cleaning	<i>Cleaning the mask</i>	Soak all reprocessable parts of the mask 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 until visibly clean but not for less than 10 seconds. Pay close attention to crevices, cavities and corners, such as the join between the silicone seal and plastic housing. Rinse by submerging in 5 litres of demineralised water and agitating for at least 10 seconds. Repeat rinse.
	<i>Cleaning the headgear</i>	Soak the headgear assembly in a solution of mildly alkali, anionic detergent e.g. Alconox, 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), 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 litres of demineralised water while agitating and squeezing for at least 30 seconds. Repeat submerged rinse. Repeat submerged rinse as necessary to ensure that all detergent residue is removed.
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 for 12 minutes, ensuring that no air bubbles are present on the device surface. 2. Rinse thoroughly following the manufacturer's rinsing instructions. 	Place the disassembled mask components in an APTIMAX® 6 Instrument Tray. Wrap the tray in one sheet of 2-ply or two sheets of 1-ply H400 Sterilization Wrap. Do not stack mask components within the tray or wrap mask components within the wrapped tray. Do not stack trays within trays or trays on top of each other. Run a standard cycle in a STERRAD NX or 100NX Sterilization System or a short cycle in a STERRAD 100S Sterilization System according to the manufacturer's 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.		
Reassembly	Reassemble the mask according to the Mask Assembly and the Advanced Assembly/Disassembly instructions given in the Vitera 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 as it may result in inadequate disinfection/sterilization and adverse health effects:</p> <ul style="list-style-type: none"> • Frequency of cleaning, methods of cleaning or the use of cleaning agents, other than those specified, 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. • 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. • 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. • Do not clean the mask in a dishwasher as this may compromise the function of the mask. • Do not clean the mask with products containing alcohol, anti-bacterial agents, antiseptic, bleach, chlorine or moisturizer as these may compromise the function of the mask. <p>NB. If your Fisher & Paykel Healthcare mask weakens or cracks, discontinue use and seek replacement immediately.</p>		

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.
5. Product of Alconox Inc.

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