

This guide is intended for multi-patient use of the F&P Solo™ 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 F&P Solo Use and Care Guide under ‘Cleaning Your Mask at Home’.

Mask Components	Thermal Disinfection In line with EN ISO 15883, the uncertainty range for disinfection temperature is -0 °C and +5 °C		
	1 min at 90 °C (194 °F)	10 mins at 80 °C (176 °F)	30 mins at 75 °C (167 °F)
F&P Solo Mask Headgear	Replace these parts with new parts between patients		
<ul style="list-style-type: none"> - Frame - Tube - Swivel - Nasal Cushion* - Pillows Cushion* 	-	Maximum 25 Cycles	Maximum 25 Cycles

*Replace cushion if it discolors.
Each cycle is limited to one day of use.

⚠ General Warnings and Cautions

The guidelines 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.	
Warning	Deviations from the recommended methods of reprocessing may result in inadequate disinfection/sterilization and adverse health effects.
Warning	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.
Caution	Only clean the mask with cleaning products specified in the cleaning guidelines provided in these instructions, as any other products may result in an adverse reaction if cleaning residue is left behind.
Caution	Do not clean the mask with products containing alcohol, antiseptic, bleach, chlorine, or moisturizer as these may compromise the function of the mask.
Caution	Do not clean the mask in a dishwasher as this may compromise the function of the mask.

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 guidelines provided in the F&P Solo Use and Care Guide. ⚠ Caution: Failure to fully disassemble the mask may compromise the effectiveness of cleaning and the subsequent disinfection steps which may result in a range of harms, some of which are severe may compromise the effectiveness of cleaning and the subsequent disinfection steps which may result in a range of harms, some of which are severe.
Cleaning	Masks should always be properly cleaned before further reprocessing. ⚠ WARNING: Failure to properly clean this device may result in ineffective disinfection/sterilization and adverse health effects.
	1. Soak all reprocessable parts in a solution of mild alkaline anionic detergent according to the manufacturer's instructions (e.g. Alconox™ ¹ at 1% concentration and 50 °C) for 5 minutes, ensuring that no air bubbles are present on the device surface.
	2. Using a soft non-metallic brush (e.g. medium-hard toothbrush), vigorously brush the mask parts until visibly clean but not for less than 30 seconds. An additional narrow bottle brush is required to access the Mask Tube. Brush the components while submerged and out of the solution. Pay close attention to crevices, cavities and corners, such as the join between the silicone cushion and plastic surrounds and the internal surfaces of the frame.
	3. Vigorously brush the joint between the frame and tube alternating between the inside and outside surfaces for at least 30 seconds.
	4. Manually rotate the swivel for at least 10 seconds, while submerged in the detergent solution.
	5. Repeat steps 1 to 4 (total soaking time of 10 minutes).
	6. Rinse by submerging in 5 liters of fresh demineralised water and agitating for at least 10 seconds. Repeat rinse.
	7. Manually rotate the swivel for at least 10 seconds, while submerged in the demineralised water.
8. Ensure the mask is visibly clean before continuing. If not, repeat steps 1-7.	
Drying	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 disinfection.
Disinfection or Sterilization	Thermal Disinfection
	For all reprocessable components:
	Run a disinfection cycle in a legally marketed automatic washer-disinfector using one of the time/temperature combinations shown in the table above. 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 ₀ of 600
Caution	The use of STERRAD™ ² or Autoclave as a reprocessing method may lead to mask degradation and adverse health effects.
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 Assembling your Mask guidelines provided in the F&P Solo Use and Care Guide. To ensure traceability, mask components belonging to an individual mask must be reassembled back into the same mask after cleaning, excluding components requiring replacement as marked in the table above.
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).

1. Alconox is a trademark of Alconox, Inc.

2. Sterrad is a registered trademark of ASP Global Manufacturing GmbH.

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