




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 patient users.

If you use the mask as a single-patient user in the home, please refer to your mask instructions under “cleaning your mask at home” instructions.

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

	High Level Disinfection	Sterilization		
	Thermal Disinfection	STERRAD		
		100S	100NX	NX
F&P Eson™ 	1 min at 90 °C (194 °F) 10 min at 80 °C (176 °F) 30 min at 75 °C (167 °F)	✓	✓	✓
F&P Pilairo™ Q 	10 min at 80 °C (176 °F) 30 min at 75 °C (167 °F)	✗	✗	✗
F&P Simplus™ 	10 min at 80 °C (176 °F)	✓	✓	✓

Validated disinfection and sterilization procedures

In the procedures below, only one of the following two disinfection or sterilization procedures needs to be performed. Follow the sequence for reprocessing. All masks have been validated for 20 cycles.

The following components cannot be reprocessed:

- Diffuser mat – replace between patients
- Headgear – clean between patients

1. Remove any gross soiling on the mask by wiping or rinsing in potable water.

2 Disassembly

Disassemble the mask according to the instructions shown in the relevant mask's Instructions For Use.

3. Cleaning

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. Alconox¹ according to the manufacturer's instructions (at 1 % concentration and 25 °C for 10 min), 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. Rinse by submerging in 5 litres of potable water and agitating for at least 10 seconds. Repeat rinse.

4. Drying

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.

5. Disinfection and/or sterilization

High Level Disinfection

Soak in a water bath or run a disinfection cycle in an automatic washer-disinfector using one of the time/temperature combinations (refer to table on page 1) to disinfect the mask components. 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. In line with EN ISO 15883, the uncertainty range for the disinfection temperature is -0 °C to +5 °C (0 °F to 9 °F).

Sterilization

Utilize a STERRAD NX, 100S or 100NX Sterilization System², according to the manufacturer's instructions, using the pouch method.

6. Drying

Allow all components to air dry out of direct sunlight.

7. 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.

8. Reassembly

Reassemble the mask according to the instructions shown in the relevant mask's Instructions For Use.

9. 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)

Cleaning the headgear

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 potable water, ensuring that all soap residues are removed.
3. Leave all parts to air dry out of direct sunlight before reassembling.

General Warnings and Cautions:

The instructions provided above have been validated as being capable of preparing the masks for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

The following actions may deteriorate or damage the mask and shorten its life.

(If your Fisher & Paykel Healthcare mask weakens or cracks, discontinue use and seek replacement immediately):

- 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.

1. Product of Alconox Inc.

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

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