

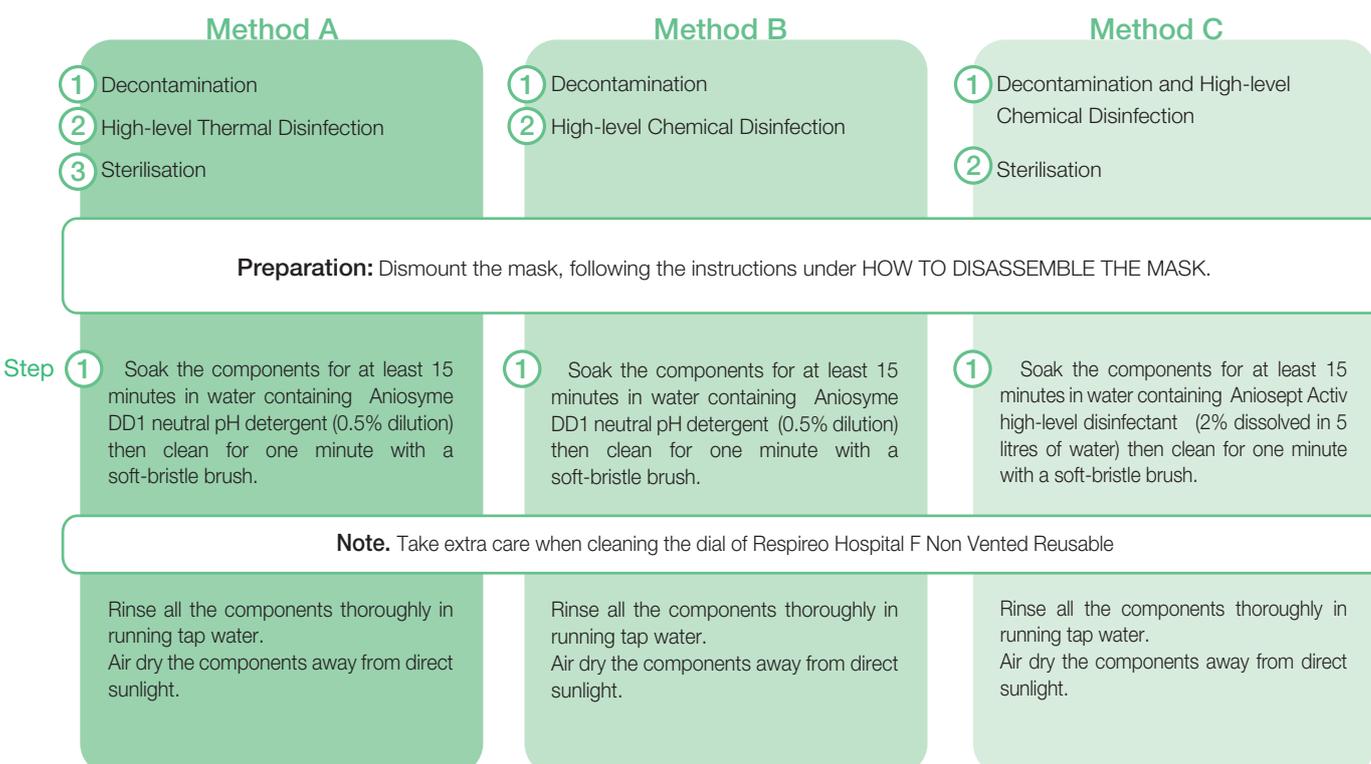
Disinfection and sterilisation guide for multi-patient use of masks

This guide provides instructions on how to clean, disinfect and sterilise the mask in accordance with UNI EN ISO 17664:2005 when it is used by more than one patient.

		Respireo Soft Baby Vented / Non Vented	Respireo Hospital F Non Vented Reusable
Decontamination	Neutral pH detergent Aniosyme DD1 (diluted at 0,5%)	✓	✓
Disinfection	High-level thermal According to EN ISO 15883-1 : 70°C - 100min, 75°C - 30min, 80°C - 10min, 90°C - 1min European requirements 93°C - 10min	✓*	✓
	High-level chemical Following manufacturer's instructions : Opaster, Opaster Plus, Aniosept Activ (dilué à 2% dans 5l H ₂ O), Anioxyde1000, Cidex OPA	✓	✓
Sterilisation	Sterrad™ 100S, NX, 100NX	✓	✓
	Autoclave 121°C - 20 min (250°F)	✓*	✓
Validated number of cycles		12	20

Important notes

- ⓘ This procedure must only be performed at hospitals or healthcare facilities.
- ⓘ Only one of the following disinfection or sterilisation methods must be used with the mask.
- ⓘ Select the desired disinfection/sterilisation method and follow all the steps.
- ⓘ Replace the mask if there is any signs of deterioration (e.g. cracks, scratches, breaks or tears).
- ⓘ The headgear must not be disinfected or sterilised.
- ⓘ * In the case of a high level thermal disinfection or a sterilization with autoclave, the tubing must be changed between each patient.



Step 2 Using a certified automatic hot water disinfecting system, soak the components in a solution of Aniosyme DLM Maxi neutral pH detergent (0.5% dilution). This detergent can be used in combination with Anios RHW neutral pH rinsing agent (0.08% dilution).

The cleaning cycle must comply with one of the following temperature-time combinations:

- 70°C - 100 minutes
- 75°C - 30 minutes
- 80°C - 10 minutes
- 90°C - 1 minute
- 93°C/ 200° F - 10 minutes (European requirement)

Drying takes place during the cleaning cycle.

2 Soak the components in one of the following high-level disinfectant solutions, following the manufacturer's instructions:

- Aniosept Activ (2% dissolved in 5 litres of water)
- Anioxyde 1000
- CIDEX OPA
- OPASTER
- OPASTER PLUS

Rinse the components thoroughly in tap water for at least one minute. Perform this operation 3 times, using clean water each time. Air dry the components away from direct sunlight.

2 STERRAD 100S/NX/100NX	AUTOCLAVE
Pack and sterilise the components as instructed by the manufacturer of the STERRAD sterilising system.	Sterilise the components in an autoclave at 121°C (250°F) for 15 minutes.
Drying takes place during the sterilisation process.	Air dry the components away from direct sunlight.

Step 3

STERRAD 100S/NX/100NX	AUTOCLAVE
Pack and sterilise the components as instructed by the manufacturer of the STERRAD sterilising system.	Sterilise the components in an autoclave at 121°C (250°F) for 15 minutes.
Drying takes place during the sterilisation process.	Air dry the components away from direct sunlight.

Inspection

Inspect each component of the mask carefully. If any component shows signs of deterioration (e.g. cracks, scratches, fractures or tears), it should be discarded and replaced. Slight discolouration of the silicone components is quite normal.

Reassembly

Reassemble the mask, following the instructions under HOW TO REASSEMBLE THE MASK.

Storage

Store in a dry, dust-free environment away from direct sunlight, between the temperatures of -25°C and +50°C.

Note. The above instructions have been validated by Air Liquide Medical Systems S.p.A. as guidelines for preparing a medical device for reuse. It is up to the person in charge of the process to ensure that the operations are performed using suitable materials, devices and personnel in order to achieve the desired result. This generally requires validation and systematic monitoring of the entire process. Failure by the person in charge of the process to follow the instructions provided should be assessed to determine its actual effectiveness and possible undesirable consequences.



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