

Guide for multi-patient use of RESPIREO SOFT BABY, RESPIREO SOFT BABY NON VENTED, RESPIREO SOFT CHILD, RESPIREO SOFT CHILD NON VENTED, RESPIREO SOFT NASAL, RESPIREO SOFT NASAL SILENT, RESPIREO SOFT FACIAL, and RESPIREO HOSPITAL F NON VENTED REUSABLE, masks

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

Warnings:

- **RESPIREO SOFT NASAL, RESPIREO SOFT NASAL SILENT and RESPIREO HOSPITAL F NON VENTED REUSABLE** masks must not be disinfected/sterilised for more than 20 cycles.
- **RESPIREO SOFT BABY, RESPIREO SOFT BABY NON VENTED, RESPIREO SOFT CHILD and RESPIREO SOFT CHILD NON VENTED** masks must not be disinfected/sterilised for more than 12 cycles.
- The tube assembly of **RESPIREO SOFT BABY, RESPIREO SOFT BABY NON VENTED, RESPIREO SOFT CHILD and RESPIREO SOFT CHILD NON VENTED** must not be disinfected using neither high-level thermal disinfection nor autoclave sterilization.
- For **RESPIREO SOFT NASAL, RESPIREO SOFT NASAL SILENT and RESPIREO SOFT FACIAL** the autoclave sterilization is inapplicable
- This procedure must only be performed at hospitals or healthcare facilities.
- Only one of the following disinfection or sterilization methods must be used with the mask.
- Select the desired disinfection/sterilization method and follow all the stages in order.
- Replace the mask if it shows signs of deterioration (e.g. cracks, scratches, fractures or tears).
- The headgear must not be disinfected or sterilised.

	1. DECONTAMINATION 2. HIGH-LEVEL THERMAL DISINFECTION 3. STERILISATION	1. DECONTAMINATION 2. HIGH-LEVEL CHEMICAL DISINFECTION	1. DECONTAMINATION AND HIGH-LEVEL CHEMICAL DISINFECTION 2. STERILISATION
Preparation	Take the mask apart, following the instructions under HOW TO DISASSEMBLE THE MASK. Turn the knob fully anticlockwise to clean the screw inside*.		
Step 1	Soak the components for at least 15 minutes in water containing a neutral pH detergent (i.e. gigazyme [®] with 1% dilution) then clean for one minute with a soft-bristle brush. Note. Take extra care when cleaning the adjusting screw*.	Soak the components for at least 15 minutes in water containing a neutral pH detergent (i.e. gigazyme [®] Xtra with 1% dilution) then clean for one minute with a soft-bristle brush. Note. Take extra care when cleaning the adjusting screw*.	Soak the components for at least 15 minutes in water containing a high-level disinfectant (i.e. perform [®] 2% dissolved in 5 liters of water) then clean for one minute with a soft-bristle brush. Note. Take extra care when cleaning the adjusting screw*.
	Rinse all the components thoroughly in running tap water.	Rinse all the components thoroughly in running tap water.	Rinse all the components thoroughly in running tap water.
	Air dry the components away from direct sunlight.	Air dry the components away from direct sunlight.	Air dry the components away from direct sunlight.
Step 2	Using a certified automatic hot water disinfection system, soak the components in a solution of a neutral pH detergent, in combination with a neutral pH rinsing agent if deemed appropriate. 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 - 10 minutes (European requirement)	Soak the components in one of the following high-level disinfectant solutions, following the manufacturer's instructions: - gigasept [®] PAA concentrate** - gigasept [®] pearls** - perform [®] - CIDEX OPA;	AUTOCLAVE
			Sterilise the components in an autoclave at 121°C (250°F) for not longer than 20 minutes.

	Drying takes place automatically after the cleaning cycle.	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.	Drying takes place during the sterilization process.
Step 3	AUTOCLAVE		
	Sterilise the components in an autoclave at 121°C (250°F) for not longer than 20 minutes.		
	Drying takes place during the sterilisation process.		
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.		

*Only for RESPIREO HOSPITAL F NON VENTED REUSABLE

** N.A. for SOFT Baby vented and SOFT Child vented

Note. The above instructions have been validated by Air Liquide Medical Systems S.r.l. 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. The manufacturer do not respond in case the process do not comply with the instructions provided, both for its actual effectiveness or any possible undesirable consequences.

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