

The following disinfection methods are validated for Respiroics multi-patient use masks in the hospital/institutional environment per regulatory guidelines. If the mask is for single patient use or single use please refer to the Instructions for Use included with the product for home cleaning and/or disposal.

Note: See the **Headgear and Fabric Parts** section for additional instructions on fabric frames and using fabric headgear between patients.

The recommended disinfection methods are identified by mask product (see table) and approved for use on the mask and/or mask parts. Review the notes (ⓘ) section for exceptions or deviations.

⚠ Warnings

- For single patient use, clean as indicated in the **Instructions for Use** included with the product.
- Masks with port caps: Open or remove the port cap prior to disinfecting the mask.
- Make sure all parts are dry before use.

⚠ Caution: Follow all instructions, including application and rinsing, from the manufacturer of the treatment products. Any deviation from these instructions, the manufacturer’s instructions, or agents not listed in this guide may impact the performance of the product. Review all applicable instructions for additional warnings and cautions.

I. High-Level Disinfection for Masks (No Headgear/No Fabric)

A. Cleaning (Pre-Treatment)

1. Disassemble the mask according to the **Instructions for Use** included with the product.
2. Prepare a commercially available, enzymatic cleaner (Example: MEDIZIME LF) in accordance with the manufacturer’s instructions.
3. Completely immerse the mask parts in the cleaner/water solution. Ensure there are no air pockets present inside the mask parts while soaking.
4. Use a soft bristle brush to clean the mask parts for at least 3 minutes, giving extra attention to any cavities or crevices.

Note: If compatible with the manufacturer’s instructions, the detergent may be applied within the washer/disinfection cycle.

5. Remove the mask components from the cleaner/water mixture and rinse them a minimum of 1 time with 1.5 gallons/5 liters of water. Rinse for at least 1 minute.
6. Air dry out of direct sunlight.
7. Visually inspect each mask component for cleanliness.
8. Repeat the cleaning steps until the mask components are visibly clean.
9. Discard and replace any mask components that cannot be cleaned.

B. High-Level Disinfection (Chemical and Thermal)

1. Perform high-level disinfection per manufacturer’s instructions of the treatment product.

Note: Ensure there are no air pockets present inside the mask parts while soaking.

2. Rinse the mask 1 (minimum) additional time with 2 gallons/7.57 liters of water and air dry out of direct sunlight.

Note: For Gigasept FF and Anioxyde 1000, ensure a minimum of 3 additional rinses. For each rinse, immerse completely in 2 gallons/7.57 liters of fresh water for a minimum of 1 minute per rinse. Do not reuse the water for rinsing or any other purposes.

3. Inspect the mask for damage or wear (cracking, crazing, tears, damage resulting in gel exposure, etc.).
4. Masks with entrainment valves: Verify the entrainment valve functions correctly, as outlined in the Instructions for Use included with the product.
5. Discard and replace any mask components that cannot be disinfected.

Notes:

- After disinfection, discoloration of the cushion and a slight odor are normal.
- † Anioxyde 1000 and Gigasept FF are not available for use in the United States.

Disinfection Table for Masks (No Headgear/No Fabric)

Product	Thermal					Chemical				ⓘ Notes
	Max Cycles					Cidex OPA	Wavicide	Anioxyde 1000 †	Gigasept FF †	
	70° C for 100 minutes	75° C for 30 minutes	80° C for 10 minutes	90° C for 1 minute	93° C for 10 minutes					
Nasal and Pillows Masks										
ComfortClassic		ⓘ (30)						ⓘ (30)	ⓘ (30)	Foam forehead spacer is for single patient use only.
ComfortFusion		30		30		30	30			
ComfortGel	30		30	30	30	ⓘ (30)	30			Cidex OPA for faceplate and forehead arm only.
ComfortGel Blue / Profile Lite 2	30	30	30	30	30	30	30	ⓘ (30)	30	Anioxyde for faceplate assembly and flap only.
ComfortLite 2		30		30		30	30			
ComfortSelect	ⓘ (30)			30		30				Approved at 70° for 30 minutes only.
DreamWear Gel Pillows	ⓘ (30)	ⓘ (30)	30	30	30	30	30	30	20	Entire mask must be fully submerged for the following thermal treatments: 70°C, 75°C.

II. Headgear and Fabric Parts

A. Single Patient Headgear and Fabric Parts

If the mask product is not specifically noted for thermal headgear disinfection, headgear and fabric parts must be replaced between patients. For single patient use in a hospital or institution, fabric mask parts must be replaced weekly, or earlier if necessary.

B. Multi-Patient Headgear

Headgear may be disinfected using the instructions below. See table for approved methods.

1. Cleaning (Pre-Treatment)

1. Disassemble the mask according to the **Instructions for Use** included with the product.
2. Inspect the fabric parts for damage or wear. Discard and replace any components as necessary.
3. Mix 1 teaspoon (5 ml) of liquid detergent per 1 gallon (3.8 liters) of warm potable water (80–90°F/27–32 °C).
4. Completely submerge the fabric parts in the warm water/detergent mixture and soak for 5 minutes.
5. Agitate the fabric parts in the water/detergent mixture for an additional 5 minutes.
6. Remove the mask parts from the water/detergent mixture and rinse with 1 gallon (3.8 liters) of warm water for at least 1 minute.

2. Disinfection Methods

Headgear can be disinfected using the following methods.

a) Manual High-Level Disinfection

1. Soak the headgear at the temperature and time indicated in the table below.
2. Air dry out of direct sunlight. Make sure the headgear is completely dry before use.
3. Inspect the headgear. Discard and replace if headgear is damaged or worn (deformation, tears, etc.).

Note: Headgear thermal disinfection may cause discoloration of the material. This is normal and will not impact patient safety or headgear performance.

b) Disinfection with Isopropyl Alcohol

1. Submerge the headgear in room temperature 70% isopropyl alcohol and soak for 5 minutes.
2. Agitate for 5 minutes.
3. Remove and rinse thoroughly with 3.8 liters/1 gallon of water at 80–90°F (27–32 °C).
4. Rinse the headgear again with 3.8 liters/1 gallon of water at 80–90°F (27–32 °C).
5. Pat dry and lay the headgear flat or line dry. Make sure the headgear is completely dry before use.
6. Inspect the headgear. Discard and replace if headgear is damaged or worn (deformation, tears, etc.).

Disinfection Table for Headgear Only

Product	Thermal					Chemical
	Max Cycles					
	70° C for 100 minutes	75° C for 30 minutes	80° C for 10 minutes	90° C for 1 minute	93° C for 10 minutes	70% isopropyl alcohol
DreamWear Gel Pillows		30				
DreamWear Silicone Pillows		30				
DreamWear Under the Nose		30				
DreamWisp Nasal Mask		30				
Therapy Mask 3100 NC/ Therapy Mask 3100 SP	30	30	30	30	30	15

Contact Us

The information contained in the **Disinfection Guide for Professional Use** is subject to change. Access the latest version of the Disinfection Guide at www.philips.com/IFU or by contacting customer service at +1-724-387-4000 or Respiration Deutschland: +49 (0) 8152 93060.

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