

# Cleaning and Disinfection Instructions for Clinical Use

## ComfortGel Blue

**⚠ Caution**

- These cleaning and disinfection instructions are for **Clinical Use** only.
- The following processes are validated for the ComfortGel Blue nasal mask when used in accordance with the instructions provided by the manufacturer of the cleaning and disinfection products and/or processes. Any deviation from said instructions or the cleaning agents listed below may impact the performance or durability of the product. Review those instructions for additional warnings and cautions.
- The gel cushion is not compatible with Sterrad. If Sterrad is the only option available, replace the gel cushion for each use.

**⚠ Warning**

- Inspect the mask components after disinfection and replace any components that are worn or damaged.

**📌 Notes**

- The headgear cannot be processed using the cleaning and disinfection methods listed. The headgear must be replaced or hand/machine washed and allowed to air dry before reuse, as indicated in the **Instructions for Use** included with the product.
- After disinfection, discoloration of the cushion and a slight odor is normal.

**Cleaning**

- Disassemble the mask per the **Instructions for Use** included with the product.
- Clean the mask using a soft bristle brush to adequately remove adhering substances from each component while soaking in a commercially available, anionic detergent such as MediZyme (used thermal) or Manu Klenz (used with chemical and gas plasma). Extra attention should be given to the crevices and cavities during cleaning.

**📌 Note:** If compatible with the manufacturer's instructions, the detergent may be applied within the washer/disinfector cycle.

- Rinse the mask with potable water and air dry out of direct sunlight. If cleaning manually, use a minimum 5 liters per mask.

**High-Level Disinfection**

The following high-level disinfection processes are intended for multi-patient use in a clinical or hospital/institution environment only. For home cleaning or single patient use, refer to the **Instructions for Use** included with the product.

**Thermal Disinfection:** Apply only one treatment option using a certified hot water disinfection system.

TEMPERATURE	TIME	MAXIMUM CYCLES
70° C	100 minutes	30
	or	
75° C	30 minutes	30
	or	
80° C	10 minutes	30
	or	
90° C	1 minute	30
	or	
93° C	10 minutes	30

1. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
2. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.

**Chemical Disinfection:** Apply only one treatment option following the manufacturer's instructions.

TREATMENT	EXPOSURE TIME	ACTIVE INGREDIENTS	SOLUTION	RINSE	MAXIMUM CYCLES
Cidex Activated Dialdehyde Solution	45 minutes	2.4% Glutaraldehyde	Full Strength	Potable Water, 5 Liters per Mask (minimum)	30
		or			

Continued

TREATMENT	EXPOSURE TIME	ACTIVE INGREDIENTS	SOLUTION	RINSE	MAXIMUM CYCLES
Cidex OPA	12 minutes	0.55% Ortho-Phthalaldehyde	Full Strength	Potable Water, 5 Liters per Mask (minimum)	30
or					
Wavicide	45 minutes	2.65% Glutaraldehyde	Full Strength	Potable Water, 5 Liters per Mask (minimum)	30
or					
Control III	10 minutes	10% Alkyl Dimethyl Benzyl Ammonium Chloride  10% Alkyl Dimethyl Ethyl Benzyl Ammonium Chloride	8 ml per liter	Potable Water, 5 Liters per Mask (minimum)	30

1. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
2. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask if the cushion becomes hardened.

**Hydrogen Peroxide Gas Plasma**

 **Caution:** Not compatible with the gel cushion.

TREATMENT	EXPOSURE TIME	MAXIMUM CYCLES
Sterrad 100	Machine Controlled	30

1. Rinse thoroughly with drinking quality water and air dry out of direct sunlight. Make sure the mask is dry before use. Lay the headgear flat or line dry. Do not place the headgear into the dryer.
2. Inspect all parts for damage or wear; replace any parts that have visibly deteriorated (cracking, crazing, tears, etc). Replace the mask and/or mask components as necessary.

Visit us on-line at [www.sleepapnea.com](http://www.sleepapnea.com) or contact Respiroics Customer Service to obtain mask cleaning and disinfection instructions.

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