

Cleaning and Disinfection Instructions for Clinical Use

FULLLIFE

⚠ Caution

- These cleaning and disinfection instructions are for **Clinical Use** only.
- The following processes are validated for the FullLife full face 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.
- Autoclave is validated for use on the FullLife mask cushions only.

⚠ Warning

- Inspect the mask components after disinfection and replace any components that are worn or damaged.
- Entrainment Valve Elbow Only: Verify the entrainment valve flapper moves freely after cleaning and disinfection. Replace if the flapper does not function correctly.

📌 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 with autoclave and 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/disinfecter 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 mask 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
75° C	30 minutes	10
or		
90° C	1 minute	10
or		
93° C	10 minutes	10

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					
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					

TREATMENT	EXPOSURE TIME	ACTIVE INGREDIENTS	SOLUTION	RINSE	MAXIMUM CYCLES
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

Hydrogen Peroxide Gas Plasma

TREATMENT	EXPOSURE TIME	MAXIMUM CYCLES
Sterrad 100	Machine Controlled	30

Autoclave

 Caution: Process is for the cushion only.

TEMPERATURE	EXPOSURE TIME	MAXIMUM CYCLES
121° C	15 minutes	5
or		
126° C	10 minutes	5
or		
134° C	3 minutes	5

Visit us on-line at www.respironics.com or contact customer service to obtain mask cleaning and disinfection instructions.

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