

# FITLIFE

## INSTRUCTIONS FOR CLEANING AND DISINFECTION

### Caution

- For Clinical Use Only.
- The following processes are validated for the **FITLIFE** total face mask with built-in exhalation elbows and standard elbows when used in accordance with the cleaning and disinfection manufacturer's instructions. Any deviation from the manufacturer's instructions or agents listed below may impact the performance or durability of the product. See manufacturer's instructions for additional warnings and cautions.
- See the **Instructions for Use** included with the product for additional warnings and cautions.

### Warning


- Inspect the mask components after disinfection and replace any components that are worn or damaged. See the **Instructions for Use** included with the product for additional warnings and cautions.
- Entrainment Valve Elbow: 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 thermal treatments) or Manu Klenz (used with chemical and gas plasma treatments). 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

Mask and cushions may be reused after cleaning and disinfection by one of the thermal, chemical or gas plasma options below.

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

TEMPERATURE	TIME	MAXIMUM CYCLES
70° C	100 minutes	10
or		
80° C	10 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)	10
or					
Cidex OPA	12 minutes	0.55% Ortho-Phthalaldehyde	Full Strength	Potable Water, 5 Liters per Mask (minimum)	10
or					
Wavicide	45 minutes	2.65% Glutaraldehyde	Full Strength	Potable Water, 5 Liters per Mask (minimum)	10
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)	10

#### Hydrogen Peroxide Gas Plasma

TREATMENT	EXPOSURE TIME	MAXIMUM CYCLES
Sterrad 100	Machine Controlled	10

Visit us on-line at [www.respironics.com](http://www.respironics.com) or contact customer service to obtain mask cleaning and disinfection instructions.

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