

FITLIFE

INSTRUCTIONS FOR CLEANING AND DISINFECTION

Caution

- For Clinical Use Only.
- The following processes are validated for the FITLIFE multi-patient use 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
- Open or remove the port cap located on the elbow prior to cleaning and disinfection.

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.
- Exhalation/Air Entrainment (EE) Valve Elbow only: Verify that the air entrainment valve flapper moves freely after cleaning and disinfection. Replace the elbow 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 and autoclave) or Manu Klenz (used with chemical and gas plasma treatments). Extra attention should be given to the crevices and cavities during cleaning.
- Rinse the mask and components with potable water (minimum 5 liters per mask) and air dry out of direct sunlight.

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

HIGH-LEVEL DISINFECTION

The following high-level disinfection processes are intended for the FITLIFE 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.

Autoclave

| TEMPERATURE | TIME | MAXIMUM CYCLES | NOTES |
|-------------|------------|----------------|--|
| 121°C | 15 minutes | 5 | Gravity displacement cycle No sterilization bag |

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

| TEMPERATURE | TIME | MAXIMUM CYCLES |
|-------------|-------------|----------------|
| 70° C | 100 minutes | 10 |
| | or | |
| 75° C | 30 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 or contact customer service to obtain mask cleaning and disinfection instructions.

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