



ComfortGel™ Full and ComfortGel™ Full SE Instructions for Cleaning and Disinfection

⚠ CAUTION

- For Clinical Use Only.
- The following processes are validated for the ComfortGel Full (shown) and ComfortGel Full SE (Standard Elbow) masks, 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.
- The gel cushion and Comfort Flap® are not compatible with CIDEX® OPA, STERRAD® or Thermal processes. Use CIDEX® activated dialdehyde solution, Wavicide or Control III only to disinfect the gel cushion and/or ComfortFlap. If these options are not available to you, replace the cushion and flap for each use.
- See the *Instructions for Use* included with the product for additional warnings and cautions.



⚠ WARNING

- Disassemble the mask per the *Instructions for Use* included with the product. The Comfort Flap must be detached from the faceplate and cleaned and disinfected separately.
- Inspect the mask components after disinfection and replace any components that are damaged. See the *Instructions for Use* included with the product for additional warnings and cautions.
- DO NOT clean or disinfect the mask with the oxygen port cap in the closed position. Open the port cap or remove the port cap completely prior to any cleaning or disinfection process.
- 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 before reuse as indicated in the *Instructions for Use* included with the product.
- After disinfection, discoloration or a slight odor of the cushion is normal.

CLEANING

- Disassemble the mask per the *Instructions for Use* included with the product.
- Clean the mask with a medical grade detergent such as Manu Klenz® or MediZyme®. As required, use a soft bristle brush to remove adhering substances, paying particular attention to crevices and cavities.
- Rinse the mask with potable water and air dry out of direct sunlight. If cleaning manually, use a minimum 5 liters of water per mask.
- NOTE: If compatible with the manufacturer's instructions, the detergent may be applied within the washer/disinfector cycle.

DISINFECTION

- Mask may be reused after cleaning and disinfection by one of the following processes.

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

NOTE: Not compatible with the gel cushion or Comfort Flap.

TEMPERATURE	TIME	MAXIMUM CYCLES
75° C	30 minutes	30
or		
90° C	1 minute	30

Continued

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

NOTE: CIDEX OPA is not compatible with the gel cushion or Comfort Flap.

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					
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

NOTE: Not compatible with the gel cushion or Comfort Flap.

TREATMENT	EXPOSURE TIME	MAXIMUM CYCLES
STERRAD®	Machine Controlled	30

Visit www.respironics.com or contact Customer Service to obtain additional mask cleaning and disinfection instructions or to order a product catalog for replacement parts.

Respironics: 1-800-345-6443 (USA or Canada only) or 724-387-4000

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