

WiZARD 310 & WiZARD 320

DISINFECTION GUIDE

Clinical Use Only

This guide is intended for the single patient reuse and multi-patient reuse of the WiZARD 310 and WiZARD 320 in a sleep lab, clinic, or hospital.

This guide describes the manufacturer’s recommended and validated procedures for daily cleaning and weekly disinfection of the mask for single patient reuse.

⚠ Note: When the mask is intended to use between patients, cleaning and disinfection instruction should be both conducted after each use.

WiZARD 310 & WiZARD 320 component	Thermal disinfection	Chemical disinfection	Validated number of cycles
	Pasteurization	CIDEX™ OPA	
cushion, mask frame with elbow part, and flexible tube	v	v	20

Disinfection Guide	
Thermal disinfection <ul style="list-style-type: none"> ● 90°C(194°F): 1 minute, or ● 93°C(199.4°F): 10 minutes 	Chemical disinfection <p>Soak at the 20°C (68°F) Cidex OPA (0.55%) ortho-phthalaldehyde for 12 minutes</p>

1.1. Disassembly and Cleaning

1.1.1. Disassembly

Before cleaning, take the mask components apart according to the below instructions.

- (1). Detach the flexible tube from the elbow part of the mask frame.
- (2). Unhook the headgear buckles from the mask frame. No need to detach the buckle from the headgear strap.
- (3). Unthread the upper headgear straps from the mask frame.
- (4). Detach the mask cushion from the mask frame.

1.1.2. Cleaning and drying

- **Cushion/ Frame with Elbow part/ Flexible tube**

- (1). Hand wash the mask in warm water (approximately 30°C/86°F) using mild soap or diluted dish-washing detergents. Clean thoroughly to remove residual grease.
- (2). Use a soft bristle brush to clean the expiratory port.
- (3). Rinse all parts of the mask thoroughly with drinking quality water.
- (4). Inspect to ensure the components are clean and detergent free. Wash and rinse again, if necessary.
- (5). Allow to air dry. Keep out of direct sunlight.

⚠ **CAUTION:** Do not use bleach, chlorine, alcohol, scented oils, or aromatic based solutions. These solutions may damage the mask, cause cracks, and reduce the life of the product. Do not iron the headgear strap.

- **Headgear strap:**

- (1). Soak in warm water (appropriate 30°C/86°F) using a mild liquid detergent for 10 minutes.
- (2). Rub and squeeze the soaking item. Also, clean with a soft bristle brush for 5 minutes, especially the Velcro strap part.
- (3). Squeeze to remove excess solution.
- (4). Rinse by repeatedly squeezing under running water until the water is clear. Repeat two more times. Squeeze to remove excess water.
- (5). Inspect to ensure the headgear strap is clean and detergent free. Wash and rinse again if necessary.
- (6). Allow to air dry. Keep out of direct sunlight.

⚠ **CAUTION:** Do not place the headgear strap into the dryer.

⚠ **NOTES:** The headgear strap does not require disinfection due to the headgear strap is for single patient reuse. The headgear strap should be replaced between patients.

1.2. Disinfection and Drying

	THERMAL DISINFECTION	CHEMICAL DISINFECTION
DISASSEMBLY, CLEANING, AND DRYING	Please refer to section 1.1 for the cleaning procedure.	
DISINFECTION AND DRYING	(1). Soak the disinfectable mask component (excluding the headgear strap) in a certified hot water disinfection system. Set the temperature and time as followings: <ul style="list-style-type: none"> ● 90°C (194 °F): 1 minute, or ● 93°C (199.4 °F): 10 minutes 	(1). Soak the disinfectable mask components (excluding the headgear strap) in the following solutions according to the manufacturer’s instructions: Soak at the 20°C (68°F) Cidex OPA (0.55%) ortho-

	<p>(1). Afterward, remove the mask components from the hot water disinfection system.</p> <p>(2). Allow to air dry. Keep out of direct sunlight.</p>	<p>phthaladehyde for 12 minutes</p> <p>(2). Thoroughly rinse the mask components by immersing them completely in drinking quality water (8 liters per mask).</p> <p>(3). Repeat step TWO (2) twice, for a total of 3 rinses, with large volumes of fresh water to remove Cidex OPA Solution residues.</p> <p>⚠ Note: Three separate, large volume water immersion rinses are required.</p> <p>(4). Allow to air dry. Keep out of direct sunlight.</p>
<p>INSPECTION</p>	<p>Inspect each mask component. If any visible deterioration of mask component is apparent (cracking, crazing, tears etc.), the mask component should be discarded and replaced. Slight discolored of the silicone components may occur and is acceptable.</p>	
<p>REASSEMBLY, PACKING, AND STORAGE</p>	<ul style="list-style-type: none"> ● Reassemble the mask according to the instructions in the Instructions for Use. ● Store in a dry, dust-free environment. Keep out of direct sunlight. ● Storage temperature: -15°C to 60°C (+5°F to 140°F). 	

⚠ **CAUTIONS**

- Mask components should not be subjected to autoclave or ethylene-oxide gas sterilization.
- When using detergents, or disinfectants, always follow the manufacturer's instructions.
- Do not iron the headgear strap as the material is heat sensitive and might be damaged.



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