

Disinfection Guide

This guide is intended for single patient reuse and multi-patient reuse of WiZARD 510 nasal mask in a sleep lab, clinic or hospital. Please refer to cleaning instructions in the User's Manual. This guide describes Apex'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.

WiZARD 510 nasal mask

WiZARD 510 nasal mask component	Thermal disinfection	Chemical disinfection	Validated number of cycles
	Pasteurization	CIDEX™ OPA	
Cushion	v	v	30
Frame, elbow flexible tube1 and Swivel Hose	v	v	30

Disinfection Guide

Physical Disinfection (Pasteurization)
76°C(168.8F) : 30 min

Chemical high level disinfection
Cidex OPA (0.55%) ortho-phthaladehyde: 12 min
soaking temperature: 20°C (68°F)

Validated high level disinfection procedures

Disassembly

1. Pull the cushion out of the frame.
2. Remove headgear clips on mask frame.
3. Push the quick release button then disconnect the swivel hose.

Cleaning and drying

Cushion:

1. Soak the component in warm water (approximately 86°F/30°C) with mild liquid detergent (Prolystica® 2X Neutral Detergent 4 mL per L) for up to 10 minutes.
2. Whilst immersed in the solution, clean with a soft bristle brush for 2 minute. Brush inside and outside of the cushion and the frame connect part.
3. Rinse by shaking vigorously in running water until the water is clear at appropriate 30°C for 1 minute. Repeat for one more minute using fresh water.
4. Inspect to ensure the cushion is clean and detergent free. Wash and rinse again, if necessary.
5. Leave the cushion to air dry out of direct sunlight.

Headgear:

1. Soak the headgear in warm water (approximately 86°F/30°C) with mild liquid detergent (Prolystica® 2X Neutral Detergent 4 mL per L) for up to 10 minutes.
2. Whilst immersed in the solution, rub and squeeze the headgear, and then clean with a soft bristle brush for 5 minutes. Pay particular attention to 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 is clean and detergent free. Wash and rinse again, if necessary.
6. Leave the headgear to air dry out of direct sunlight.

Elbow/ Flexible tube/ Frame/ Swivel Hose:

1. Rinse the frame, elbow, flexible tube and swivel hose under running water. Clean with a soft brush until dirt is removed.
2. Soak the component in warm water (approximately 86°F/30°C) with a mild liquid detergent (Prolystica® 2X Neutral Detergent 4 mL per L) for up to 10 minutes. Rotate all connections three times around 360 degrees.
3. Whilst immersed in the solution, thoroughly brush the areas of the frame inside and outside where the elbow connects.
4. Brush the elbow and around the vent holes for an additional 1 minute. Pay particular attention to all crevices and cavities.
5. Brush the flexible tube surface, inside, outside and the swivel hose connect port.
6. Rinse by shaking vigorously in running water from one end of the component and repeat the other end of the component for 1 minute.
7. Inspect to ensure the components are clean and detergent free. Wash and rinse again, if necessary.
8. Leave the components to air dry out of direct sunlight.

Notes :

The headgear does not require disinfection or sterilization due to the headgear is for single patient reuse. The headgear should be replaced between patients. The cleaning procedure is detailed in the instructions for use.

Disinfection and drying**Physical Disinfection (Pasteurization)**

1. Using a certified hot water disinfection system (or respective hospitals equivalent disinfection procedure), soak the disinfectable mask components (excluding the headgear) using a temperature-time combination:
 - 168.8°F (76°C) for 30min
2. Once completion, remove the mask components from the hot water disinfection system.
3. Allow the mask components to air dry out of direct sunlight.

Chemical high level disinfection

1. Soak the disinfectable mask components (excluding the headgear) in the following solutions according to the manufacturer's instructions:
 - Cidex OPA (0.55%) ortho-phthalaldehyde for 12 minutes, soaking temperature is 20°C (68°F)
2. Thoroughly rinse the mask components by immersing it completely in drinking quality water (8 litres per mask).
3. Repeat procedure TWO (2) additional 2 times, for a total of 3 rinses, with large volumes of fresh water to remove Cidex OPA Solution residues. (Note: Three separate, large volume water immersion rinses are required.)
4. Allow the mask components to air dry out of direct sunlight.

Inspection

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.

Reassembly

Reassemble the mask according to the instructions in the Instructions for Use.

Packaging and storage

Store in a dry, dust-free environment away from direct sunlight.
Storage temperature: +5°F to 140°F (-15°C to 60°C).

CAUTIONS

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