

**WiZARD™****Disinfection Guide**

## Full Face Masks, Nasal Masks, Nasal Pillows Masks

This guide is intended for multipatient use of WiZARD full face mask, nasal mask or nasal pillows mask in a sleep lab, clinic or hospital. If the mask is used as a single user in the home, refer to the Instructions for Use for cleaning instructions.

This guide describes Apex's recommended and validated procedures for cleaning and disinfection of the mask. However, the steps for disinfection of masks vary regionally. As a result, each healthcare facility should consult its own procedures before carrying out those within this guide.

| <b>Apex validated disinfection procedures</b> |                                    |   |  |                            |
|---|------------------------------------|---|--|----------------------------|
| Mask  | Replace new parts between patients | High level thermal disinfection   | High level chemical disinfection                             | Validated number of cycles |
|   |                                    | <b>prEN ISO 15883-1</b><br>158°F (70°C):100 min<br>176°F (80°C):10 min<br>194°F (90°C):1 min<br><b>Specific European regional requirements</b><br>199.4°F (93°C):10 min | <b>Anioxyde™ 1000</b><br>Peracetic acid 0.15% for 30 minutes |                            |
| <b>Full face masks</b>                        |                                    |   |  |                            |
| WiZARD 220                                    | *                                  | √   | √  | 20                         |
| <b>Nasal masks</b>                            |                                    |   |  |                            |
| WiZARD 210                                    | *                                  | √   | √  | 20                         |
| <b>Nasal Pillows masks</b>                    |                                    |   |  |                            |
| WiZARD 230                                    |                                    | √**   | √  | 15                         |

\* Open or remove the port cap prior to disinfecting the mask.

\*\* Short tube assembly validated to 158°F (70°C).

| <b>Validated high level disinfection procedures</b> |  |                                  |
|---|--|----------------------------------|
|   | High level thermal disinfection  | High level chemical disinfection |
| Disassembly   | 1. Detach the short tube, unhook the buckles and unthread the headgear straps.<br>2. Remove the silicone cushion and the forehead support pad.   |                                  |
| Cleaning and drying                                 | 1. Clean the mask and components with a soft bristle brush and soap. Pay extra attention to all crevices and cavities during cleaning.<br>2. Rinse the mask components thoroughly under running potable water.<br>3. Allow the components to air dry out of direct sunlight before high level disinfection.<br><br><b>Notes :</b><br><i>The headgear does not require disinfection or sterilization. However, it is necessary to thoroughly wash the headgear before using between patients. The cleaning procedure is detailed in the instructions for use.</i> |                                  |

| <b>Validated high level disinfection procedures</b>  |   |  |
|--|---|--|
|  | High level thermal disinfection   | High level chemical disinfection   |
| Disinfection or sterilization and drying   | <p>1. Using a certified hot water disinfection system, soak the disinfectable mask components (excluding the headgear) using a temperature-time combination:</p> <p><b>prEN ISO 15883-1</b></p> <ul style="list-style-type: none"> <li>• 158 °F (70 °C) for 100 minutes (Short tube of WiZARD 230 was validated to 70 °C only.)</li> <li>• 176 °F (80 °C) for 10 minutes</li> <li>• 194 °F (90 °C) for 1 minute</li> </ul> <p><b>Specific European regional requirements</b></p> <ul style="list-style-type: none"> <li>• 199.4 °F (93 °C) for 10 minutes</li> </ul> <p>2. Once completion, remove the mask components from the hot water disinfection system.</p> <p>3. Allow the mask components to air dry out of direct sunlight.</p> | <p>1. Soak the disinfectable mask components (excluding the headgear) in the following solutions according to the manufacturer's instructions:</p> <ul style="list-style-type: none"> <li>• Peracetic acid 0.15%(Anioxyde 1000)for 30 minutes</li> </ul> <p>2. Rinse the mask components in potable water (five litres per mask).</p> <p>3. Allow the mask components to air dry out of direct sunlight.</p> |
| 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 discolouration 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.<br>Storage temperature: -4 °F to 140 °F (-20 °C to 60 °C).   |  |
| <b>Disassembling the forehead support pad before cleaning</b>  |   |  |
| These instructions only apply to full face mask and nasal mask.  |   |  |
| 1. Firmly push the forehead support pad against the mask frame then pull forehead support pad out of the mask frame. |   |  |
| <b>Cleaning the headgear</b>   |   |  |
| The headgear does not require disinfection. Thoroughly washing the headgear between patients is acceptable.          |   |  |
| 1. Handwash the headgear in warm 86 °F (30 °C) water with mild soap.   |   |  |
| 2. Rinse well in fresh water and allow it to air dry out of direct sunlight.   |   |  |

## 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.