

# Disinfection and sterilization guide

**Rx Only**  
Clinical use only

This guide is intended for multipatient use of the AirFit N20 / AirTouch N20 ResMed nasal masks in a sleep lab, clinic or hospital. If you use the mask as a single user in the home, refer to the User Guide for cleaning instructions. This guide describes ResMed's validated procedures for cleaning, disinfection and sterilization of the mask in accordance with ISO17664.

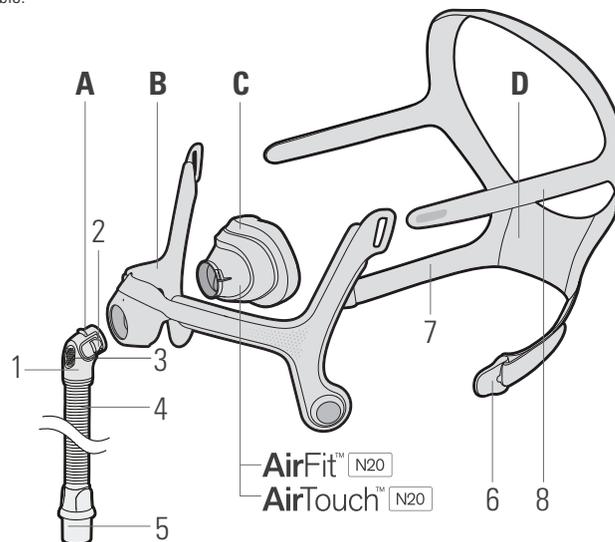
| AirFit N20 / AirTouch N20 mask component <sup>1</sup> | High level thermal disinfection           |   | High level chemical disinfection                  | Sterilization                                     |  | Validated number of cycles <sup>2</sup> |
|---|---|---|---|---|--|---|
|   | Thermal water bath 194°F (90°C) for 1 min | Thermal water bath 199.4-203°F (93-95°C) for 10 min | CIDEX™ OPA Ortho-phthalaldehyde 0.55% 12 min soak | STERRAD™ 100S Short cycle (boosters not required) | STERRAD™ NX Standard or advanced cycle |   |
| • AirFit N20 cushion                                  | ✓   | —   | ✓   | ✓   | ✓                                      | 30                                      |
| • AirTouch N20 cushion <sup>3</sup>                   | —   | —   | —   | —   | —                                      | —                                       |
| • Magnetic clip                                       | ✓   | —   | —   | —   | —                                      | 30                                      |
| • Multi-hole elbow and short tube <sup>4</sup>        | ✓   | —   | —   | —   | —                                      | 30                                      |
| • Frame / headgear                                    | —   | ✓   | —   | —   | —                                      | 30                                      |

<sup>1</sup> This mask may not be available in all regions. For full details regarding the correct use of this mask, please refer to the specific User Guide.

<sup>2</sup> If a healthcare facility requires an additional disinfection or sterilization cycle after reassembly, the number of validated cycles must be halved.

<sup>3</sup> The AirTouch N20 cushion is intended for single-patient reuse in both home and hospital/institutional environments and recommended to be replaced monthly.

<sup>4</sup> The multi-hole elbow and short tube are not separable.



- A Multi-hole elbow and short tube
- 1 Elbow
- 2 Side buttons
- 3 Vent
- 4 Short tube
- 5 Swivel
- B Frame
- C Cushion
- D Headgear
- 6 Magnetic clips
- 7 Lower headgear straps
- 8 Upper headgear straps
- A+B+C Frame system
- A+B+C+D Complete system

## Validated disinfection and sterilization procedures

|                            |   |  |  |
|----------------------------|---|--|--|
| <b>Disassembly</b>         | Disassemble the mask according to the instructions in the User Guide. Magnetic clips must be removed from the lower headgear straps.  |  |  |
| <b>Cleaning and drying</b> | <b>AirFit N20 cushion / magnetic clips</b>  | <b>Multi-hole elbow and short tube</b>   | <b>Frame / headgear</b>  |
|                            | <ol style="list-style-type: none"> <li>1. Make a solution of Alconox® by diluting with drinking quality water at 1%, ie, 10 g per liter, at 77-86°F (25-30°C), according to the manufacturer's instructions.</li> <li>2. Whilst in the solution, thoroughly clean the mask component with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities.</li> <li>3. Rinse the component by agitating it vigorously in drinking quality water, 5 liters per component at 77-86°F (25-30°C) for 1 minute.<br/>Repeat the process by using fresh water for another 1 minute.</li> <li>4. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li> <li>5. Allow the component to air dry out of direct sunlight.</li> </ol> | <ol style="list-style-type: none"> <li>1. Make a solution of Alconox by diluting with drinking quality water at 1%, ie, 10 g per liter, at 113-131°F (45-55°C), according to the manufacturer's instructions.</li> <li>2. Soak the mask component in the solution for 5 minutes. Rotate all connections three times around 360 degrees.</li> <li>3. Whilst in the solution, thoroughly clean the component with a test tube brush for an additional 1 minute. Pay particular attention to all crevices and cavities.</li> <li>4. Rinse the component by agitating it vigorously in drinking quality water, 5 liters per component at 77-86°F (25-30°C) for 1 minute.<br/>Repeat the process by using fresh water for another 1 minute.</li> <li>5. Rinse the component under fast-running drinking quality tap water (113-131°F (45-55°C)) from one end of the component, for 20 seconds. Repeat the process from the other end of the component.</li> <li>6. Shake the component vigorously to remove excess water.</li> <li>7. Inspect and if required, repeat washing until visually clean.</li> <li>8. Allow the component to air dry out of direct sunlight.</li> </ol> | <ol style="list-style-type: none"> <li>1. Make a solution of Alconox by diluting with drinking quality water at 1%, ie, 10 g per liter, at 68-86°F (20-30°C), according to the manufacturer's instructions.</li> <li>2. Soak the mask component in the solution for 3 minutes.</li> <li>3. Thoroughly clean the mask component with a soft bristle brush for 2 minute while continuing to soak it in the solution. Pay particular attention to all crevices and cavities.</li> <li>4. Squeeze the component to remove excess solution.</li> <li>5. To rinse the component, repeatedly squeeze it under running drinking quality tap water at 68-86°F (20-30°C) for 30 seconds. Repeat the process by using fresh water two more times.</li> <li>6. Squeeze the component to remove excess water.</li> <li>7. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li> <li>8. Allow the component to air dry out of direct sunlight.</li> </ol> |

<sup>1</sup> Failure to clean the mask component as indicated may result in inadequate disinfection and sterilization.

In the procedures below, only **one** of the following three disinfection or sterilization procedures needs to be performed.

|   |   |  |  |
|---|---|--|--|
| <b>Disinfection or sterilization and drying</b> | <b>High level thermal disinfection</b>  | <b>High level chemical disinfection</b>  | <b>STERRAD Sterilization</b>   |
|   | <b>AirFit N20 cushion / magnetic clips / multi-hole elbow and short tube / frame / headgear</b><br><br><ol style="list-style-type: none"> <li>1. Fully immerse the mask component in a hot water bath using a temperature-time combination, ensuring there are no air bubbles:<br/><b>AirFit N20 cushion / magnetic clips / multi-hole elbow and short tube:</b> <ul style="list-style-type: none"> <li>• 194°F (90°C) for 1 minute.</li> </ul> <b>Frame / headgear:</b> <ul style="list-style-type: none"> <li>• 199.4-203°F (93-95°C) for 10 minutes.</li> </ul> </li> <li>2. Remove the component from the hot water bath.</li> <li>3. Shake the component to remove excess water.</li> <li>4. Allow the component to air dry out of direct sunlight.</li> </ol> | <b>AirFit N20 cushion</b><br><br><ol style="list-style-type: none"> <li>1. Fully immerse and soak the mask component in a commercially available solution according to the manufacturer's instructions and agitate to ensure there are no air bubbles: For example: <ul style="list-style-type: none"> <li>• Ortho-phthalaldehyde 0.55% (eg, CIDEX OPA) at 68-77°F (20-25°C) for 12 minutes</li> </ul> </li> <li>2. Rinse the component in drinking quality water, 7.5 liters per component: <ul style="list-style-type: none"> <li>• 68-86°F (20-30°C) for 1 minute</li> </ul> Repeat the process by using fresh water for two more times.<sup>2</sup> </li> <li>3. Shake the component to remove excess water.</li> <li>4. Allow the component to air dry out of direct sunlight.</li> </ol> | <b>AirFit N20 cushion</b><br><br><ol style="list-style-type: none"> <li>1. Dry the mask component thoroughly.<br/>If the component is wet, the sterilization cycle may fail.</li> <li>2. Package the component prior to sterilization as described in the manufacturer's instructions for the STERRAD Sterilization System.<br/>Note: The use of pouches is not recommended.</li> <li>3. Sterilize the component by following the manufacturer's instructions. <ul style="list-style-type: none"> <li>• STERRAD 100S: Short cycle (boosters not required)</li> <li>• STERRAD NX: Standard or advanced cycle</li> </ul> </li> <li>4. Rinse and agitate in drinking quality water, 5 liters per component at 68-86°F (20-30°C) for 1 minute.</li> <li>5. Shake the component to remove excess water.</li> <li>6. Allow the component to air dry out of direct sunlight.</li> </ol> |
| <b>Inspection</b>                               | Perform a visual inspection of the component. If any visible deterioration is apparent (cracking, crazing, tears etc), the component should be discarded and replaced. Slight discoloration of the silicone components may occur and are acceptable.  |  |  |
| <b>Reassembly</b>                               | Reassemble the mask according to the instructions in the User Guide.  |  |  |
| <b>Packaging and storage</b>                    | Store in a dry, dust-free environment away from direct sunlight.<br><b>Storage temperature:</b> -4°F to 140°F (-20°C to 60°C).  |  |  |

<sup>2</sup> Failure to adequately rinse the component may result in toxic levels of residual CIDEX OPA.



## GENERAL WARNINGS AND CAUTIONS

- ResMed cannot give any assurance that deviations from the procedures listed in this guide (eg, exceeding the number of reprocessing cycles), and their effect on the performance or safety of the product, will be acceptable.
- 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. In the event of conflict, this guide takes precedence.
- Do not iron the headgear as the material is heat sensitive and will be damaged