

Disinfection guide

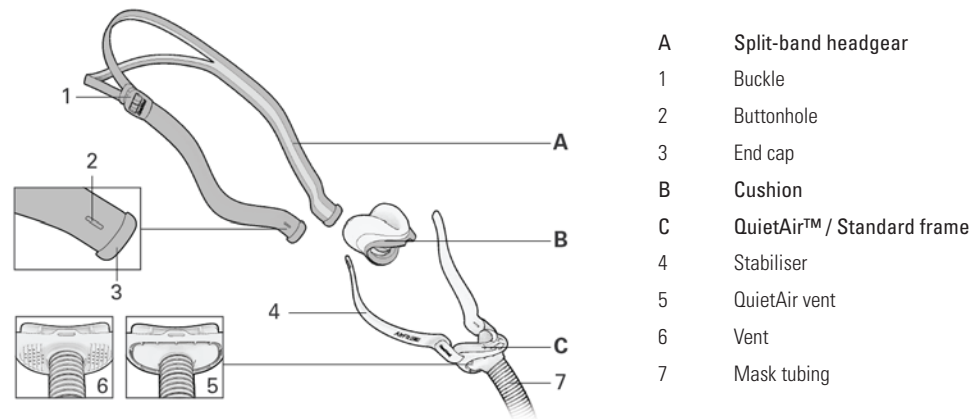
Clinical use only

This guide is intended for multi-patient use of the AirFit™ N30 nasal mask 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. The processor is responsible for ensuring that reprocessing is completed in accordance with ResMed's validated procedures.

Mask component ¹	Cleaning		Validated number of cycles
	Mild Alkaline, Anionic Detergent e.g. Alconox	Neodisher Mediclean Forte	
	Thermal Disinfection		
	Manual	Washer-Disinfector	
• Cushion	✓	✓	30
• Standard frame	✓	✓	30
• QuietAir™ frame ²	–	–	–
• Split-band headgear	✓	✓	30

¹ May not be available in all regions. For full details regarding the correct use of this mask, please refer to the User Guide. For a list of available replacement parts, check the Product Guide on ResMed.com

² Not intended for multi-patient re-use.



Thermal disinfection procedure

1. Disassembly	Disassemble the mask according to the instructions in the User Guide.
2. Cleaning	<ol style="list-style-type: none"> 1. Make a solution of a mild alkaline, anionic detergent and water¹ as per manufacturer's instructions. ResMed has validated the following: <ul style="list-style-type: none"> • Alconox 1% concentration (10 g/L) 30-55°C 2. Soak all mask components for 5 to 10 minutes. Ensure there are no air bubbles. 3. After the soaking time, while keeping the components in the solution, clean the inside and outside with a soft bristle brush as follows. Pay particular attention to the crevices and cavities. <ul style="list-style-type: none"> • Cushion / frame / headgear 1 minute brushing 4. Rinse the components as follows under running water¹ ($\leq 60^{\circ}\text{C}$) directly contacting all surfaces. <ul style="list-style-type: none"> • Cushion / frame 30-60 seconds rinsing • Headgear 1 minute rinsing, while squeezing repeatedly
3. Inspection and drying	<ol style="list-style-type: none"> 1. Inspect and if required, repeat all steps in section [2. Cleaning] until visually clean.² 2. Squeeze the headgear to remove excess water. 3. Allow the components to air dry out of direct sunlight.³
4. Disinfection	<ol style="list-style-type: none"> 1. Soak the mask components in a hot water¹ bath using one of the following temperature-time combinations: <ul style="list-style-type: none"> • 75°C for 30 minutes • 80°C for 10 minutes • 90-93°C for 1 to 10 minutes. 2. Squeeze the headgear to remove excess water. 3. Allow the components to air dry out of direct sunlight.
5. Inspection	Perform a visual inspection of each mask component. If any visible deterioration of a 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.
6. Reassembly	Reassemble the mask according to the instructions in the User Guide.
7. Storage and transportation	For storage and transportation details, check the User Guide.

¹ For all cleaning, rinsing and disinfection steps, use drinking quality water. Where local regulation impose water quality requirements for medical device reprocessing, these requirements must be met.

² Failure to clean the mask component as indicated may result in inadequate disinfection.

³ Drying is not required if thermal disinfection is continued immediately.

Thermal disinfection procedures - Washer-Disinfector

1. Disassembly	Disassemble the mask according to the instructions in the User Guide.																											
2. Washer-Disinfector¹	<ol style="list-style-type: none"> Soak the mask components in a 5 litre rinse bath of cold tap water¹ for 1 minute. Ensure there are no air bubbles on the components. Rinse each component under cold running tap water¹ for 30 seconds. Ensure internal surfaces are flushed. Transfer the components into an ISO 15883 series compliant washer-disinfector. For the standard frame component, place on a spray nozzle³ to facilitate water flow through the mask tubing. Components should be orientated to ensure effective drainage. Set the washer-disinfector using the following settings: <table border="1" data-bbox="443 352 1655 549"> <thead> <tr> <th>Phase/Stage</th> <th>Recirculation time (minutes)</th> <th>Temperature (°C)</th> <th>Detergent</th> </tr> </thead> <tbody> <tr> <td>Pre-wash</td> <td>4</td> <td>Cold</td> <td>–</td> </tr> <tr> <td>Wash</td> <td>10</td> <td>43-60</td> <td>2-10 mL/L (0.2-1%) Neodisher Mediclean Forte</td> </tr> <tr> <td>Neutralisation</td> <td>6</td> <td>43-60</td> <td>1-2 mL/L (0.1-0.2%) Neodisher Z</td> </tr> <tr> <td>Final Rinse</td> <td>3</td> <td>43-60</td> <td>–</td> </tr> <tr> <td>Thermal Disinfection</td> <td>5-10</td> <td>90-93</td> <td>–</td> </tr> </tbody> </table> 				Phase/Stage	Recirculation time (minutes)	Temperature (°C)	Detergent	Pre-wash	4	Cold	–	Wash	10	43-60	2-10 mL/L (0.2-1%) Neodisher Mediclean Forte	Neutralisation	6	43-60	1-2 mL/L (0.1-0.2%) Neodisher Z	Final Rinse	3	43-60	–	Thermal Disinfection	5-10	90-93	–
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² Failure to clean the mask component as indicated may result in inadequate disinfection.

³ Use a washer-disinfector load carrier/rack containing spray/injector nozzles.



GENERAL WARNINGS AND CAUTIONS

- Always follow cleaning and disinfection instructions. Some cleaning products may damage the mask, its parts and their function, or leave harmful residual vapours. Any deviations from the procedures listed in this guide, including exceeding the specified number of maximum cycles, can have an adverse effect on the mask and consequently the safety or the quality of therapy.
- Mask components should not be subjected to autoclave or ethylene-oxide gas sterilisation.
- When using detergents, disinfectants or equipment, always follow the manufacturer's instructions. In the event of conflict, this guide takes precedence.
- Always follow safe operating practices, including the use of appropriate personal protective equipment (PPE), as required. Refer to the manufacturer's safety instructions for more details.