

Disinfection guide

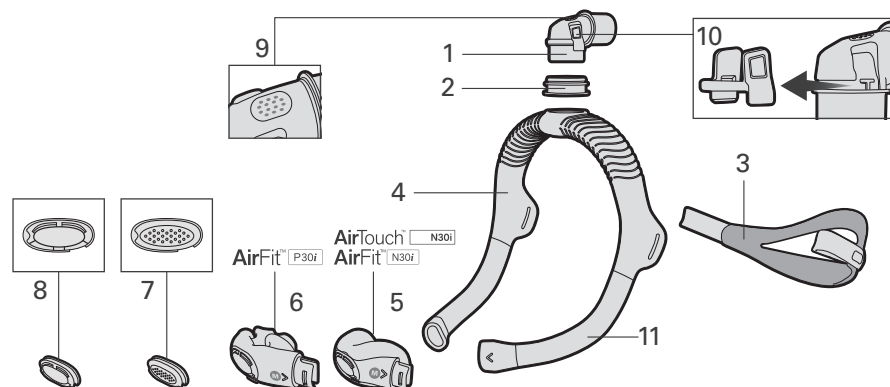
Clinical use only

This guide provides the reprocessing instructions for the AirTouch N30i, AirFit N30i and AirFit P30i masks, which are intended for multi-patient reuse 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. Potable water with hardness ≤150 mg/L is recommended for all cleaning, rinsing and disinfection steps. Where local regulation impose water quality requirements for medical device reprocessing, these requirements shall be met.

Mask component ¹	Cleaning			Validated number of cycles
	Alconox (mild alkaline, anionic detergent)		Neodisher Mediclean forte (alkaline, enzymatic detergent)	
	Thermal disinfection			
	Manual		Automated Washer-Disinfector	
	75°C for 30 minutes 80°C for 10 minutes	90 to 93°C for 1 to 10 minutes	A0 of 3000 to 11,971 (90 to 93°C for 5 to 10 minutes)	
Frame (AirTouch N30i)	✓ (30 cycles)	✓ (15 cycles)	✓ (30 cycles)	15 or 30
Cushion (AirTouch N30i)		✓	✓	30
Cushion (AirFit N30i)		✓	✓	
Cushion (AirFit P30i)		✓	–	
Multi-hole vent		✓	✓	
Frame (SLM) (SLM AirFit N30i, SLM AirFit P30i) ²		✓	✓	
Frame (AirFit N30i, AirFit P30i)		–	✓	
Elbow body / elbow clip / elbow ring		✓	✓	
Headgear		✓	✓	
QuietAir™ vent	Not intended for multi-patient use			–

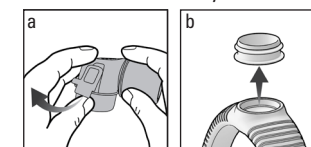
¹ This mask may not be available in all regions. For full details regarding the correct use of these masks, please refer to the specific User Guide. For a list of available replacement parts for each mask system, check the Product Guide on ResMed.com.

² The frame of the Sleep Lab Mask (SLM) does not contain fabric sleeves.



- 1 Elbow body
- 2 Elbow ring
- 3 Headgear
- 4 Frame
- 5 AirTouch N30i / AirFit N30i cushion
- 6 AirFit P30i cushion
- 7 Multi-hole vent
- 8 QuietAir vent
- 9 Elbow Vent
- 10 Elbow clip
- 11 Sleeves

Additional disassembly



Thermal disinfection procedure - Manual

1. Disassembly	1. Disassemble the mask according to the instructions in the User Guide. 2. Additionally: • Remove the elbow clip away from the elbow body by firmly levering one side of the elbow clip. (Fig. a.) • Pull the elbow ring out of the frame. (Fig. b.)
2. Cleaning	1. Make a solution of a mild alkaline, anionic detergent and water as per manufacturer's instructions. ResMed has validated: • Alconox 1% concentration 30-55°C 2. Soak the mask components for 5-10 minutes in the solution. 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 (e.g., soft bristle toothbrush) as follows. The inside of the frame requires a soft bristle tube/ bottle brush of an appropriate size to extend and contact all internal surfaces. Pay particular attention to the crevices and cavities. • Cushion (AirFit N30i , AirFit P30i) / elbow body 30 seconds brushing • Elbow clip / elbow ring / multi-hole vent 10 seconds brushing • Cushion (AirTouch N30i) / frame (SLM) / headgear 1 minute brushing • Frame (AirTouch N30i) 2 minutes brushing, comprising 1 minute for the external surfaces and 1 minute for the internal surfaces 4. Rinse the components as follows under running water at 20-60°C directly contacting all surfaces. • Cushion (AirFit N30i , AirFit P30i) / frame (SLM) / elbow body / elbow clip / elbow ring 30 to 60 seconds rinsing • Multi-hole vent 10 seconds rinsing • Cushion (AirTouch N30i) / headgear 1 minute rinsing, while squeezing repeatedly • Frame (AirTouch N30i) 2 minutes rinsing, comprising of 1 minute for the external surfaces, while squeezing repeatedly, and 1 minute for the internal surfaces
3. Inspection and drying	1. Inspect all components to ensure they are visually clean. If not, repeat all steps in section [2. Cleaning] until all components are visually clean. If the sleeve on the frame becomes twisted, it can be repositioned when wet. 2. Squeeze the fabric components to remove excess water. 3. Allow the components to air dry out of direct sunlight. Drying is not required if thermal disinfection is continued immediately.
4. Disinfection	1. Fully immerse the mask components in a hot water bath using one of the following temperature-time combinations. Agitate the components in the water bath to ensure no air bubbles are trapped. • 75°C for 30 minutes, OR • 80°C for 10 minutes, OR • 90-93°C for 1 to 10 minutes 2. Squeeze the fabric components 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, pilling etc.), the component should be discarded and replaced. Slight discolouration of the silicone and fabric components may occur and are acceptable. Disinfecting fabric components together may result in dye transfer stains and are acceptable.
6. Reassembly	1. Push the elbow clip onto the elbow body until it clicks into place. 2. Insert the elbow ring into the top of the frame. 3. Reassemble the mask according to the instructions in the User Guide.
7. Storage and transportation	For storage and transportation details, check the User Guide.

Thermal disinfection procedure - WD

1. Disassembly	1. Disassemble the mask according to the instructions in the User Guide. 2. Additionally: - Remove the elbow clip away from the elbow body by firmly levering one side of the elbow clip. (Fig. a.) - Pull the elbow ring out of the frame. (Fig. b.)																								
2. Pre-wash	1. Soak the mask components in a 5 litre rinse bath of cold water for 1 minute. Ensure there are no air bubbles on the components. 2. Rinse the components under cold running water for 30 seconds. Ensure internal surfaces are flushed.																								
3. WD	1. Transfer the components into an ISO 15883 series compliant washer-disinfector. Components should be orientated to ensure effective drainage 2. Set the washer-disinfector using the following settings: <table><tr><th>Phase/Stage</th><th>Recirculation time (minutes)</th><th>Temperature (°C)</th><th>Detergent</th></tr><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></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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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.
- Failure to thoroughly clean and disinfect the mask component as indicated may result in inadequate disinfection.
- 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.