

Disinfection guide

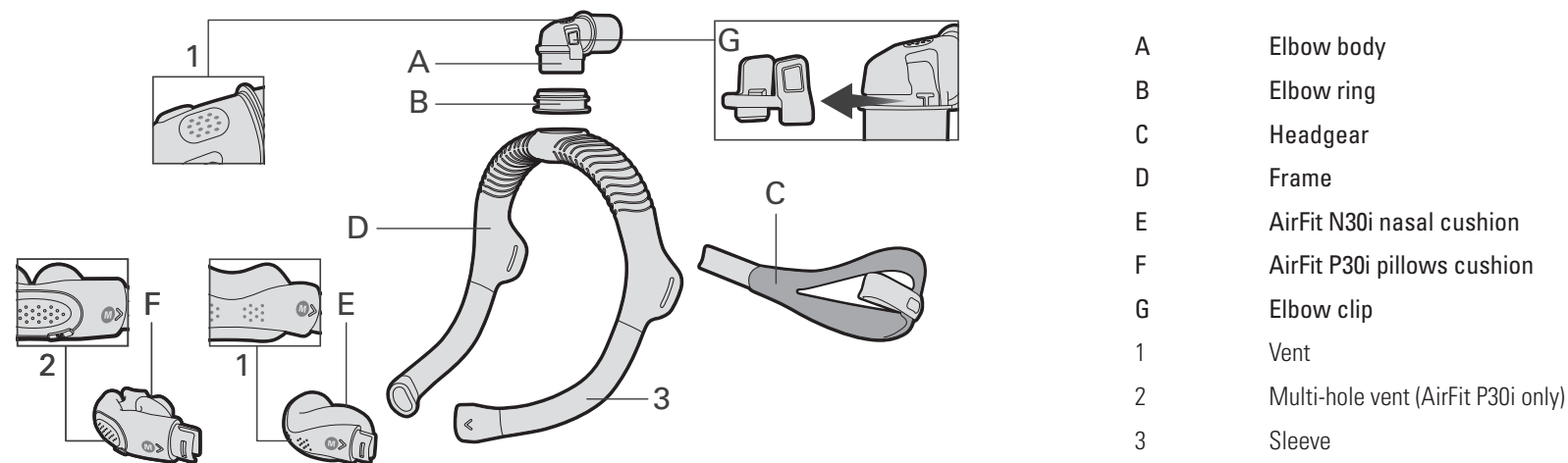
Clinical use only

This guide is intended for multi-patient re-use of the AirFit N30i and AirFit P30i masks in a sleep lab, clinic or hospital. If you use the mask as a single patient 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 eg, Alconox	Neodisher Mediclean forte	
	Thermal disinfection		
	Manual	Washer-Disinfector (WD)	
• AirFit N30i cushion	✓	✓	30
• AirFit P30i cushion	✓	–	30
• Multi-hole vent	✓	–	30
• Frame (with sleeves)	–	✓	30
• Frame (SLM) ²	✓	✓	30
• Elbow body / elbow clip / elbow ring	✓	✓	30
• Headgear	✓	✓	30

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 sleeves.



Thermal disinfection procedure - Manual

1. Disassembly	<div><div>1. Disassemble the mask according to the instructions in the User Guide.</div><div>2. Additionally:<ul style="list-style-type: none">Firmly pull the elbow clip away from the elbow body.Pull the elbow ring out of the frame.(AirFit P30i only) Peel the multi-hole vent from the AirFit P30i cushion</div></div>
2. Cleaning	<div><div>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 30-55°C temperature</div><div>2. Soak the mask components for 5-10 minutes in the solution. Ensure there are no air bubbles.</div><div>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">AirFit N30i cushion / AirFit P30i cushion / elbow body 30 seconds brushingElbow clip / elbow ring / multi-hole vent (AirFit P30i only) 10 seconds brushingFrame (SLM) / headgear 1 minute brushing²</div><div>4. Rinse the components as follows under running water¹ (≤60°C) directly contacting all surfaces.<ul style="list-style-type: none">AirFit N30i cushion / AirFit P30i cushion / frame (SLM) / elbow body / elbow clip / elbow ring / multi-hole vent (AirFit P30i only) 30 to 60 seconds rinsingHeadgear 1 minute rinsing, while squeezing repeatedly</div></div>
3. Inspection / Drying	<div><div>1. Inspect and if required, repeat washing until visually clean.³</div><div>2. Squeeze the headgear to remove excess water.</div><div>3. Allow the components to air dry out of direct sunlight.⁴</div></div>
4. Disinfection	<div><div>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 minutes80°C for 10 minutes90-93°C for 1 to 10 minutes</div><div>2. Squeeze the headgear to remove excess water.</div><div>3. Allow the components to air dry out of direct sunlight.</div></div>
5. Inspection	<div>Perform a visual inspection of each mask component. If any visible deterioration of a component is apparent (cracking, crazing, tears etc), the component should be discarded and replaced. Slight discolouration of the silicone components may occur and is acceptable.</div>
6. Reassembly	<div><div>1. Push the elbow clip onto the elbow body until it clicks into place.</div><div>2. Insert the elbow ring into the top of the frame.</div><div>3. (AirFit P30i only) Align the tab in the AirFit P30i cushion with the notch in the multi-hole vent. Insert the multi-hole vent into the AirFit P30i cushion.</div><div>4. Reassemble the mask according to the instructions in the User Guide.</div></div>
7. Packaging and storage	<div>For storage details, check the User Guide.</div>

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 A soft bristle tube/bottle brush (≥ 2 cm diameter) is required to clean the inside of the frame.

³ Failure to clean the mask component as indicated may result in inadequate disinfection.

⁴ Drying is not required if disinfection is continued immediately.

Thermal disinfection procedure - WD

1. Disassembly	<div>1. Disassemble the mask according to the instructions in the User Guide.</div> <div>2. Additionally:<ul style="list-style-type: none">Firmly pull the elbow clip away from the elbow body.Pull the elbow ring out of the frame.</div>																								
2. WD ¹	<div>1. 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.</div> <div>2. Rinse the components under cold running tap water¹ for 30 seconds.</div> <div>3. Transfer the components into an ISO 15883 series compliant washer-disinfector.</div> <div>4. Set the washer-disinfector using the following settings:</div> <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°C</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°C	-
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°C	-																						
3. Inspection / Drying	<div>1. Inspect and if required, repeat section [2. WD] until visually clean.²</div> <div>2. Squeeze the headgear to remove excess water.</div> <div>3. Allow the components to air dry out of direct sunlight.</div>																								
4. 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.																								
5. Reassembly	<div>1. Push the elbow clip onto the elbow body until it clicks into place.</div> <div>2. Insert the elbow ring into the top of the frame.</div> <div>3. Reassemble the mask according to the instructions in the User Guide.</div>																								
6. Packaging and storage	For storage details, check the User Guide.																								

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

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



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.



ResMed Ltd
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153 Australia

See ResMed.com for other ResMed locations worldwide. AirFit is a trademark and/or registered trademark of the ResMed family of companies. Alconox is a trademark of Alconox Inc. Neodisher is a trademark of Chemische Fabric Dr Weigert. For patent and other intellectual property information, see ResMed.com/ip. © 2019 ResMed Ltd. 608525/3 2019-02



ResMed.com