

Disinfection guide

Clinical use only

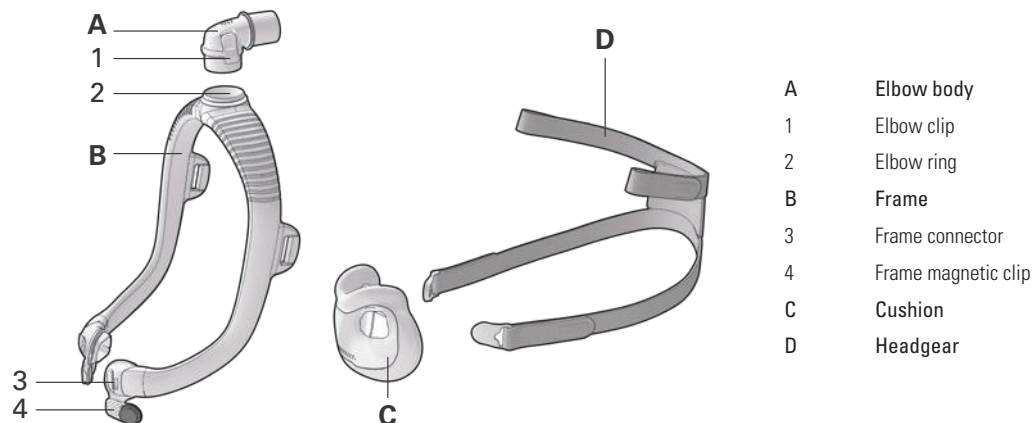
This guide is intended for multi-patient use of the AirFit™ F30i full face mask in a sleep lab, clinic or hospital. If you use the mask as a single user in the home, refer to the User Guide for cleaning instructions. The processor is responsible for ensuring that reprocessing is completed in accordance 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
• Frame / frame magnetic clips	✓	✓	30
• Elbow body / elbow clip / elbow ring	✓	✓	30
• Headgear ²	✓	✓	30
• Soft wraps ³	–	–	–

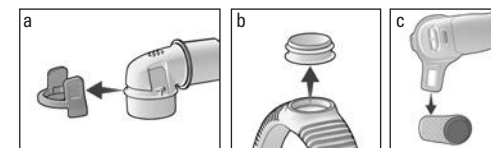
¹ May not be available in all regions. For full details regarding the correct use of this mask, please refer to the User Guide. For a list of available replacement parts, check the Product Guide on ResMed.com

² Headgear includes headgear magnetic clips.

³ Not intended for multi-patient re-use.



Additional disassembly



Thermal disinfection procedures - Manual

1. Disassembly	<ol style="list-style-type: none"> Disassemble the mask according to the instructions in the User Guide. Additionally: <ul style="list-style-type: none"> Firmly pull the elbow clip away from the elbow body. (Fig a.) Pull the elbow ring out of the frame. (Fig b.) Firmly slide the frame magnetic clip from the frame connector. Repeat on the other side. (Fig c.)
2. Cleaning	<ol style="list-style-type: none"> 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 Soak all mask components for 5 to 10 minutes. Ensure there are no air bubbles. 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"> Elbow body 30 seconds brushing Elbow clip / elbow ring / frame magnetic clips 10 seconds brushing Cushion / frame² / headgear 1 minute brushing 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 / frame magnetic clips / elbow body / elbow clip / elbow ring 30-60 seconds rinsing Headgear 1 minute rinsing, while squeezing repeatedly
3. Inspection and drying	<ol style="list-style-type: none"> Inspect and if required, repeat all steps in section [2. Cleaning] until visually clean.³ Squeeze the headgear to remove excess water. Allow the components to air dry out of direct sunlight.⁴
4. Disinfection	<ol style="list-style-type: none"> 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. Squeeze the headgear to remove excess water. Allow the components to air dry out of direct sunlight.
5. Inspection	<p>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.</p>
6. Reassembly	<ol style="list-style-type: none"> Push the elbow clip onto the elbow body until it clicks into place. Insert the elbow ring into the top of the frame. Firmly slide the frame magnetic clip onto the frame connector. Repeat on the other side. Reassemble the mask according to the instructions in the User Guide.
7. Storage and transportation	<p>For storage and transportation details, check the User Guide.</p>

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

² A soft bristle tube/bottle brush 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 thermal disinfection is continued immediately.

Thermal disinfection procedures - Washer-Disinfector

1. Disassembly	<ol style="list-style-type: none"> Disassemble the mask according to the instructions in the User Guide. Additionally: <ul style="list-style-type: none"> Firmly pull the elbow clip away from the elbow body. (Fig a.) Pull the elbow ring out of the frame. (Fig b.) Firmly slide the frame magnetic clip from the frame connector. Repeat on the other side. (Fig c.) 																								
2. Washer-Disinfector	<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. Components should be orientated to ensure effective drainage. Set the washer-disinfector using the following settings: <table border="1" data-bbox="445 459 1655 652"> <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.

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.