

# Disinfection guide

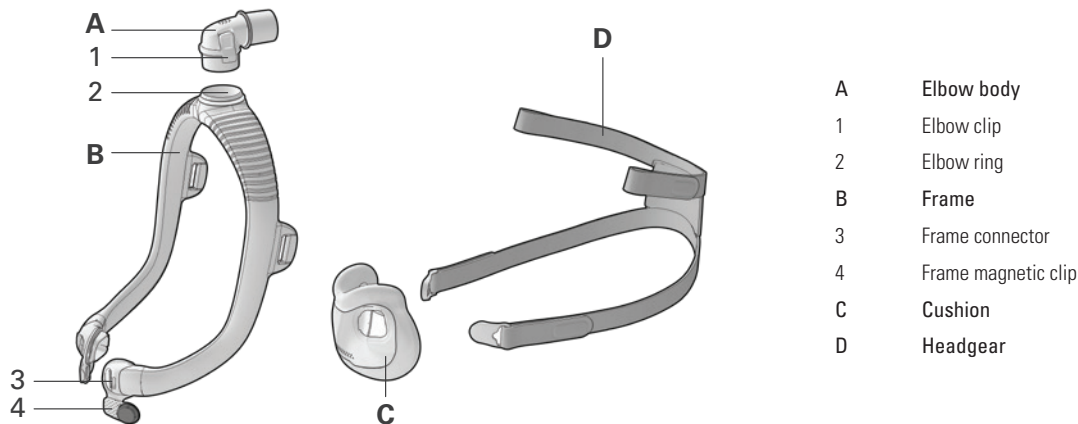
This guide is intended for multi-patient re-use of the AirFit™ F30i full face mask in a sleep lab, clinic or hospital. If you use the mask as a single user in the home, refer to the User Guide for cleaning instructions. The processor is responsible for ensuring that reprocessing is completed in accordance with ResMed's validated procedures.

Mask component <sup>1</sup>	Cleaning - Mild alkaline, anionic detergent eg, Alconox	Validated number of cycles
	Thermal Disinfection 167°F (75°C) for 30 minutes OR 194-199°F (90-93°C) for 1 to 10 minutes	
• Cushion	✓	30
• Frame / frame magnetic clips	✓	30
• Elbow body / elbow clip / elbow ring	✓	30
• Headgear <sup>2</sup>	✓	30
• Soft wraps <sup>3</sup>	-	-

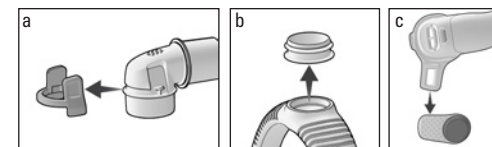
<sup>1</sup> May not be available in all regions. For full details regarding the correct use of this mask, please refer to the User Guide. For a list of available replacement parts, check the Product Guide on ResMed.com.

<sup>2</sup> Headgear includes headgear magnetic clips.

<sup>3</sup> Not intended for multi-patient re-use.



Additional disassembly



# Thermal disinfection procedure

<b>1. Disassembly</b>	<ol style="list-style-type: none"> <li>Disassemble the mask according to the instructions in the User Guide.</li> <li>Additionally: <ul style="list-style-type: none"> <li>Firmly pull the elbow clip away from the elbow body. (Fig a.)</li> <li>Pull the elbow ring out of the frame. (Fig b.)</li> <li>Firmly slide the frame magnetic clip from the frame connector. Repeat on the other side. (Fig c.)</li> </ul> </li> </ol>
<b>2. Cleaning</b>	<ol style="list-style-type: none"> <li>Make a solution of a mild alkaline, anionic detergent and water<sup>1</sup> as per manufacturer's instructions. ResMed has validated the following: <ul style="list-style-type: none"> <li><b>Alconox</b> 1% concentration (10 g/L) 86-131°F (30-55°C)</li> </ul> </li> <li>Soak all mask components for 5 to 10 minutes. Ensure there are no air bubbles.</li> <li>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"> <li><b>Elbow body</b> 30 seconds brushing</li> <li><b>Elbow clip / elbow ring / frame magnetic clips</b> 10 seconds brushing</li> <li><b>Cushion / frame<sup>2</sup> / headgear</b> 1 minute brushing</li> </ul> </li> <li>Rinse the components as follows under running water<sup>1</sup> at 68-140°F (20-60°C) directly contacting all surfaces. <ul style="list-style-type: none"> <li><b>Cushion / frame / frame magnetic clips / elbow body / elbow clip / elbow ring</b> 30-60 seconds rinsing</li> <li><b>Headgear</b> 1 minute rinsing, while squeezing repeatedly</li> </ul> </li> </ol>
<b>3. Inspection and drying</b>	<ol style="list-style-type: none"> <li>Inspect and if required, repeat all steps in section [2. Cleaning] until visually clean.<sup>3</sup></li> <li>Squeeze the headgear to remove excess water.</li> <li>Allow the mask components to air dry out of direct sunlight.<sup>4</sup></li> </ol>
<b>4. Disinfection</b>	<ol style="list-style-type: none"> <li>Soak the mask components in a hot water<sup>1</sup> bath using one of the following temperature-time combinations. Ensure there are no air bubbles. <ul style="list-style-type: none"> <li>167°F (75°C) for 30 minutes OR</li> <li>194-199°F (90-93°C) for 1 to 10 minutes</li> </ul> </li> <li>Squeeze the headgear to remove excess water.</li> <li>Allow the components to air dry out of direct sunlight.</li> </ol>
<b>5. Inspection</b>	<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 discoloration of the silicone components may occur and is acceptable.</p>
<b>6. Reassembly</b>	<ol style="list-style-type: none"> <li>Push the elbow clip onto the elbow body until it clicks into place.</li> <li>Insert the elbow ring into the top of the frame.</li> <li>Firmly slide the frame magnetic clip onto the frame connector. Repeat on the other side.</li> <li>Reassemble the mask according to the instructions in the User Guide.</li> </ol>
<b>7. Storage and transportation</b>	<p>For storage and transportation details, check the User Guide.</p>

<sup>1</sup> For all cleaning, rinsing and disinfection steps, use drinking quality water.

<sup>2</sup> A soft bristle tube/bottle brush is required to clean the inside of the frame.

<sup>3</sup> Failure to clean the mask component as indicated may result in inadequate disinfection.

<sup>4</sup> Drying is not required if thermal disinfection is continued immediately.



## 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 sterilization.
- 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.