

# Disinfection guide

Clinical use only

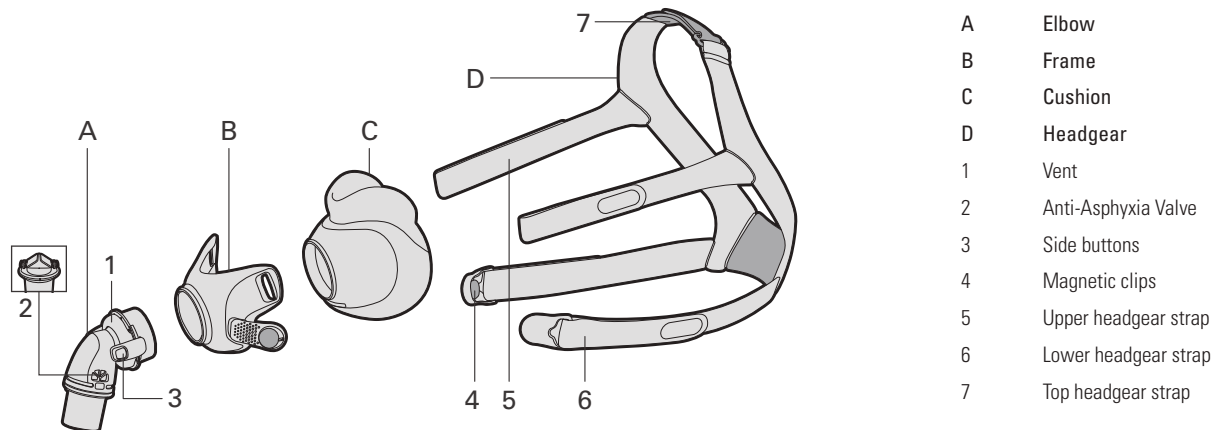
This guide is intended for multi-patient re-use of the AirFit F30 full face mask in a sleep lab, clinic or hospital. If you use the mask as a single user in the home, refer to the User Guide for cleaning instructions. This guide describes ResMed's recommended and validated procedures for cleaning and disinfection of the mask in accordance with ISO17664.

AirFit F30 mask component <sup>1</sup>	Cleaning - Alconox		Cleaning - Neodisher MediClean forte	Validated number of cycles <sup>2</sup>
	Thermal Disinfection - Manual 90°C for 1 minute	Thermal Disinfection - Manual 93°C for 10 minutes	Thermal Disinfection - Washer Disinfector (WD) 90-93°C for 5-10 minutes	
• Cushion	✓	–	✓	30
• Standard elbow	✓	–	✓	30
• QuietAir elbow <sup>3</sup>	–	–	–	–
• Frame	✓	–	✓	30
• Headgear	–	✓	✓	30

<sup>1</sup>This mask may not be available in all regions. For full details regarding the correct use of this mask, 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.

<sup>2</sup> If a healthcare facility requires an additional disinfection cycle after reassembly, the number of validated cycles must be halved.

<sup>3</sup> Replace these parts with new parts between patients.



# Thermal disinfection procedure

<b>1. Disassembly</b>	Disassemble the mask according to the instructions in the User Guide.																																																			
<b>2. Cleaning</b>	<p><b>Cushion / frame / headgear / standard elbow (manual):</b></p> <ol style="list-style-type: none"> <li>Rinse the frame and standard elbow under running water<sup>1</sup> as follows. <table border="1" data-bbox="432 261 1178 324"> <tr> <td>• Frame</td> <td>20-25°C</td> <td>1 minute rinse.</td> </tr> <tr> <td>• Standard elbow</td> <td>15-25°C</td> <td>1 minute rinse.</td> </tr> </table> </li> <li>Soak the mask components as follows. Ensure there are no air bubbles. <table border="1" data-bbox="432 354 1755 477"> <tr> <td>• Cushion</td> <td>1-2% Alconox solution</td> <td>20-25°C</td> <td>1 minute soak.</td> </tr> <tr> <td>• Frame</td> <td>1-2% Alconox solution</td> <td>35-40°C</td> <td>5 minutes soak, then vigorously agitate for another 5 minutes.</td> </tr> <tr> <td>• Headgear</td> <td>1-2% Alconox solution</td> <td>20-30°C</td> <td>3 minutes soak.</td> </tr> <tr> <td>• Standard elbow</td> <td>1.5-2% Alconox solution</td> <td>40-50°C</td> <td>5 minutes soak, then vigorously agitate for another 3 minutes.</td> </tr> </table> </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. <table border="1" data-bbox="432 505 1268 628"> <tr> <td>• Cushion</td> <td>1 minute clean.</td> </tr> <tr> <td>• Frame</td> <td>1 minute clean.</td> </tr> <tr> <td>• Headgear</td> <td>2 minutes clean. Afterwards squeeze to remove excess solution.</td> </tr> <tr> <td>• Standard elbow</td> <td>1 minute clean.</td> </tr> </table> </li> <li>Rinse the components in water<sup>1</sup> as follows. <table border="1" data-bbox="432 656 1734 748"> <tr> <td>• Cushion</td> <td>5 liters</td> <td>13-18°C</td> <td>Vigorously agitate for 1 minute then repeat one more time.</td> </tr> <tr> <td>• Frame</td> <td>5 liters</td> <td>15-20°C</td> <td>Vigorously agitate for 1 minute.</td> </tr> <tr> <td>• Standard elbow</td> <td>5 liters</td> <td>15-25°C</td> <td>Vigorously agitate for 1 minute.</td> </tr> </table> </li> <li>Rinse the components under running water<sup>1</sup> as follows. <table border="1" data-bbox="432 776 1463 868"> <tr> <td>• Frame</td> <td>20-25°C</td> <td>1 minute rinse.</td> </tr> <tr> <td>• Headgear</td> <td>20-25°C</td> <td>Repeatedly squeeze for 90 seconds.</td> </tr> <tr> <td>• Standard elbow</td> <td>15-25°C</td> <td>1 minute rinse. Afterwards shake to remove excess water.</td> </tr> </table> </li> </ol> <p><b>Standard elbow (ultrasonic bath):</b></p> <ol style="list-style-type: none"> <li>Rinse and clean the component with a soft bristle brush under running water<sup>1</sup> at 20-30°C for 1 minute. Pay particular attention to all crevices, cavities and rotate moveable parts.</li> <li>Fill two-thirds of an ultrasonic cleaner with 1% Alconox solution at 20-30°C and sonicate for 20 minutes. Ensure the component is fully immersed in the solution. Use a basket/tray to prevent contact between the component and the tank.</li> <li>Rinse the component by agitating vigorously in 5 liters of water<sup>1</sup> at 20-30°C for 1 minute. Repeat one more time.</li> </ol>	• Frame	20-25°C	1 minute rinse.	• Standard elbow	15-25°C	1 minute rinse.	• Cushion	1-2% Alconox solution	20-25°C	1 minute soak.	• Frame	1-2% Alconox solution	35-40°C	5 minutes soak, then vigorously agitate for another 5 minutes.	• Headgear	1-2% Alconox solution	20-30°C	3 minutes soak.	• Standard elbow	1.5-2% Alconox solution	40-50°C	5 minutes soak, then vigorously agitate for another 3 minutes.	• Cushion	1 minute clean.	• Frame	1 minute clean.	• Headgear	2 minutes clean. Afterwards squeeze to remove excess solution.	• Standard elbow	1 minute clean.	• Cushion	5 liters	13-18°C	Vigorously agitate for 1 minute then repeat one more time.	• Frame	5 liters	15-20°C	Vigorously agitate for 1 minute.	• Standard elbow	5 liters	15-25°C	Vigorously agitate for 1 minute.	• Frame	20-25°C	1 minute rinse.	• Headgear	20-25°C	Repeatedly squeeze for 90 seconds.	• Standard elbow	15-25°C	1 minute rinse. Afterwards shake to remove excess water.
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<b>3. Inspection and drying</b>	<ol style="list-style-type: none"> <li>Inspect and if required, repeat washing until visually clean.<sup>2</sup></li> <li>Squeeze the headgear to remove excess water.</li> <li>Allow the mask components to air dry out of direct sunlight.<sup>3</sup></li> </ol>																																																			
<b>4. Disinfection and drying</b>	<ol style="list-style-type: none"> <li>Soak the mask components in a hot water<sup>1</sup> bath using the following temperature-time combinations. Ensure there are no air bubbles. <table border="1" data-bbox="432 1149 1136 1213"> <tr> <td>• Cushion / frame / standard elbow</td> <td>90°C</td> <td>1 minute soak</td> </tr> <tr> <td>• Headgear</td> <td>93°C</td> <td>10 minutes soak</td> </tr> </table> </li> <li>Squeeze the headgear to remove excess water.</li> <li>Allow the mask components to air dry out of direct sunlight.</li> </ol>	• Cushion / frame / standard elbow	90°C	1 minute soak	• Headgear	93°C	10 minutes soak																																													
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<b>5. Inspection</b>	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 are acceptable.																																																			
<b>6. Reassembly</b>	Reassemble the mask according to the instructions in the User Guide.																																																			
<b>7. Packaging and storage</b>	Store in a dry, dust-free environment away from direct sunlight. <b>Storage temperature:</b> -20°C to 60°C.																																																			

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

<sup>2</sup> Failure to clean the mask component as indicated may result in inadequate disinfection.

<sup>3</sup> Drying is not required if thermal disinfection is continued immediately.

## Thermal disinfection procedure - WD

<b>1. Disassembly</b>	Disassemble the mask according to the instructions in the User Guide.																								
<b>2. WD<sup>1</sup></b>	<ol style="list-style-type: none"> <li>1. Soak the mask components in a 5 litre rinse bath of cold tap water<sup>1</sup> for 1 minute. Ensure there are no air bubbles on the components.</li> <li>2. Rinse the components under cold running tap water<sup>1</sup> for 30 seconds.</li> <li>3. Transfer the components into an ISO 15883 series compliant washer-disinfector.</li> <li>4. Set the washer-disinfector using the following settings:</li> </ol> <table border="1"> <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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<b>3. Inspection / Drying</b>	<ol style="list-style-type: none"> <li>1. Inspect and if required, repeat section [2. WD] until visually clean.<sup>2</sup></li> <li>2. Squeeze the headgear to remove excess water.</li> <li>3. Allow the components to air dry out of direct sunlight.</li> </ol>																								
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<sup>1</sup> 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.

<sup>2</sup> Failure to clean the mask component as indicated may result in inadequate disinfection.



## GENERAL WARNINGS AND CAUTIONS

- ResMed cannot give any assurance that deviations from the procedures listed in this guide (eg, exceeding the number of reprocessing cycles), and their effect on the performance or safety of the product, will be acceptable.
- Mask components should not be subjected to autoclave or ethylene-oxide gas sterilization.
- When using detergents or disinfectants, always follow the manufacturer's instructions. In the event of conflict, this guide takes precedence.
- Do not iron the headgear as the material is heat sensitive and will be damaged