

Disinfection guide

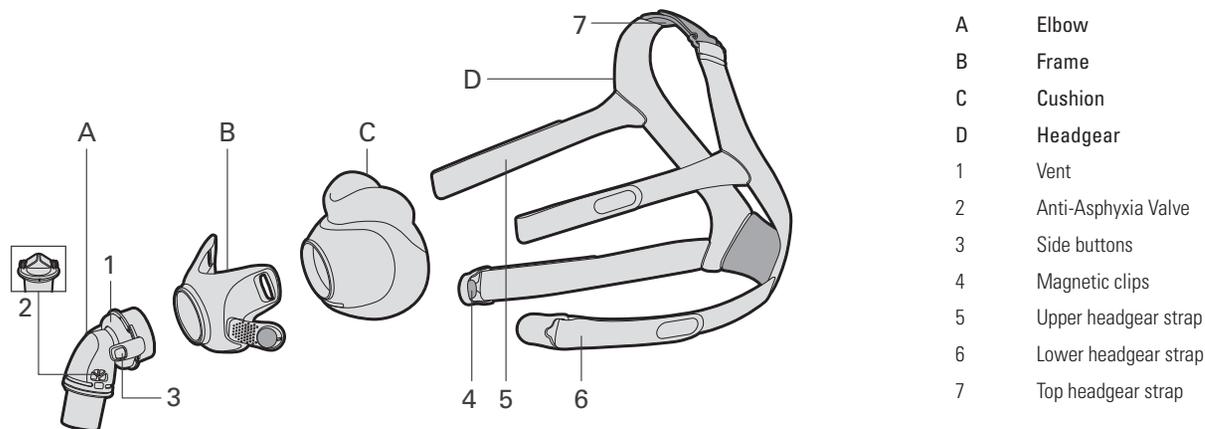
This guide is intended for multi-patient re-use of the AirFit F30 full face mask in a sleep lab, clinic or hospital. If you use the mask as a single user in the home, refer to the User Guide for cleaning instructions. This guide describes ResMed's recommended and validated procedures for cleaning and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

AirFit F30 mask component ¹	Cleaning - Alconox			Validated number of cycles ²
	High level thermal disinfection - Manual			
	167°F (75°C) for 30 minutes	194°F (90°C) for 1 minute	200°F (93°C) for 10 minutes	
• Cushion	✓	✓	–	30
• Standard elbow	✓	✓	–	30
• QuietAir elbow ³	–	–	–	–
• Frame	✓	✓	–	30
• Headgear	✓	–	✓	30

¹ 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.

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

³ Replace these parts with new parts between patients.



- A Elbow
- B Frame
- C Cushion
- D Headgear
- 1 Vent
- 2 Anti-Asphyxia Valve
- 3 Side buttons
- 4 Magnetic clips
- 5 Upper headgear strap
- 6 Lower headgear strap
- 7 Top headgear strap

Thermal disinfection procedure

1. Disassembly	Disassemble the mask according to the instructions in the User Guide.																																																			
2. Cleaning	<p>Cushion / frame / headgear / standard elbow (manual):</p> <p>1. Rinse the frame and standard elbow under running water¹ as follows.</p> <table border="1" data-bbox="436 264 1178 326"> <tr> <td>• Frame</td> <td>68-77°F (20-25°C)</td> <td>1 minute rinse.</td> </tr> <tr> <td>• Standard elbow</td> <td>59-77°F (15-25°C)</td> <td>1 minute rinse.</td> </tr> </table> <p>2. Soak the mask components as follows. Ensure there are no air bubbles.</p> <table border="1" data-bbox="436 358 1755 477"> <tr> <td>• Cushion</td> <td>1-2% Alconox solution</td> <td>68-77°F (20-25°C)</td> <td>1 minute soak.</td> </tr> <tr> <td>• Frame</td> <td>1-2% Alconox solution</td> <td>95-104°F (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>68-86°F (20-30°C)</td> <td>3 minutes soak.</td> </tr> <tr> <td>• Standard elbow</td> <td>1.5-2% Alconox solution</td> <td>104-122°F (40-50°C)</td> <td>5 minutes soak, then vigorously agitate for another 3 minutes.</td> </tr> </table> <p>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.</p> <table border="1" data-bbox="436 505 1268 630"> <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> <p>4. Rinse the components in water¹ as follows.</p> <table border="1" data-bbox="436 659 1734 751"> <tr> <td>• Cushion</td> <td>5 liters</td> <td>55-64°F (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>59-68°F (15-20°C)</td> <td>Vigorously agitate for 1 minute.</td> </tr> <tr> <td>• Standard elbow</td> <td>5 liters</td> <td>59-77°F (15-25°C)</td> <td>Vigorously agitate for 1 minute.</td> </tr> </table> <p>5. Rinse the components under running water¹ as follows.</p> <table border="1" data-bbox="436 781 1463 873"> <tr> <td>• Frame</td> <td>68-77°F (20-25°C)</td> <td>1 minute rinse.</td> </tr> <tr> <td>• Headgear</td> <td>68-77°F (20-25°C)</td> <td>Repeatedly squeeze for 90 seconds.</td> </tr> <tr> <td>• Standard elbow</td> <td>59-77°F (15-25°C)</td> <td>1 minute rinse. Afterwards shake to remove excess water.</td> </tr> </table> <p>Standard elbow (ultrasonic bath):</p> <p>1. Rinse and clean the component with a soft bristle brush under running water¹ at 68-86°F (20-30°C) for 1 minute. Pay particular attention to all crevices, cavities and rotate moveable parts.</p> <p>2. Fill two-thirds of an ultrasonic cleaner with 1% Alconox solution at 68-86°F (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.</p> <p>3. Rinse the component by agitating vigorously in 5 liters of water¹ at 68-86°F (20-30°C) for 1 minute. Repeat one more time.</p>	• Frame	68-77°F (20-25°C)	1 minute rinse.	• Standard elbow	59-77°F (15-25°C)	1 minute rinse.	• Cushion	1-2% Alconox solution	68-77°F (20-25°C)	1 minute soak.	• Frame	1-2% Alconox solution	95-104°F (35-40°C)	5 minutes soak, then vigorously agitate for another 5 minutes.	• Headgear	1-2% Alconox solution	68-86°F (20-30°C)	3 minutes soak.	• Standard elbow	1.5-2% Alconox solution	104-122°F (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	55-64°F (13-18°C)	Vigorously agitate for 1 minute then repeat one more time.	• Frame	5 liters	59-68°F (15-20°C)	Vigorously agitate for 1 minute.	• Standard elbow	5 liters	59-77°F (15-25°C)	Vigorously agitate for 1 minute.	• Frame	68-77°F (20-25°C)	1 minute rinse.	• Headgear	68-77°F (20-25°C)	Repeatedly squeeze for 90 seconds.	• Standard elbow	59-77°F (15-25°C)	1 minute rinse. Afterwards shake to remove excess water.
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3. Inspection and drying	<p>1. Inspect and if required, repeat washing until visually clean.²</p> <p>2. Squeeze the headgear to remove excess water.</p> <p>3. Allow the mask components to air dry out of direct sunlight.³</p>																																																			
4. Disinfection and drying	<p>1. Soak the mask components in a hot water¹ bath using the following temperature-time combinations. Ensure there are no air bubbles.</p> <table border="1" data-bbox="436 1154 1094 1260"> <tr> <td rowspan="2">• Cushion / frame / standard elbow</td> <td>167°F (75°C)</td> <td>30 minutes soak OR</td> </tr> <tr> <td>194°F (90°C)</td> <td>1 minute soak</td> </tr> <tr> <td rowspan="2">• Headgear</td> <td>167°F (75°C)</td> <td>30 minutes soak OR</td> </tr> <tr> <td>200°F (93°C)</td> <td>10 minutes soak</td> </tr> </table> <p>2. Squeeze the headgear to remove excess water.</p> <p>3. Allow the mask components to air dry out of direct sunlight.</p>	• Cushion / frame / standard elbow	167°F (75°C)	30 minutes soak OR	194°F (90°C)	1 minute soak	• Headgear	167°F (75°C)	30 minutes soak OR	200°F (93°C)	10 minutes soak																																									
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5. 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 discoloration of the silicone components may occur and are acceptable.																																																			
6. Reassembly	Reassemble the mask according to the instructions in the User Guide.																																																			
7. Packaging and storage	Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -4°F to 140°F (-20°C to 60°C).																																																			

¹ For all cleaning, rinsing and disinfection steps, use drinking quality water.

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

³ Drying is not required if thermal disinfection is continued immediately.



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