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.

<table>
<thead>
<tr>
<th>AirFit F30 mask component¹</th>
<th>Cleaning - Alconox</th>
<th>Thermal Disinfection - Manual</th>
<th>Thermal Disinfection - Manual</th>
<th>Validated number of cycles²</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>191°F (90°C) for 1 minute</td>
<td>200°F (93°C) for 10 minute</td>
<td></td>
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<tr>
<td>• Cushion</td>
<td>✓</td>
<td></td>
<td></td>
<td>30</td>
</tr>
<tr>
<td>• Standard elbow</td>
<td>✓</td>
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<td>30</td>
</tr>
<tr>
<td>• QuietAir elbow³</td>
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<tr>
<td>• Frame</td>
<td>✓</td>
<td></td>
<td></td>
<td>30</td>
</tr>
<tr>
<td>• Headgear</td>
<td></td>
<td></td>
<td>✓</td>
<td>30</td>
</tr>
</tbody>
</table>

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.
Thermal disinfection procedure

1. Disassembly
Disassemble the mask according to the instructions in the User Guide.

Cushion / frame / headgear / standard elbow (manual):
1. Rinse the frame and standard elbow under running water\textsuperscript{1} as follows.
   - Frame 68-77°F (20-25°C) 1 minute rinse.
   - Standard elbow 59-77°F (15-25°C) 1 minute rinse.

2. Soak the mask components as follows. Ensure there are no air bubbles.
   - 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 68-88°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.

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.
   - Cushion 1 minute clean.
   - Frame 1 minute clean.
   - Headgear 2 minutes clean. Afterwards squeeze to remove excess solution.
   - Standard elbow 1 minute clean.

4. Rinse the components in water\textsuperscript{1} as follows.
   - 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.

5. Rinse the components under running water\textsuperscript{1} as follows.
   - 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.

Standard elbow (ultrasonic bath):
1. Rinse and clean the component with a soft bristle brush under running water\textsuperscript{1} at 68-86°F (20-30°C) for 1 minute. Pay particular attention to all crevices, cavities and rotate moveable parts.
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.
3. Rinse the component by agitating vigorously in 5 liters of water\textsuperscript{1} at 68-86°F (20-30°C) for 1 minute. Repeat one more time.

2. Cleaning

3. Inspection and drying
1. Inspect and if required, repeat washing until visually clean.\textsuperscript{2}
2. Squeeze the headgear to remove excess water.
3. Allow the mask components to air dry out of direct sunlight.\textsuperscript{3}

4. Disinfection and drying
1. Soak the mask components in a hot water\textsuperscript{1} bath using the following temperature-time combinations. Ensure there are no air bubbles.
   - Cushion / frame / standard elbow 194°F (90°C) 1 minute soak
   - Headgear 200°F (93°C) 10 minutes soak
2. Squeeze the headgear to remove excess water.
3. Allow the mask components to air dry out of direct sunlight.

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).

\textsuperscript{1} For all cleaning, rinsing and disinfection steps, use drinking quality water.
\textsuperscript{2} Failure to clean the mask component as indicated may result in inadequate disinfection.
\textsuperscript{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 (e.g., 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