

Disinfection guide

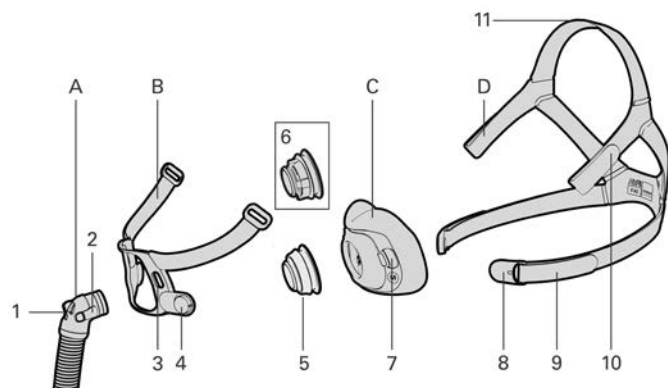
Clinical use only

This guide is intended for multi-patient re-use of the AirFit F40 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. Potable water with hardness ≤150 mg/L is recommended for all cleaning, rinsing and disinfection steps. Where local regulation impose water quality requirements for medical device reprocessing, these requirements shall be met.

Mask component ¹	Cleaning		Validated number of cycles
	Alconox™ (Mild alkaline, anionic detergent)	Neodisher™ Mediclean Forte (Alkaline, enzymatic detergent)	
	Thermal Disinfection		
	Manual 75°C for 30 minutes 80°C for 10 minutes 90-93°C for 1 to 10 minutes	Washer-disinfector A0 of 3000 to 11 971 (90-93°C for 5-10 minutes)	
Cushion	✓	✓	30
Frame	✓	✓	
Multi-hole vent ring	✓	✓	
Elbow and short tube	✓	✓	
Headgear	✓	✓	
Magnetic clip	✓ (30 cycles)	✓ (15 cycles)	15 or 30
QuietAir™ vent ring	–	–	Not intended for multi-patient use ²

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

² Replace with new parts between patients.



A	Elbow and short tube	7	Cushion stud
B	Frame	8	Magnetic clip
C	Cushion	9	Lower headgear strap
D	Headgear	10	Upper headgear strap
1	Anti-asphyxia valve (AAV)	11	Top headgear strap
2	Side button		
3	Frame stud hole		
4	Frame magnet		
5	QuietAir vent ring		
6	Multi-hole vent ring		

Manual cleaning and disinfection procedure

1. Disassembly	Disassemble the mask according to the instructions in the User Guide. Keep the magnetic clips attached to the lower headgear straps.
2. Cleaning	1. Make a solution of a mild alkaline, anionic detergent and water as per manufacturer's instructions. ResMed has validated: • Alconox 1% concentration (10 g/L) 30-55°C 2. Soak all mask components for 5 to 10 minutes. Ensure there are no air bubbles. 3. After the soaking time, while keeping the components in the solution, clean the inside and outside with a soft bristle brush as follows. A soft bristle tube/bottle brush is required to clean the inside of the multi-hole elbow and short tube. Pay particular attention to the crevices and cavities. • Cushion / frame / headgear 1 minute brushing • Multi-hole vent ring 1 minute brushing, followed by 1 minute agitating in the solution. Pay particular attention to the vent holes. • Elbow and short tube 30 seconds brushing including minimum 15s of brushing inside of the short tube 4. Rinse the components as follows under running water at 20-60°C directly contacting all surfaces. • Cushion / multi-hole vent ring / elbow and short tube 30-60 seconds rinsing • Frame 30-60 seconds rinsing, while squeezing the fabric component repeatedly and thoroughly • Headgear 90 seconds rinsing, while squeezing repeatedly and thoroughly
3. Inspection and drying	1. Inspect and if required, repeat all steps in section [2. Cleaning] until visually clean. 2. Squeeze the fabric components to remove excess water. 3. Allow the mask components to air dry out of direct sunlight. Drying is not required if thermal disinfection is continued immediately.
4. Disinfection	1. Fully immerse the mask components in a hot water bath using one of the following temperature-time combinations. Agitate the components in the water bath to ensure no air bubbles are trapped. • 75°C for 30 minutes, OR • 80°C for 10 minutes, OR • 90-93°C for 1 to 10 minutes 2. Squeeze the fabric components to remove excess water. 3. Allow the 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 discolouration of the silicone components may occur and is acceptable.
6. Reassembly	Reassemble the mask according to the instructions in the User Guide.
7. Storage and transportation	For storage and transportation details, check the User Guide.

Automated washer disinfecter procedure

1. Disassembly	Disassemble the mask according to the instructions in the User Guide. Keep the magnetic clips attached to the lower headgear straps.			
2. Pre-wash	1. Soak the mask components in a 5 litre rinse bath of cold water for 1 minute. Ensure there are no air bubbles on the components. 2. Rinse each component under cold running water for 30 seconds. Ensure internal surfaces are flushed.			
3. Washer-disinfecter	1. Transfer the components into an ISO 15883 series compliant washer-disinfecter. Items should be oriented to ensure effective drainage. For the elbow and short tube, place on a spray nozzle of a load carrier/rack to facilitate water flow through the mask tubing. All other components can be placed in the basket of the rack			
	2. Set the washer-disinfecter with reference to the cleaning chemical instructions for use, and the following conditions:			
	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	-
4. Inspection and drying	1. Inspect and if required, repeat all steps in section [2. Washer-disinfecter] until visually clean. 2. Squeeze the fabric components 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 is acceptable.			
6. Reassembly	Reassemble the mask according to the instructions in the User Guide.			
7. Storage and transportation	For storage and transportation details, check the User Guide.			

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 vapors. 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.
- Failure to thoroughly clean and disinfect the mask component as indicated may result in inadequate disinfection.
- 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.