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Clinical use only

# Disinfection guide

This guide provides the reprocessing instructions for the Sleep Lab Mask (SLM) variants of the AirFit<sup>™</sup> F30i, AirFit F30i Non Magnetic and AirFitX30i masks only, which are intended for multi-patient reuse in a sleep lab, clinic or hospital. The Sleep Lab Mask variant is identified by the "SLM" acronym on the packaging label and a Unique Device Identifier labeling on the mask. 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.

### AirFit F30i, AirFit X30i

			Cleaning	
Mask system		1	Alconox™ (mild alkaline, anionic detergent)	
			Thermal high level disinfection	
AirFit F30i	AirFit X30i	Mask component	167°F (75°C) for 30 minutes OR 194-199°F (90-93°C) for 1 to 10 minutes	Validated number of cycles
٠	-	AirFit F30i cushion	$\checkmark$	30
٠	•	Frame / frame magnets	$\checkmark$	
•	•	Elbow body / elbow clip / elbow ring	$\checkmark$	
٠	•	Headgear and magnetic clips	$\checkmark$	
_	•	AirFit X30i oral cushion	$\checkmark$	
_	•	Multi-hole vent	$\checkmark$	
_	•	QuietAir™ vent	-	Not intended for multi-patient
_	•	AirFit X30i pillows / pillows connector	-	re-use

Mask and components 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 Res/Med.com.



#### AirFit F30i Non Magnetic

	Cleaning	
	Alconox (mild alkaline, anionic detergent)	
	Thermal high level disinfection	Validated number of cycles
Mask component	167°F (75°C) for 30 minutes OR 194-199°F (90-93°C) for 1 to 10 minutes	
AirFit F30i cushion	$\checkmark$	
Frame / frame clips	$\checkmark$	20
Elbow body / elbow clip / elbow ring	$\checkmark$	- 30
Headgear and mask clips	$\checkmark$	

Mask and components 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.



4 Elbow ring

6

Additional disassembly



- A Elbow body
- B Frame
- C Cushion
- D Headgear
- 1 Vent holes (cushion)
- 2 Vent holes (elbow)
- 3 Elbow clip
- 7 Mask clip8 Lower headgear strap

Frame connector and frame clip

of frame connector)

5 Anti-Asphyxia valve (inside the left and right

9 Upper headgear strap

## Thermal disinfection procedure

	<ol> <li>Disassemble the mask according to the instructions in the User Guide.</li> <li>Additionally for both AirFit F30i and AirFit X30i:</li> </ol>				
	Firmly pull the elbow clip away from the elbow body. (Fig a.)				
	<ul> <li>Pull the elbow ring out of the frame. (Fig b.)</li> </ul>				
1. Disassembly	<ul> <li>Firmly slide the frame magnetic clip from the frame connector. Repeat on the other side. (Fig c.)</li> </ul>				
1. Disassembly	3. Additionally for AirFit X30i:				
	Peel the multi-hole vent from the oral cushion. (Fig d.)				
	<ul> <li>Firmly pull the pillows (including connector) away from the oral cushion (Fig. e) and discard.</li> </ul>				
	<ul> <li>4. Discard any mask components not intended for multi-patient re-use.</li> </ul>				
	1. Make a solution of a mild alkaline, anionic detergent and water as per manufacturer's instructions. ResMed has validated the following:				
	• Alconox 1% concentration (10 g/L) 86-131°F (30-55°C)				
	2. Soak all mask components for 5 to 10 minutes. Ensure there are no air bubbles.				
	<ol> <li>After the soaking time, while keeping the components in the solution, clear follows. Pay particular attention to the crevices and cavities.</li> </ol>	In the inside and outside with a soft bristle tube/bottle brush (inside the frame) or soft bristle brush (all other components) as			
2. Cleaning	Elbow body	30 seconds brushing			
	• Elbow clip / elbow ring / frame magnetic clips / multi-hole vent	10 seconds brushing			
	AirFit F30i cushion / AirFit X30i oral cushion / frame / headgear	1 minute brushing			
	4. Rinse the components as follows under running water at 68-140°F (20-60°	C) directly contacting all surfaces.			
	• Headgear	1 minute rinsing, while squeezing repeatedly			
	All other mask components	30-60 seconds rinsing			
	1. Inspect and if required, repeat all steps in section [2. Cleaning] until visually clean. Failure to clean the mask component as indicated may result in inadequate disinfection.				
3. Inspection and drying	2. Squeeze the headgear 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.				
	1. Soak the mask components in a hot water bath using one of the following temperature-time combinations. Ensure there are no air bubbles.				
	<ul> <li>167°F (75°C) for 30 minutes OR</li> </ul>				
4. Disinfection	• 194-199°F (90-93°C) for 1 to 10 minutes				
	2. Squeeze the headgear 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 replace				
Slight discoloration of the silicone components may occur and is acceptable.					
	1. Push the elbow clip onto the elbow body until it clicks into place.				
	2. Insert the elbow ring into the top of the frame.				
6. Reassembly	3. Firmly slide the frame magnetic clip onto the frame connector. Repeat on the other side.				
0. 110000011101y	4. Reassemble the mask according to the instructions in the User Guide.				
	Additionally for the AirFit X30i				
	5. Align the tab in the oral cushion with the notch in the multi-hole vent. Insert the multi-hole vent into the oral cushion.				
7. Storage and transportation	For storage and transportation details, check the User Guide.				



#### $m \ \ M$ 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.
- Failure to clean and disinfect the mask 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.



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