

AirTouch 1 N30i **Air**Fit[™] N30*i* **Air**Fit[™] P30*i*

Clinical use only

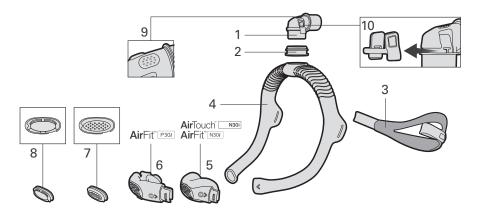
Disinfection guide

This guide provides the reprocessing instructions for the Sleep Lab Mask (SLM) variants of the AirTouch N30i, AirFit N30i, and AirFit P30i 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.

	Cleaning		
	Mild alkaline, anionic detergent (e.g. Alconox)		
	Thermal Disinfection - Manual		
Mask component ¹	167°F (75°C) for 30 minutes 194-199°F (90-93°C) for 1 to 10 minutes	Validated number of cycles	
Cushion (AirTouch N30i)	✓		
Cushion (AirFit N30i)	✓		
Cushion (AirFit P30i)	✓		
Multi-hole vent	✓	30	
Frame (SLM) ²	\checkmark		
Elbow body/ elbow clip/ elbow ring	\checkmark		
Headgear	\checkmark		
QuietAir™ vent³	Not intended for multi-patient use	-	

¹ Masks and components 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.

³ Replace with new parts between patients



1	Elbow body	
2	Elbow ring	
3	Headgear	
4	Frame (SLM)	
5	AirTouch / AirFit N30i cushion	
6	AirFit P30i cushion	
7	Multi-hole vent	
8	QuietAir vent	
9	Elbow vent	
10	Elbow clip	

Additional disassembly





² The frame of the Sleep Lab Mask (SLM) does not contain fabric sleeves.

Thermal disinfection procedure

1. Disassembly	 Disassemble the mask according to the instructions in the User Guide. Additionally: Remove the elbow clip away from the elbow body by firmly levering one side of the elbow clip (Fig. a.) Pull the elbow ring out of the frame. (Fig. b.) 		
	1. Make a solution of a mild alkaline, anionic detergent and water as per manufacturer's instructions. ResMed has validated: • Alconox 1% concentration (10g/L) 86-131°F (30-55 °C) 2. Soak all mask components for 5 to 10 minutes. Ensure there are no air bubbles.		
2. Cleaning	3. After the soaking time, while keeping the components in the solution, clean the inside and outside with a soft bristle brush (e.g., soft bristle toothbrush) as follows. The inside of the frame requires a soft bristle tube/bottle brush of an appropriate size to extend and contact all internal surfaces. Pay particular attention to the crevices and cavities. • Cushion (AirFit N30i, AirFit P30i) / elbow body 30 seconds brushing		
	Elbow clip / elbow ring / multi-hole vent	10 seconds brushing	
	 Cushion (AirTouch N30i) / frame (SLM) / headgear Rinse the components as follows under running water at 68-140°F (20-60°C) directly contacting all surfaces. 		
	Headgear / Cushion (AirTouch N30i) Multi-hole vent	1 minute rinsing, while squeezing repeatedly 10 seconds rinsing	
	All other components	30-60 seconds rinsing	
3. Inspection and drying	 Inspect all components to ensure they are visually clean. If not, repeat all steps in section [2. Cleaning] until all components are visually clean. Squeeze the fabric components to remove excess water. Allow the mask components to air dry out of direct sunlight. Drying is not required if thermal disinfection is continued immediately. 		
4. Disinfection	 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 167°F (75°C) for 30 minutes, OR 194-199°F (90-93°C) for 1 to 10 minutes Squeeze the fabric components to remove excess water. 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, pilling etc), the mask component should be discarded and replaced. Slight discoloration of the silicone and fabric components may occur and are acceptable. Disinfecting fabric components together may result in dye transfer stains and are acceptable.		
6. Reassembly	 Push the elbow clip onto the elbow body until it clicks into place. Insert the elbow ring into the top of the frame. 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 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 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.



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