



# Disinfection guide

Clinical use only

This guide is intended for multi-patient re-use of a ResMed full face mask, nasal mask or nasal pillows system ('mask') in a sleep lab, clinic or hospital. If you use the mask as a single patient 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.

Mask <sup>1</sup>		Replace with new parts between patients	Cleaning		Validated number of cycles
			Mild alkaline, Anionic detergent (eg, Alconox)	Neodisher Mediclean Forte	
			Thermal Disinfection		
			Manual	Washer-Disinfector (WD)	
Full face masks	Ultra Mirage	Valve membrane	✓	✓	15
	Ultra Mirage NV	-	✓	✓	
	Mirage Liberty	Swivel and inlet tube	✓	✓	20
	Mirage Quattro	-	✓	✓	
	Quattro FX <sup>2</sup>	-	✓	✓	
	Quattro FX NV	-	✓	✓	
	Quattro Air <sup>2</sup>	-	✓	✓	
	Quattro Air NV	-	✓	✓	
AirFit F10 <sup>2</sup>	-	✓	✓		
Nasal masks	Ultra Mirage NV Nasal	-	✓	✓	15
	Ultra Mirage II	-	✓	✓	
	Mirage Activa LT	-	✓	✓	20
	Mirage Micro	-	✓	✓	
	Mirage FX <sup>2</sup>	-	✓	✓	
	Swift FX Nano <sup>2</sup>	-	✓	✓	
	AirFit N10 <sup>2</sup>	-	✓	✓	
Nasal pillows systems	Mirage Swift II	Short tube	✓	✓	15
	Swift LT <sup>2</sup>	-	✓	✓	20
	Swift FX <sup>2</sup> / Swift FX Bella <sup>2</sup>	-	✓	✓	
	AirFit P10 <sup>2</sup>	Headgear clip	✓	✓	

<sup>1</sup>This mask may not be available in all regions. For full details regarding the correct use of these masks, 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.

<sup>2</sup>Includes all colour variants (eg, For Her) and AirFit P10 for AirMini cushion.

# Thermal disinfection procedure - Manual

<b>1. Disassembly</b>	Disassemble the mask according to the instructions in the User Guide <sup>1</sup> .
<b>2. Cleaning</b>	<ol style="list-style-type: none"> <li>1. Make a solution of a mild alkaline, anionic detergent and water<sup>2</sup> as per manufacturer's instructions. ResMed has validated the following: <ul style="list-style-type: none"> <li>• Alconox 1% concentration (10 g/L) 30-55°C temperature</li> </ul> </li> <li>2. Soak all mask components for 5 to 10 minutes. Ensure there are no air bubbles.</li> <li>3. After the soaking time, while keeping the components in the solution, clean the inside and outside of each component with a soft bristle brush for 1 minute. Pay particular attention to the crevices and cavities.</li> <li>4. Rinse the components as follows under running water<sup>2</sup> at 20-60°C directly contacting all surfaces: <ul style="list-style-type: none"> <li>• All components (excluding headgear) 30-60 seconds rinsing</li> <li>• Headgear 1 minute rinsing, while squeezing repeatedly</li> </ul> </li> </ol>
<b>3. Inspection and drying</b>	<ol style="list-style-type: none"> <li>1. Inspect and if required, repeat all steps of [2. Cleaning] section until visually clean.<sup>3</sup></li> <li>2. Squeeze the headgear to remove excess water.</li> <li>3. Allow the components to air dry out of direct sunlight.<sup>4</sup></li> </ol>
<b>4. Disinfection</b>	<ol style="list-style-type: none"> <li>1. Soak the mask components in a hot water bath<sup>2</sup> using one of the following temperature-time combinations. <ul style="list-style-type: none"> <li>• 70°C for 100 minutes, OR</li> <li>• 75°C for 30 minutes, OR</li> <li>• 80°C for 10 minutes, OR</li> <li>• 90-93°C for 1 to 10 minutes</li> </ul> </li> <li>2. Squeeze the headgear to remove excess water.</li> <li>3. Allow the components to air dry out of direct sunlight.</li> </ol>
<b>5. Inspection</b>	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.
<b>6. Reassembly</b>	Reassemble the mask according to the instructions in the User Guide.
<b>7. Storage and transportation</b>	For storage and transportation details, check the User Guide.

<sup>1</sup> Disassemble the swivel from the short tube for Swift FX, Swift FX Nano, AirFit P10 and AirFit N10.

<sup>2</sup> For all cleaning, rinsing and disinfection steps, use drinking quality water. Where local regulations impose water quality requirements for medical device reprocessing, these requirements must be met.

<sup>3</sup> Failure to clean the mask component as indicated may result in inadequate disinfection.

<sup>4</sup> Drying is not required if thermal disinfection is continued immediately.

# Thermal disinfection procedure - Washer-Disinfector

<b>1. Disassembly</b>	Disassemble the mask according to the instructions in the User Guide. <sup>1</sup>																								
<b>2. Washer-Disinfector</b>	<p>1. Soak the mask components in a 5 litre rinse bath of cold tap water<sup>2</sup> for 1 minute. Ensure there are no air bubbles on the components.</p> <p>2. Rinse each component under cold running tap water<sup>2</sup> for 30 seconds. Ensure internal surfaces are flushed.</p> <p>3. Transfer the components into an ISO 15883 series compliant washer-disinfector<sup>3</sup>. Items should be oriented to ensure effective drainage.</p> <p>4. Set the washer-disinfector using the following settings:</p> <table border="1" data-bbox="477 336 1621 595"> <thead> <tr> <th>Phase/Stage</th> <th>Recirculation time (minutes)</th> <th>Temperature (°C)</th> <th>Detergent</th> </tr> </thead> <tbody> <tr> <td>Pre-wash</td> <td>4</td> <td>Cold</td> <td>-</td> </tr> <tr> <td>Wash</td> <td>10</td> <td>43-60</td> <td>2-10 mL/L (0.2-1%) Neodisher MediClean forte</td> </tr> <tr> <td>Neutralisation</td> <td>6</td> <td>43-60</td> <td>1-2 mL/L (0.1-0.2%) Neodisher Z</td> </tr> <tr> <td>Final Rinse</td> <td>3</td> <td>43-60</td> <td>-</td> </tr> <tr> <td>Thermal Disinfection</td> <td>5-10</td> <td>90-93</td> <td>-</td> </tr> </tbody> </table>	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	-
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<sup>1</sup> Disassemble the swivel from the short tube for Swift FX, Swift FX Nano, AirFit P10 and AirFit N10.

<sup>2</sup> For all washing, rinsing and disinfection steps, use drinking quality water. Where local regulations impose water quality requirements for medical device reprocessing, these requirements shall be met.

<sup>3</sup> A washer-disinfector load carrier/rack containing spray/injector nozzles is required for components with short tube/tubing, e.g. AirFit P10 frame, to facilitate water flow through the mask tubing

<sup>4</sup> Failure to clean the mask component as indicated may result in inadequate disinfection.



## 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.
- Mask components should not be subjected to autoclave or ethylene-oxide gas sterilisation.
- 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.