

# Disinfection and sterilisation guide

Clinical use only

This guide is intended for multipatient 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 user in the home, refer to the User Guide for cleaning instructions. This guide describes ResMed's recommended and validated procedures for cleaning, disinfection and sterilisation of the mask in accordance with ISO17664.

Note: Only masks listed in the table below have been validated for reprocessing between patients.

Mask <sup>1</sup>	Replace these parts with new parts between patients	High level thermal disinfection	High level chemical disinfection			Sterilisation		Validated number of cycles <sup>2</sup>
		EN ISO 15883-1 70°C-100 min; 75°C-30 min 80°C-10 min; 90°C-1 min European regional requirements 93°C-10 min	Anioxyde™ 1000 Peracetic acid 0.15% for 30 minutes	CIDEX™ OPA Orthophthal- aldehyde 0.55% for 20 minutes	CIDEX™ Plus Glutaraldehyde 3.4% for 20 minutes	STERRAD™		
						100S	NX	
Full face masks								
Mirage Liberty	Swivel, inlet tube	✓	✓	✓		✓	✓	20
Mirage Quattro <sup>3</sup>	None	✓	✓	✓		✓	✓	20
Quattro FX <sup>7</sup> / Quattro FX for Her <sup>7</sup>	None	✓	✓	✓		✓	✓	20
Quattro FX NV <sup>7</sup>	None	✓	✓	✓		✓	✓	20
Ultra Mirage	Valve membrane	✓	✓	✓	✓	✓		15
Ultra Mirage Non-vented	None	✓	✓	✓	✓	✓	✓	15
Mirage Series 2	Valve membrane	✓	✓	✓	✓	✓		15
Mirage Non-vented Series 2	None	✓	✓	✓	✓	✓		15
Quattro Air <sup>7</sup> / Quattro Air For Her <sup>7</sup>	None	✓	✓ <sup>8</sup>	✓			✓	20
Quattro Air NV <sup>7</sup>	None	✓	✓ <sup>8</sup>	✓			✓	20
AirFit F10 <sup>7</sup> / AirFit F10 for Her <sup>7</sup>	None	✓	✓ <sup>8</sup>	✓			✓	20
Nasal masks								
Mirage	Swivel, short tubing	✓	✓	✓	✓	✓		15
Mirage Activa	Swivel, inlet tube	✓	✓	✓	✓	✓		15
Mirage Activa LT <sup>3</sup>	None	✓	✓	✓		✓	✓	20
Mirage FX <sup>7</sup> / Mirage FX for Her <sup>7</sup>	None	✓	✓ <sup>8</sup>	✓				20
Mirage SoftGel <sup>3</sup>	None	✓	✓	✓		✓ <sup>6</sup>	✓ <sup>6</sup>	20
Mirage Kidsta	Swivel, inlet tube	✓	✓	✓	✓	✓		15

Mask <sup>1</sup>	Replace these parts with new parts between patients	High level thermal disinfection	High level chemical disinfection			Sterilisation		Validated number of cycles <sup>2</sup>
		EN ISO 15883-1 70°C-100 min; 75°C-30 min 80°C-10 min; 90°C-1 min European regional requirements 93°C-10 min	Anioxyde™ 1000 Peracetic acid 0.15% for 30 minutes	CIDEX™ OPA Orthophthal- aldehyde 0.55% for 20 minutes	CIDEX™ Plus Glutaraldehyde 3.4% for 20 minutes	STERRAD™		
						100S	NX	
Mirage Micro <sup>3</sup>	None	✓	✓	✓		✓	✓	20
Mirage Vista	Swivel, inlet tube	✓	✓	✓	✓	✓		15
Ultra Mirage II	None	✓	✓	✓	✓			15
Ultra Mirage Non-vented	None	✓	✓	✓	✓	✓		15
Mirage Non-vented	Swivel, short tubing		✓		✓			15
Swift FX Nano / Swift FX Nano for Her	None	✓	✓ <sup>9</sup>	✓		✓ <sup>5</sup>	✓ <sup>5</sup>	20
AirFit N10 <sup>7</sup> / AirFit N10 for Her <sup>7</sup>	None	✓	✓	✓			✓	20
Nasal pillows systems								
Swift FX / Swift FX for Her / Swift FX Bella / Swift FX Bella Gray	None	✓	✓	✓		✓ <sup>5</sup>	✓ <sup>5</sup>	20
Swift LT	None	✓	✓	✓		✓ <sup>5</sup>	✓ <sup>5</sup>	20
Swift LT for Her / Swift LT-F	None	✓	✓	✓		✓ <sup>5</sup>	✓ <sup>5</sup>	20
Mirage Swift II	None	✓ <sup>4</sup>	✓	✓	✓	✓		15
Mirage Swift	None	✓ <sup>4</sup>	✓	✓	✓	✓		15
AirFit P10 / AirFit P10 for Her	None	✓	✓ <sup>8</sup>	✓			✓	20

<sup>1</sup> Not all masks are 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 Components Card on [www.resmed.com](http://www.resmed.com).

<sup>2</sup> If a healthcare facility requires an additional disinfection or sterilisation cycle after reassembly, the number of validated cycles must be halved.

<sup>3</sup> Alternative disassembly available. See "Disassembling the masks before cleaning".

<sup>4</sup> Short tube assembly validated to 70°C.

<sup>5</sup> Short tube assembly cannot be treated via STERRAD sterilisation.

<sup>6</sup> Cushion cannot be treated via STERRAD sterilisation.

<sup>7</sup> Some components cannot be treated. Alternative cleaning must be used. See "Cleaning other components".

<sup>8</sup> Disinfection using this method is validated for 15 cycles only.

<sup>9</sup> Some components require additional cleaning. See "Validated disinfection and sterilisation procedures".

# Validated disinfection and sterilisation procedures

In the procedures below, only **one** of the following three disinfection or sterilisation procedures needs to be performed.

	High level thermal disinfection	High level chemical disinfection	Sterilisation
<b>Disassembly</b>	Disassemble the mask according to the instructions in the User Guide.		
<b>Cleaning and drying</b>	1. Clean the individual parts of the mask with a soft bristle brush for one minute while soaking them in one of the following detergents or disinfectants according to manufacturer's instructions. Pay particular attention to all crevices and cavities.		
	<ul style="list-style-type: none"> <li>• neodisher MediZym (concentration at 2% for 30 minutes),</li> <li>• neodisher MediClean forte (AirFit N10, AirFit F10, Swift LT and Activa LT only—concentration at 1%) or</li> <li>• Alconox (diluted at 1%).</li> </ul>	<ul style="list-style-type: none"> <li>• Aniosyme DD1 (diluted at 0.5% for 15 minutes) or</li> <li>• Alconox (diluted at 1%).</li> </ul>	<ul style="list-style-type: none"> <li>• Alconox (diluted at 1%).</li> </ul>
	2. Rinse the components twice by agitating them vigorously in drinking quality water (five litres per mask).		
<b>Pre-disinfection and drying</b>	Additional cleaning requirements when using Aniosyme DD1. These instructions apply only to: <ul style="list-style-type: none"> <li>• Swift FX Nano</li> <li>• Swift FX Nano for Her</li> </ul> After using the Aniosyme DD1 pre-cleaner, rinse the Swift FX Nano elbow assembly under running water for a minimum of 1 minute or until no visible solid is present on the elbow.		
	3. Allow the mask components to air dry out of direct sunlight.		
<b>Disinfection or sterilisation and drying</b>	1. Using a certified hot water disinfection system, soak the disinfectable mask components using a temperature-time combination <sup>1</sup> : <b>EN ISO 15883-1:</b> <ul style="list-style-type: none"> <li>• 70°C for 100 minutes</li> <li>• 75°C for 30 minutes</li> <li>• 80°C for 10 minutes</li> <li>• 90°C for 1 minute.</li> </ul> <b>Specific European regional requirements:</b> <ul style="list-style-type: none"> <li>• 93°C for 10 minutes.</li> </ul> 2. On completion, remove the mask components from the hot water disinfection system. 3. Allow the mask components to air dry out of direct sunlight.	1. Fully immerse and soak the disinfectable mask components in one of the following commercially available solutions according to the manufacturer's instructions: <ul style="list-style-type: none"> <li>• peracetic acid 0.15% (eg, Anioxyde 1000) for 30 minutes,</li> <li>• ortho-phthalaldehyde 0.55% (eg, CIDEX OPA) for 20 minutes or</li> <li>• glutaraldehyde 3.4% (eg, CIDEX Plus) for 20 minutes</li> </ul> When using these solutions follow the combinations: <ul style="list-style-type: none"> <li>• Aniosyme DD1 with Anioxyde 1000 or</li> <li>• Alconox with CIDEX OPA or CIDEX Plus.</li> </ul> 2. Rinse the mask components in drinking quality water (five litres per mask). 3. Allow the mask components to air dry out of direct sunlight.	1. Package the mask components prior to sterilisation as described in the manufacturer's instructions for the STERRAD Sterilisation System. ResMed masks have been validated using the tray method.  Note: The use of pouches is not recommended. 2. Sterilise the mask following the manufacturer's instructions for the STERRAD Sterilisation System.  Note: Drying is achieved as part of the sterilisation process.
<b>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>Reassembly</b>	Reassemble the mask according to the instructions in the User Guide.		
<b>Packaging and storage</b>	Store in a dry, dust-free environment away from direct sunlight. <b>Storage temperature:</b> -20°C to 60°C.		

<sup>1</sup> Calculated and predicted from known thermal inactivation kinetics of vegetative micro-organisms subjected to thermal disinfection (EN ISO 15883-1) and they are inclusive of the time-temperature combination recommended by the APIC (Associations for Professionals in Infection Control and Epidemiology) and RKI (Robert Koch Institute).



## Disassembling the masks before cleaning

These instructions apply only to:

- Mirage Quattro
- Mirage Micro
- Mirage Activa LT
- Mirage SoftGel.

As an alternate to the disassembly instructions shown in the relevant user guide for removing the forehead support and dial from the mask frame, you can disassemble these components as follows:

1. Unscrew the dial so that the forehead support protrudes about halfway from the mask frame.
2. Firmly push the forehead support against the mask frame until the dial clicks and detaches from the mask frame.
3. Fully unscrew and remove the dial, then pull forehead support out of the mask frame.

## Cleaning the headgear

The headgear does not require disinfection and should not be washed in disinfection chemicals. Thoroughly washing the headgear between patients is acceptable.

1. Handwash the headgear in warm 30°C water using mild soap.
2. Rinse well and allow it to air dry out of direct sunlight.

## Cleaning other components

These instructions apply only to:

- AirFit N10 / AirFit N10 for Her - Soft sleeves
- AirFit F10 / AirFit F10 for Her - Frame, Soft sleeves
- Quattro Air / Quattro Air For Her / Quattro Air NV - Frame
- Quattro FX / Quattro FX for Her - Spring frame, Soft sleeves
- Quattro FX NV - Spring frame, Soft sleeves
- Mirage FX / Mirage FX for Her - Frame.

The component does not require disinfection and should not be washed in disinfection chemicals. Thoroughly washing the component between patients is acceptable.

1. Handwash the component in warm 30°C water using mild soap.
2. Rinse well and allow it to air dry out of direct sunlight.



### GENERAL WARNINGS AND CAUTIONS

- ResMed cannot give any assurance that deviations from the procedures listed in this guide (eg, exceeding the number of reprocessing cycles), and their effect on the performance of the product, will be acceptable.
- Mask components should not be subjected to autoclave or ethylene-oxide gas sterilisation.
- When using detergents, disinfectants or sterilisation agents, always follow the manufacturer's instructions.
- Do not iron the headgear as the material is heat sensitive and will be damaged.