

# Disinfection and sterilisation guide

Clinical use only

This guide is intended for multipatient use of the AirFit™ F20 / AirTouch™ F20 ResMed full face 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.

AirFit F20 / AirTouch F20 mask component <sup>1</sup>	Cleaning							Validated number of cycles <sup>2</sup>
	Alconox	Neodisher <sup>4</sup>	Alconox	Aniosyme DD1	Gigazyme	Alconox	Alconox	
	Thermal disinfection		Chemical disinfection			Sterilisation		
	Manual	AWD <sup>5</sup>	CIDEX™ OPA	Anioxyde 1000	Gigasept FF	STERRAD™ 100S	STERRAD™ NX	
• AirFit F20 cushion	✓	✓	✓	✓	✓	✓	✓	30
• AirTouch F20 cushion <sup>3</sup>	–	–	–	–	–	–	–	–
• Standard elbow	✓	✓	–	–	✓	–	–	30
• QuietAir™ elbow <sup>3</sup>	–	–	–	–	–	–	–	–
• Frame	✓	✓	–	✓	✓	–	–	30
• Headgear	✓	✓	–	✓	✓	–	–	30

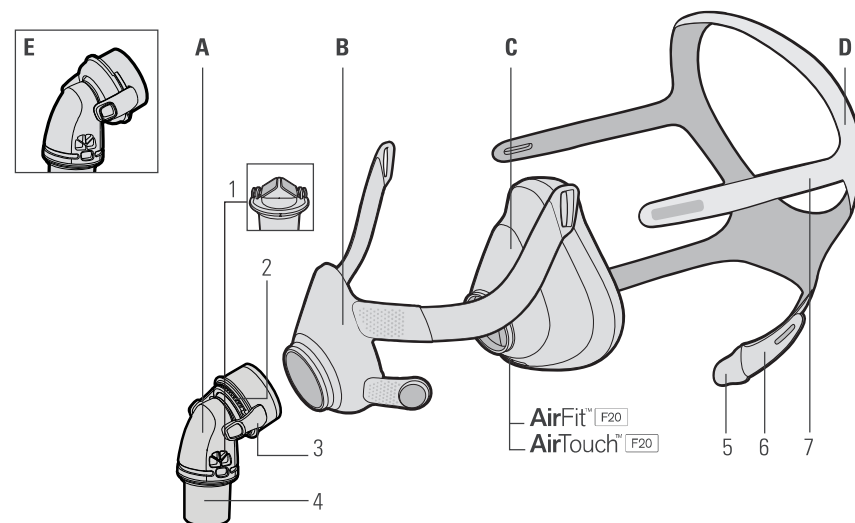
<sup>1</sup> This mask may not be available in all regions. For full details regarding the correct use of these masks, please refer to the specific User Guide. For a list of available replacement parts for each mask system, check the Product Guide on ResMed.com.

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

<sup>3</sup> This component is intended for single patient reuse.

<sup>4</sup> Neodisher MediZym or MediClean Forte.

<sup>5</sup> Automatic Washer-Disinfector.



- A

Standard elbow
- 1

Valve (AAV)
- 2

Vent
- 3

Side buttons
- 4

Swivel
- B

Frame
- C

Cushion
- D

Headgear
- 5

Magnetic clips
- 6

Lower headgear straps
- 7

Upper headgear straps
- A+B+C

Frame system
- A+B+C+D

Complete system
- E

QuietAir elbow

# Thermal disinfection procedures - Manual

Disassembly	Disassemble the mask according to the instructions in the User Guide.
Cleaning	<div><div>Alconox</div><div><div><div>AirFit F20 cushion:</div><div><div>1. Soak the component in 1% Alconox solution at 20-25°C for 1 minute.</div><div>2. Whilst immersed in the solution, clean with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities.</div><div>3. Rinse by shaking vigorously in 5 liters of drinking quality water. Repeat one more time.</div></div><div><div>Frame:</div><div><div>1. Rinse the component under running drinking quality water at 20-30°C for 1 minute.</div><div>2. Soak the component in 1% Alconox solution at 38.5-40°C for 5 minutes. Ensure no air bubbles are present and all surfaces come in contact with the solution.</div><div>3. Whilst immersed in the solution, shake vigorously for another 5 minutes while squeezing the fabric of the arms.</div><div>4. Clean with a soft bristle brush for another minute. Pay particular attention to all crevices and interfaces.</div><div>5. Rinse the component by agitating in 5 liters of drinking quality water at 19-20°C for 1 minute.</div><div>6. Rinse the component under drinking quality water at 19-20°C.</div></div><div><div>Headgear:</div><div><div>1. Make a solution of Alconox by diluting with drinking quality water at 1%, ie, 10 g per liter, at 20-30°C, according to the manufacturer's instructions.</div><div>2. Soak the component in the solution for 3 minutes.</div><div>3. Thoroughly clean the mask component with a soft bristle brush for 2 minute while continuing to soak it in the solution. Pay particular attention to all crevices and cavities.</div><div>4. Squeeze the component to remove excess solution.</div><div>5. Rinse the component by repeatedly squeezing it under running drinking quality water at 20-30°C for 30 seconds. Repeat two more times with fresh water.</div></div></div></div><div><div>Standard elbow (manual):</div><div><div>1. Rinse the component under running drinking quality water at 15-25°C for 1 minute.</div><div>2. Soak the component in 1.5-2% Alconox solution at 40-50°C for 5 minutes. Ensure no air bubbles are present and all surfaces come in contact with the solution.</div><div>3. Whilst immersed in the solution, shake vigorously for another 3 minutes. Brush the component for another minute. Pay particular attention to swivel and vents.</div><div>4. Rinse the component by vigorously agitating in 5 liters of drinking quality water at 15-25°C for 1 minute.</div><div>5. Rinse the component under running drinking quality water at 15-25°C for 1 minute.</div><div>6. Shake the component to remove excess water.</div></div><div><div>Standard elbow (ultrasonic bath):</div><div><div>1. Rinse and clean the component with a soft bristle brush under running drinking quality water at 20-30°C for 1 minute. Pay particular attention to all crevices, cavities and rotate moveable parts.</div><div>2. Fill two-thirds of an ultrasonic cleaner with 1% Alconox solution at 20-30°C and sonicate for 20 minutes. Ensure the component is fully immersed in the solution. Use a basket/tray to prevent contact between the component and the tank.</div><div>3. Rinse the component by agitating vigorously in 5 liters of drinking quality water at 20-30°C for 1 minute. Repeat one more time.</div></div></div></div></div></div></div>
Inspection / Drying	<div><div>1. Inspect and if required, repeat washing until visually clean.<sup>1</sup></div><div>2. Allow the mask components to air dry out of direct sunlight.</div></div>
Disinfection	<div><div>1. Using a hot water disinfection system, soak the disinfectable mask components using a temperature-time combination<sup>2</sup>:<ul style="list-style-type: none"><li>Cushion/standard elbow/frame: 75°C for 30 minutes; 80°C for 10 minutes; 90°C for 1 minute; 93°C for 10 minutes</li><li>Headgear: 93°C for 10 minutes</li></ul></div><div>2. On completion, remove the mask components from the hot water disinfection system. For the frame and headgear, squeeze the component to remove excess water.</div><div>3. Allow the mask components to air dry out of direct sunlight.</div></div>
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.
Reassembly	Reassemble the mask according to the instructions in the User Guide.
Packaging and storage	<div><div>Store in a dry, dust-free environment away from direct sunlight.</div><div>Storage temperature: -20°C to 60°C.</div></div>

<sup>1</sup> Failure to clean the mask component as indicated may result in inadequate disinfection and sterilisation.

<sup>2</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).

# Thermal disinfection procedures - AWD

Disassembly	Disassemble the mask according to the instructions in the User Guide.			
AWD	Neodisher MediZym		Neodisher MediClean Forte	
	AirFit F20 cushion/standard elbow/frame/headgear: Using an Automatic Washer Disinfector <sup>1</sup> , set the following machine settings:		AirFit F20 cushion/standard elbow/frame/headgear: Using an Automatic Washer Disinfector <sup>1</sup> , set the following machine settings:	
	Pre-clean	4 minutes tap water	Pre-clean	4 minutes tap water
	Clean	0.5% Neodisher MediZym (enzymatic, Dr. Weigert) for 10 minutes at 45°C	Clean	0.5% Neodisher MediClean forte (Dr. Weigert) for 10 minutes at 55°C
	Final rinse	Deionised water for 3 minutes	Neutralisation	0.1% Neodisher Z (Dr. Weigert) for 6 minutes
	Disinfection	93°C for 10 minutes	Final rinse	Deionised water for 3 minutes
	Drying	15 minutes	Disinfection	93°C for 10 minutes
			Drying	15 minutes
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.			
Reassembly	Reassemble the mask according to the instructions in the User Guide			
Packaging and storage	Store in a dry, dust-free environment away from direct sunlight. <b>Storage temperature:</b> -20°C to 60°C.			

<sup>1</sup> Validated using an EN ISO 15883-compliant AWD model: Miele & Cie, KG, Guterson, Type G 7836 CD

# Chemical disinfection procedures - CIDEX OPA

Disassembly	Disassemble the mask according to the instructions in the User Guide.
Cleaning	<div>Alconox</div> <div>AirFit F20 cushion:<ol style="list-style-type: none"><li>1. Make a solution of Alconox by diluting with drinking quality water at 1%, ie, 10 g per liter, at (20-25°C, according to manufacturer's instructions.</li><li>2. Soak the component in the solution.</li><li>3. Whilst immersed in the solution, clean with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities.</li><li>4. Rinse by shaking vigorously in 5 liters of drinking quality water. Repeat one more time using fresh water.</li></ol></div>
Inspection/Drying	<ol style="list-style-type: none"><li>1. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li><li>2. Allow the mask components to air dry out of direct sunlight.</li></ol>
Disinfection	<div>CIDEX OPA</div> <div>AirFit F20 cushion:<ol style="list-style-type: none"><li>1. Fully immerse and soak the disinfectable mask components for 12 minutes in a commercially available solution according to the manufacturer's instructions:<ul style="list-style-type: none"><li>• ortho-phthalaldehyde 0.55% (eg, CIDEX OPA) at room temperature of 68-77°F (20-25°C).</li></ul></li><li>2. Rinse the mask components 3 times in 5 liters of drinking quality water at 68-86°F (20-30°C) for 1 minute <sup>2</sup>.</li><li>3. Allow the mask components to air dry out of direct sunlight.</li></ol></div>
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.
Reassembly	Reassemble the mask according to the instructions in the User Guide.
Packaging and storage	Store in a dry, dust-free environment away from direct sunlight. <b>Storage temperature:</b> -20°C to 60°C.

<sup>1</sup> Failure to clean the mask component as indicated may result in inadequate disinfection and sterilisation.

<sup>2</sup> Failure to adequately rinse the component may result in toxic levels of residual CIDEX OPA.

# Chemical disinfection procedures - Anioxyde 1000

Disassembly	Disassemble the mask according to the instructions in the User Guide.
Cleaning	<div>Aniosyme DD1</div> <div>Manual – AirFit F20 cushion/frame/headgear: 1. Rinse each individual component with drinking quality tap water for 1 minute. 2. Soak the components in a solution of Aniosyme DD1 diluted at 0.5% with drinking quality water at 15-20°C for 8 minutes. Ensure that the components are fully immersed in the solution and there are no air bubbles. 3. Whilst immersed in the solution, clean the inside and outside of the components with a soft bristle brush for the specified number of minutes. Pay particular attention to the crevices and cavities. <div><div>• Cushion</div><div>1 minute</div><div>• Frame</div><div>1 minute</div><div>• Headgear</div><div>2 minutes</div></div> 4. Rinse the components in 5 litres of drinking quality water at 20-30°C for 1 minute. 5. Rinse both internal and external parts of the component under fast running tap water at 20-30°C for another minute.</div>
Inspection/Drying	<div>1. Inspect and if required, repeat washing until visually clean.<sup>1</sup> 2. Allow the components to air dry out of direct sunlight.</div>
Disinfection	<div>Anioxyde 1000</div> <div>AirFit F20 cushion/frame/headgear: 1. Activate the solution according to the manufacturer’s instructions. Use Anioxyde 1000 at room temperature. 2. Soak the components in the activated solution for 5 minutes. Ensure the components are fully immersed in the solution and there are no air bubbles. 3. Rinse the components in 5 litres of drinking quality water at 20-30°C for 1 minute. 4. Rinse both internal and external parts of the components under fast running tap water at 20-30°C for another minute. 5. Allow the components to air dry out of direct sunlight.</div>
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.
Reassembly	Reassemble the mask according to the instructions in the User Guide.
Packaging and storage	<div>Store in a dry, dust-free environment away from direct sunlight. Storage temperature: -20°C to 60°C.</div>

<sup>1</sup> Failure to clean the mask component as indicated may result in inadequate disinfection and sterilisation.

Chemical disinfection procedures - Gigasept FF

Disassembly	Disassemble the mask according to the instructions in the User Guide.	
Cleaning	Gigazyme	
	<p><b>Sonication – Standard elbow:</b></p> <ol style="list-style-type: none"><li>1. Rinse each individual component with cold running tap water for 1 minute.</li><li>2. Soak the components in a solution of Gigazyme diluted at 1% with drinking quality water at 23°C.</li><li>3. Sonicate the components in ultrasonic bath filled with cleaning solution for 20 minutes. Ensure that the components are fully immersed in the solution and there are no air bubbles. Follow the ultrasonic bath manufacturer's instructions.</li><li>4. Rinse the components in 5 litres of drinking quality water at 20-30°C for 1 minute.</li><li>5. Rinse both internal and external parts of the components under fast running tap water at 20-30°C for another minute.</li></ol>	<p><b>Manual – Standard elbow:</b></p> <ol style="list-style-type: none"><li>1. Rinse each individual component with cold running tap water for 1 minute.</li><li>2. Soak the components in a solution of Gigazyme diluted at 1% with drinking quality water at 23°C for 5 minutes. Ensure that the components are fully immersed in the solution and there are no air bubbles.</li><li>3. While immersed in the solution, agitate the component vigorously for another 3 minutes and brush the outside only for 1 minute. Pay particular attention to the swivel and vents.</li><li>4. Rinse the component by agitating vigorously in 5 litres of drinking quality water at 20-30°C for 1 minute.</li><li>5. Rinse both internal and external parts of the component under fast running tap water at 20-30°C for another minute.</li></ol>
	<p><b>Manual – AirFit F20 cushion/frame/headgear:</b></p> <ol style="list-style-type: none"><li>1. Rinse each individual component with cold running tap water for 1 minute.</li><li>2. Soak the components in a solution of Gigazyme diluted at 1% with drinking quality water at 23°C for 8 minutes. Ensure that the components are fully immersed in the solution and there are no air bubbles.</li><li>3. Whilst immersed in the solution, clean the inside and outside of the components with a soft bristle brush for the specified number of minutes. Pay particular attention to the crevices and cavities.<ul style="list-style-type: none"><li>• Cushion 1 minute</li><li>• Frame 1 minute</li><li>• Headgear 2 minutes</li></ul></li><li>4. Rinse the components in 5 litres of drinking quality water at 20-30°C for 1 minute.</li><li>5. Rinse both internal and external parts of the component under fast running tap water at 20-30°C for another minute.</li></ol>	
Inspection/Drying	<ol style="list-style-type: none"><li>1. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li><li>2. Allow the components to air dry out of direct sunlight.</li></ol>	
Disinfection	Gigasept FF	
	<p><b>AirFit F20 Cushion/standard elbow/frame/headgear:</b></p> <ol style="list-style-type: none"><li>1. Make a solution of Gigasept FF diluted at 5% with drinking quality cold water with a solution temperature of 15-25°C.</li><li>2. Soak the components in the solution for 15 minutes. Ensure that the components are fully immersed in the solution and there are no air bubbles. For the frame, squeeze the fabric to release any air bubbles.</li><li>3. Rinse the components in 5 litres of drinking quality water at 20-30°C for 1 minute.</li><li>4. Rinse both internal and external parts of the components under fast running tap water at 20-30°C for another minute.</li><li>5. Allow the components to air dry out of direct sunlight.</li></ol>	
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.	
Reassembly	Reassemble the mask according to the instructions in the User Guide.	
Packaging and storage	<p>Store in a dry, dust-free environment away from direct sunlight.</p> <p><b>Storage temperature:</b> -20°C to 60°C.</p>	

<sup>1</sup> Failure to clean the mask component as indicated may result in inadequate disinfection and sterilisation.

# Sterilisation procedures - STERRAD

Disassembly	Disassemble the mask according to the instructions in the User Guide.
Cleaning	<p><b>Alconox</b></p> <p><b>AirFit F20 cushion:</b></p> <ol style="list-style-type: none"><li>1. Make a solution of Alconox by diluting with drinking quality water at 1%, ie, 10 g per liter, at 20-25°C, according to manufacturer's instructions.</li><li>2. Soak the component in the solution for 1 minute.</li><li>3. Whilst immersed in the solution, clean with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities.</li><li>4. Rinse by shaking vigorously in 5 liters of drinking quality water. Repeat one more time.</li></ol>
Inspection / Drying	<ol style="list-style-type: none"><li>1. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li><li>2. Allow the mask components to air dry out of direct sunlight.</li></ol>
Sterilisation	<p><b>STERRAD</b></p> <p><b>AirFit F20 cushion:</b></p> <ol style="list-style-type: none"><li>1. Package the mask components prior to sterilisation as described in the manufacturer's instructions for the STERRAD Sterilisation System with STERRAD chemical indicators. Note: The use of pouches is not recommended.</li><li>2. Sterilise the component following the manufacturer's instructions for the STERRAD Sterilisation System:<ul style="list-style-type: none"><li>• STERRAD 100S           Short or Long cycle</li><li>• STERRAD NX           Standard or Advanced cycle</li></ul></li></ol> <p>Notes:</p> <ul style="list-style-type: none"><li>• Drying is achieved as part of the sterilisation process.</li><li>• Check STERRAD indicator strips to ensure machine has run correctly.</li></ul>
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.
Reassembly	Reassemble the mask according to the instructions in the User Guide.
Packaging and storage	Store in a dry, dust-free environment away from direct sunlight. <b>Storage temperature:</b> -20°C to 60°C.

<sup>1</sup> Failure to clean the mask component as indicated may result in inadequate disinfection and sterilisation.



## 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 or safety 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. In case of conflict, this guide takes precedence.
- Do not iron the headgear as the material is heat sensitive and will be damaged



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