

# Disinfection and sterilisation guide

Clinical use only

This guide is intended for multipatient use of the AirFit N20 / AirFit N20 for Her (referred to collectively as AirFit N20 throughout this guide) and AirFit N20 Classic ResMed nasal masks 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 N20 / AirFit N20 for Her

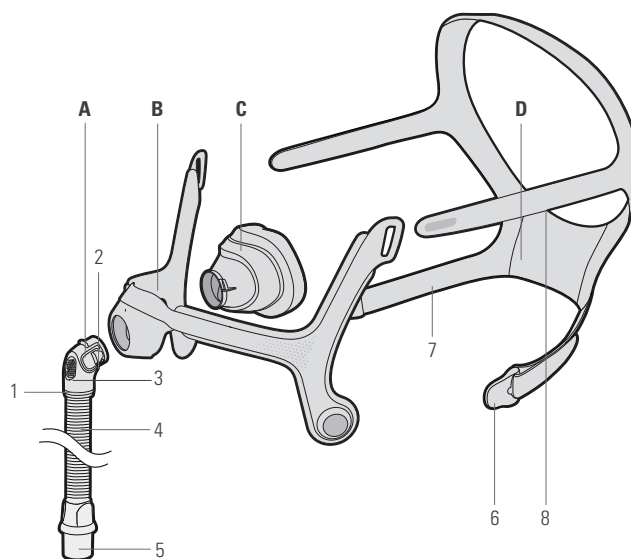
AirFit N20 / AirFit N20 for Her mask component <sup>1</sup>	Thermal disinfection		Chemical disinfection			Sterilisation		Validated number of cycles <sup>2</sup>
	Manual	AWD <sup>4</sup>	CIDEX™ OPA	Gigasept FF	Anioxyde 1000	STERRAD 100S	STERRAD NX	
• Cushion	✓	✓	✓	✓	✓	✓	✓	30
• Magnetic clips	✓	✓	–	✓	✓	–	–	30
• Elbow and short tube <sup>3</sup>	✓	✓	–	✓	✓	✓	✓	30
• 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> The elbow and short tube are not separable.

<sup>4</sup> Automatic Washer-Disinfector



- A Elbow and short tube
- 1 Elbow
- 2 Side buttons
- 3 Vent
- 4 Short tube
- 5 Swivel
- B Frame
- C Cushion
- D Headgear
- 6 Magnetic clips
- 7 Lower headgear straps
- 8 Upper headgear straps
- A+B+C Frame system
- A+B+C+D Complete system

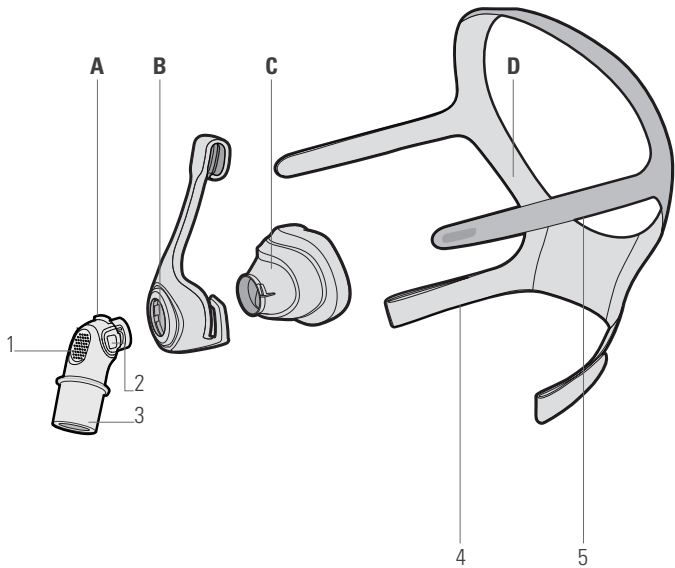
# AirFit N20 Classic

AirFit N20 Classic mask component <sup>1</sup>	Thermal disinfection		Chemical disinfection			Sterilisation		Validated number of cycles <sup>2</sup>
	Manual	AWD <sup>3</sup>	CIDEX™ OPA	Gigasept FF	Anioxyde 1000	STERRAD 100S	STERRAD NX	
• Cushion	✓	✓	✓	✓	✓	✓	✓	30
• Elbow	–	✓	–	✓	✓	–	–	30
• 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> Automatic Washer-Disinfector



- A Elbow
- 1 Vent
- 2 Side buttons
- 3 Swivel
- B Frame
- C Cushion
- D Headgear
- 4 Lower headgear straps
- 5 Upper headgear straps
- A+B+C+D Complete system

# Thermal disinfection procedures - Manual

<b>Disassembly</b>	Disassemble the mask according to the instructions in the User Guide. For the AirFit N20, magnetic clips must be removed from the lower headgear straps.
<b>Cleaning</b>	<p><b>Alconox</b></p> <div> <div> <p><b>AirFit N20 - Cushion / magnetic clips</b></p> <p><b>AirFit N20 Classic - Cushion</b></p> <ol style="list-style-type: none"> <li>1. Soak the component in a solution of Alconox diluted with drinking quality water at 1%, ie, 10 g per litre, at 25-30°C, according to manufacturer's instructions.</li> <li>2. Whilst immersed in the solution, clean with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities.</li> <li>3. Rinse by shaking vigorously in drinking quality water (five litres per component) for 1 minute. Repeat for one more minute using fresh water.</li> <li>4. Inspect and if required, repeat washing until visually clean.<sup>2</sup></li> <li>5. Allow the components to air dry out of direct sunlight.</li> </ol> </div> <div> <p><b>AirFit N20 - Elbow and short tube</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 litre, at 45-55°C, according to the manufacturer's instructions.</li> <li>2. Soak the component in the solution for 5 minutes. Rotate all connections three times around 360 degrees.</li> <li>3. Whilst immersed in the solution, thoroughly clean with a test tube brush for an additional 1 minute. Pay particular attention to all crevices and cavities.</li> <li>4. Rinse by shaking vigorously in drinking quality water (five litres per component) at 25-30°C for 1 minute. Repeat for one more minute using fresh water.</li> <li>5. Rinse under fast-running drinking quality tap water (45-55°C) from one end of the component, for 20 seconds. Repeat the process from the other end of the component.</li> <li>6. Inspect and if required, repeat washing until visually clean.<sup>2</sup></li> <li>7. Allow the components to air dry out of direct sunlight.</li> </ol> </div> </div> <div> <p><b>AirFit N20 - Frame / headgear</b></p> <ol style="list-style-type: none"> <li>1. Soak the component in a solution of Alconox diluted with drinking quality water at 1%, ie, 10 g per litre, at 20-30°C for 3 minutes, according to manufacturer's instructions.</li> <li>2. Whilst immersed in the solution, clean with a soft bristle brush for an additional 2 minutes. Pay particular attention to all crevices and cavities.</li> <li>3. Squeeze to remove excess solution.</li> <li>4. Rinse by repeatedly squeezing under drinking quality water for 30 seconds at 20-30°C. Repeat two more times. Squeeze to remove excess water.</li> <li>5. Inspect and if required, repeat washing until visually clean.<sup>2</sup></li> <li>6. Allow the components to air dry out of direct sunlight.</li> </ol> </div>
<b>Disinfection</b>	<p><b>AirFit N20 - Cushion / magnetic clips / elbow and short tube / frame / headgear</b></p> <ol style="list-style-type: none"> <li>1. Using a certified hot water disinfection system, soak the disinfectable mask components using a temperature-time combination<sup>1</sup>, ensuring there are no air bubbles:  <b>Cushion/magnetic clips/elbow and short tube (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>Frame/headgear:</b> <ul style="list-style-type: none"> <li>• 93°C for 10 minutes.</li> </ul> </li> <li>2. On completion, remove the mask components from the hot water disinfection system.</li> <li>3. Shake the components to remove excess water. For the frame and headgear, squeeze the components to remove excess water.</li> <li>4. Allow the components to air dry out of direct sunlight.</li> </ol>
<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).

<sup>2</sup> Failure to clean the mask component as indicated may result in inadequate disinfection and sterilisation.

## Thermal disinfection procedures - AWD

<b>Disassembly</b>	Disassemble the mask according to the instructions in the User Guide. For the AirFit N20, magnetic clips must be removed from the lower headgear straps.	
<b>AWD</b>	<b>Neodisher MediZym</b>	<b>Neodisher MediClean Forte</b>
	<p><b>AirFit N20 - Cushion / magnetic clips / elbow and short tube / frame / headgear</b></p> <p><b>AirFit N20 Classic - Cushion / elbow / frame / headgear</b></p> <p>Using an Automatic Washer Disinfector<sup>1</sup>, set the following machine settings:</p> <ul style="list-style-type: none"> <li>• Pre-clean 4 minutes tap water</li> <li>• Clean 0.5% Neodisher MediZym (enzymatic, Dr. Weigert) for 10 minutes at 45°C</li> <li>• Neutralisation –</li> <li>• Final rinse Deionised water for 3 minutes</li> <li>• Disinfection 93°C for 10 minutes</li> <li>• Drying 15 minutes</li> </ul>	<p><b>AirFit N20 - Cushion / magnetic clips / elbow and short tube / frame / headgear</b></p> <p><b>AirFit N20 Classic - Cushion / elbow / frame / headgear</b></p> <p>Using an Automatic Washer Disinfector<sup>1</sup>, set the following machine settings:</p> <ul style="list-style-type: none"> <li>• Pre-clean 4 minutes tap water</li> <li>• Clean 0.5% Neodisher MediClean forte (Dr. Weigert) for 10 minutes at 55°C</li> <li>• Neutralisation 0.1% Neodisher Z (Dr. Weigert) for 6 minutes</li> <li>• Final rinse Deionised water for 3 minutes</li> <li>• Disinfection 93°C for 10 minutes</li> <li>• Drying 15 minutes</li> </ul>
<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> Validated using an EN ISO 15883-compliant AWD model: Miele & Cie, KG, Guterson, Type G 7836 CD

# Chemical disinfection procedures - CIDEX OPA and Gigasept FF

<b>Disassembly</b>	Disassemble the mask according to the instructions in the User Guide. For the AirFit N20, magnetic clips must be removed from the lower headgear straps.	
<b>Cleaning</b>	<b>Alconox</b>	<b>Gigazyme</b>
	<p><b>AirFit N20 - Cushion</b></p> <p><b>AirFit N20 Classic - Cushion</b></p> <ol style="list-style-type: none"> <li>1. Soak the component in a solution of Alconox diluted with drinking quality water at 1%, ie, 10 g per litre, at 25-30°C, according to manufacturer's instructions.</li> <li>2. Whilst immersed in the solution, clean with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities.</li> <li>3. Rinse by shaking vigorously in drinking quality water (five litres per component) for 1 minute. Repeat for one more minute using fresh water.</li> <li>4. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li> <li>5. Allow the component to air dry out of direct sunlight.</li> </ol>	<p><b>AirFit N20 - Cushion / magnetic clips / elbow and short tube / frame / headgear</b></p> <p><b>AirFit N20 Classic - Cushion / elbow / frame / headgear</b></p> <p><b>Cushion/magnetic clips/elbow and short tube/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 18-28°C for 8 minutes. Ensure the components are fully immersed in the solution ensuring 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 additional number of minutes. Pay particular attention to the crevices and cavities. <ul style="list-style-type: none"> <li>• Cushion 1 minute</li> <li>• Magnetic clips 30 seconds</li> <li>• Elbow and short tube* 1 minute</li> <li>• Frame 1 minute</li> <li>• Headgear 2 minutes</li> </ul> <p>*Use a tube/small bottle brush.</p> </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> <li>6. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li> <li>7. Allow the components to air dry out of direct sunlight.</li> </ol>
<b>Disinfection</b>	<b>CIDEX OPA</b>	<b>Gigasept FF</b>
	<p><b>AirFit N20 - Cushion</b></p> <p><b>AirFit N20 Classic - Cushion</b></p> <ol style="list-style-type: none"> <li>1. Fully immerse and soak the component in CIDEX OPA at 20-25°C for 12 minutes according to the manufacturer's instructions and agitate to ensure there no air bubbles.</li> <li>2. Rinse the component in drinking quality water (7.5 litres per component) at 20-30°C for 1 minute.<sup>2</sup></li> <li>3. Repeat the process by using fresh water two more times.</li> <li>4. Allow the component to air dry out of direct sunlight.</li> </ol>	<p><b>AirFit N20 - Cushion / magnetic clips / elbow and short tube / frame / headgear</b></p> <p><b>AirFit N20 Classic - Cushion / 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 activated solution for 5 minutes. Ensure the components are fully immersed in the solution ensuring there are no air bubbles. For the frame, squeeze the fabric while immersed in the solution to release any air bubbles and soak for 15 minutes.</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>
<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> 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

<b>Disassembly</b>	Disassemble the mask according to the instructions in the User Guide. For the AirFit N20, magnetic clips must be removed from the lower headgear straps.	
<b>Cleaning</b>	<b>Aniosyme DD1</b>	<b>Aniosyme X3</b>
	<p><b>AirFit N20 - Cushion / magnetic clips / elbow and short tube / frame / headgear</b></p> <p><b>AirFit N20 Classic - Cushion</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 Aniosyme DD1 diluted at 0.5% with drinking quality water at 15-25°C for 8 minutes. Ensure the components are fully immersed in the solution ensuring 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 additional number of minutes. Pay particular attention to the crevices and cavities. <ul style="list-style-type: none"> <li>• Cushion 1 minute</li> <li>• Magnetic clips 30 seconds</li> <li>• Elbow and short tube* 1 minute</li> <li>• Frame 1 minute</li> <li>• Headgear 2 minutes</li> </ul> <p>*Use a tube/small bottle brush.</p> </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> <li>6. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li> <li>7. Allow the components to air dry out of direct sunlight.</li> </ol>	<p><b>AirFit N20 Classic - Elbow / frame</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 Aniosyme X3 diluted at 0.5% with drinking quality water at 15-25°C for 8 minutes. Ensure the components are fully immersed in the solution ensuring 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 additional number of minutes. Pay particular attention to the crevices and cavities. <ul style="list-style-type: none"> <li>• Elbow 1 minute</li> <li>• Frame 1 minute</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 components under fast running tap water at 20-30°C for another minute.</li> <li>6. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li> <li>7. Allow the components to air dry out of direct sunlight.</li> </ol>
<b>Disinfection</b>	<b>Anioxyde 1000</b>	
	<p><b>AirFit N20 - Cushion / magnetic clips / elbow and short tube / frame / headgear</b></p> <p><b>AirFit N20 Classic - Cushion / elbow / frame</b></p> <ol style="list-style-type: none"> <li>1. Activate the solution according to the manufacturer's instructions. Use Anioxyde 1000 at room temperature.</li> <li>2. Soak the components in the activated solution for 5 minutes. Ensure the components are fully immersed in the solution ensuring there are no 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>	
<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> Failure to clean the mask component as indicated may result in inadequate disinfection and sterilisation.

# Sterilisation procedures

<b>Disassembly</b>	Disassemble the mask according to the instructions in the User Guide.
<b>Cleaning</b>	<p><b>Alconox</b></p> <p><b>AirFit N20 - Cushion</b> <b>AirFit N20 Classic - Cushion</b></p> <ol style="list-style-type: none"> <li>1. Soak the component in a solution of Alconox diluted with drinking quality water at 1%, ie, 10 g per litre, at 20-25°C, according to manufacturer's instructions.</li> <li>2. Whilst immersed in the solution, clean with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities.</li> <li>3. Rinse by shaking vigorously in drinking quality water (five litres per mask). Repeat for one more minute using fresh water.</li> <li>4. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li> <li>5. Allow the components to air dry out of direct sunlight.</li> </ol> <p><b>AirFit N20 - Elbow and short tube</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 litre, at 45-55°C, according to the manufacturer's instructions.</li> <li>2. Soak the mask component in the solution for 5 minutes. Rotate all connections three times around 360 degrees.</li> <li>3. Whilst in the solution, thoroughly clean the component with a test tube brush for an additional 1 minute. Pay particular attention to all crevices and cavities.</li> <li>4. Rinse the component by agitating it vigorously in drinking quality water, 5 litres per component at 25-30°C for 1 minute. Repeat the process by using fresh water for another 1 minute.</li> <li>5. Rinse the component under fast-running drinking quality tap water (45-55°C) from one end of the component, for 20 seconds. Repeat the process from the other end of the component.</li> <li>6. Inspect and if required, repeat washing until visually clean.<sup>1</sup></li> <li>7. Allow the components to air dry out of direct sunlight.</li> </ol>
<b>Sterilisation</b>	<p><b>STERRAD 100S and NX</b></p> <p><b>AirFit N20 - Cushion / elbow and short tube</b> <b>AirFit N20 Classic - Cushion</b></p> <ol style="list-style-type: none"> <li>1. Dry the components thoroughly. If the components are wet, the sterilisation process may fail.</li> <li>2. Package the components prior to sterilisation as described in the manufacturer's instructions for the STERRAD Sterilisation System. Note: The use of pouches is not recommended.</li> <li>3. Sterilise the components following the manufacturer's instructions: <ul style="list-style-type: none"> <li>• STERRAD 100S                      Short cycle (boosters not required)</li> <li>• STERRAD NX                      Standard or Advanced cycle</li> </ul> </li> <li>4. Rinse and agitate the components in drinking quality water (5 litres per component) at 20-30°C for 1 minute.</li> <li>5. Shake the components to remove excess water.</li> <li>6. Allow the components to dry out of direct sunlight.</li> </ol>
<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> 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