

Disinfection and sterilization guide

Rx Only
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 sterilization of the mask in accordance with ISO17664.

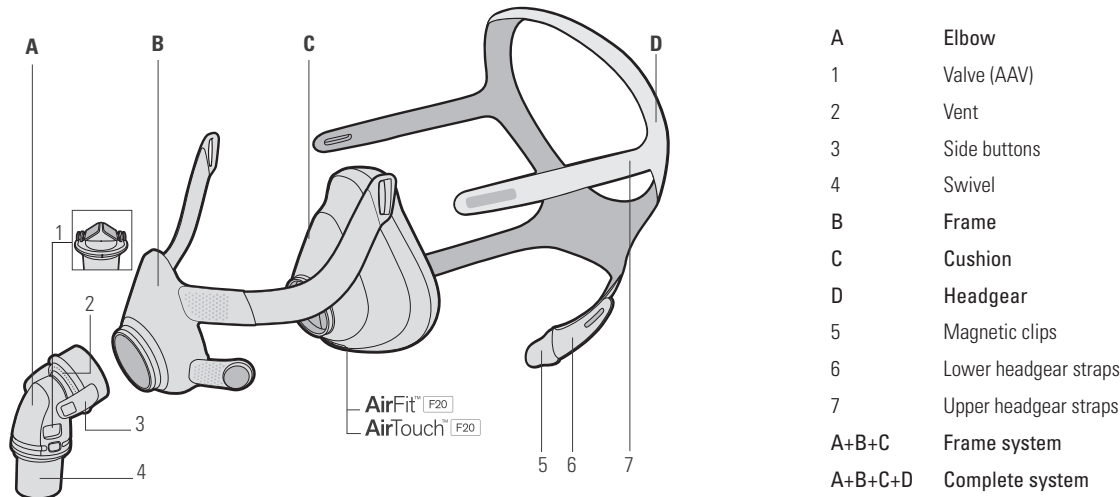
| AirFit F20 / AirTouch F20 mask component ¹ | High level thermal disinfection | | High level chemical disinfection | Sterilization | | Validated number of cycles ² |
|---|--|---------------------|--|---------------|--|---|
| | 167°F (75°C)-30 min; 176°F (80°C)-10 min; 194°F (90°C)-1 min | 200°F (93°C)-10 min | CIDEX™ OPA Ortho-phthalaldehyde 0.55% | STERRAD™ 100S | STERRAD™ NX Standard or Advanced cycle | |
| • AirFit F20 cushion | ✓ | ✓ | ✓ | ✓ | ✓ | 30 |
| • AirTouch F20 cushion ³ | — | — | — | — | — | N/V ⁴ |
| • Elbow | ✓ | ✓ | — | — | — | 30 |
| • Frame | ✓ | ✓ | — | — | — | 30 |
| • Headgear | — | ✓ | — | — | — | 30 |

¹This mask 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 Components Card on www.resmed.com.

²If a healthcare facility requires an additional disinfection or sterilization cycle after reassembly, the number of validated cycles must be halved.

³The AirTouch F20 cushion is intended for single-patient reuse in both home and hospital/institutional environments and recommended to be replaced monthly.

⁴Not validated.



Thermal disinfection procedures - Manual

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| Disassembly | Disassemble the mask according to the instructions in the User Guide. | |
| Cleaning | <p>Alconox</p> <p>AirFit F20 cushion¹:</p> <ol style="list-style-type: none"> Soak the component in 1% Alconox solution at 68-77°F (20-25°C) for 1 minute. Whilst immersed in the solution, clean with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities. Rinse by shaking vigorously in 5 liters of drinking quality water. Repeat one more time. <p>Frame:</p> <ol style="list-style-type: none"> Rinse the component under running drinking quality water at 68-86°F (20-30°C) for 1 minute. Soak the component in 1% Alconox solution at 101-104°F (38.5-40°C) for 5 minutes. Ensure no air bubbles are present and all surfaces come in contact with the solution. Whilst immersed in the solution, shake vigorously for another 5 minutes while squeezing the fabric of the arms. Clean with a soft bristle brush for another minute. Pay particular attention to all crevices and interfaces. Rinse the component by agitating in 5 liters of drinking quality water at 66-68°F (19-20°C) for 1 minute. Rinse the component under drinking quality water at 66-68°F (19-20°C). <p>Headgear:</p> <ol style="list-style-type: none"> Make a solution of Alconox by diluting with drinking quality water at 1%, ie, 10 g per liter, at 68-86°F (20-30°C), according to the manufacturer's instructions. Soak the component in the solution for 3 minutes. Thoroughly clean the mask component with a soft bristle brush for 2 minutes while continuing to soak it in the solution. Pay particular attention to all crevices and cavities. Squeeze the component to remove excess solution. Rinse the component by repeatedly squeezing it under running drinking quality water at 68-86°F (20-30°C) for 30 seconds. Repeat two more times with fresh water. | <p>Control III</p> <p>AirFit F20 cushion¹:</p> <ol style="list-style-type: none"> Make a solution of Control III by diluting with drinking quality water at 1.5-2%, ie, 15-20 g per liter, at 68-86°F (20-30°C), according to manufacturer's instructions. Soak the component in the solution for 10-15 minutes. Whilst immersed in the solution, clean with a soft bristle brush. Pay particular attention to all crevices and cavities. Rinse by shaking vigorously in 5 liters of drinking quality water. Repeat one more time. |
| Inspection / Drying | <ol style="list-style-type: none"> Inspect and if required, repeat washing until visually clean.² Allow the mask components to air dry out of direct sunlight. | |
| Disinfection | <ol style="list-style-type: none"> Using a hot water disinfection system, soak the disinfectable mask components using a temperature-time combination: <ul style="list-style-type: none"> AirFit F20 cushion/elbow/frame: 167°F (75°C) for 30 minutes; 176°F (80°C) for 10 minutes; 194°F (90°C) for 1 minute; 200°F (93°C) for 10 minutes Headgear: 200°F (93°C) for 10 minutes On completion, remove the mask components from the hot water disinfection system. Allow the mask components to air dry out of direct sunlight. | |
| 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 discoloration 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. Storage temperature: -4°F to 140°F (-20°C to 60°C). | |

¹These instructions are not intended for use with the AirTouch F20 cushion.

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

Chemical disinfection procedures - CIDEX OPA

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| Disassembly | Disassemble the mask according to the instructions in the User Guide. |
| Cleaning | <p>Alconox</p> <p>AirFit F20 cushion¹:</p> <ol style="list-style-type: none"> 1. Make a solution of Alconox by diluting with drinking quality water at 1%, ie, 10 g per liter, at 68-77°F (20-25°C), according to manufacturer's instructions. 2. Soak the component in the solution. 3. Whilst immersed in the solution, clean with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities. 4. Rinse by shaking vigorously in 5 liters of drinking quality water. Repeat one more time using fresh water. |
| Inspection / Drying | <ol style="list-style-type: none"> 1. Inspect and if required, repeat washing until visually clean.² 2. Allow the mask components to air dry out of direct sunlight. |
| Disinfection | <p>CIDEX OPA</p> <ol style="list-style-type: none"> 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"> • ortho-phthalaldehyde 0.55% (eg, CIDEX OPA) at room temperature of 68-77°F (20-25°C). 2. Rinse the mask components 3 times in 5 liters of drinking quality water at 68-86°F (20-30°C) for 1 minute.³ 3. Allow the mask components to air dry out of direct sunlight. |
| 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 discoloration 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. Storage temperature: -4°F to 140°F (-20°C to 60°C). |

¹These instructions are not intended for use with the AirTouch F20 cushion.

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

³Failure to adequately rinse the component may result in toxic levels of residual CIDEX OPA.

Sterilization procedures - STERRAD

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| Disassembly | Disassemble the mask according to the instructions in the User Guide. |
| Cleaning | <p>Alconox</p> <p>AirFit F20 cushion¹:</p> <ol style="list-style-type: none"> 1. Make a solution of Alconox by diluting with drinking quality water at 1%, ie, 10 g per liter, at 68-77°F (20-25°C), according to manufacturer's instructions. 2. Soak the component in the solution for 1 minute. 3. Whilst immersed in the solution, clean with a soft bristle brush for 1 minute. Pay particular attention to all crevices and cavities. 4. Rinse by shaking vigorously in 5 liters of drinking quality water. Repeat one more time. |
| Inspection / Drying | <ol style="list-style-type: none"> 1. Inspect and if required, repeat washing until visually clean.² 2. Allow the mask components to air dry out of direct sunlight. |
| Sterilization | <p>STERRAD</p> <ol style="list-style-type: none"> 1. Package the mask components prior to sterilization as described in the manufacturer's instructions for the STERRAD Sterilization System with STERRAD chemical indicators. Note: The use of pouches is not recommended. 2. Sterilize the mask following the manufacturer's instructions for the STERRAD Sterilization System: <ul style="list-style-type: none"> • STERRAD 100S • STERRAD NX (Standard or Advanced cycle) Notes: <ul style="list-style-type: none"> • Drying is achieved as part of the sterilization process. • Check STERRAD indicator strips to ensure machine has run correctly. |
| 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 discoloration 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. Storage temperature: -4°F to 140°F (-20°C to 60°C). |

¹These instructions are not intended for use with the AirTouch F20 cushion.

²Failure 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 sterilization.
- When using detergents, disinfectants or sterilization agents, always follow the manufacturer's instructions. In the event of conflict, this guide take precedence.
- Do not iron the headgear as the material is heat sensitive and will be damaged.