ResMed

AirFit™ F20

Disinfection and sterilization guide

℞ Only

Clinical use only

This guide is intended for multipatient use of the AirFit™ 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 / AirFit F20 for Her 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	CIDEX™ OPA Ortho-phthalaldehyde 0.55%	STERRAD™		
			100S Short cycle (boosters not required)	NX Standard or advanced cycle	
• Cushion	✓	✓	✓	✓	30
• Headgear[3]	—	—	—	—	N/V[4]
• Elbow[3]	—	—	—	—	N/V[4]
• Frame[3]	—	—	—	—	N/V[4]

[1] This 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.

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

[3] Replace these parts with new parts between patients.

[4] Not validated.

Validated disinfection and sterilization procedures

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

<table>
<tr><td>Disassembly</td><td colspan="3">Disassemble the mask according to the instructions in the User Guide.</td></tr>
<tr><td rowspan="2">Cleaning and drying</td><td colspan="2">Cushion</td><td>Headgear</td></tr>
<tr><td colspan="2">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 drinking quality water (five liters per mask). Repeat for one more time using fresh water.
5. Inspect and if required, repeat washing until visually clean.
6. Allow the mask components to air dry out of direct sunlight.</td><td>1. 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 manufacturer's instructions.
2. Soak the component in the solution for 3 minutes.
3. Whilst immersed in the solution, clean with a soft bristle brush for 2 minutes. Pay particular attention to all crevices and cavities.
4. Squeeze to remove excess water.
5. Rinse by repeatedly squeezing under drinking quality water for 30 seconds at 68-86°F (20-30°C). Repeat for two more times.
6. Inspect and if required, repeat washing until visually clean.
7. Allow the mask components to air dry out of direct sunlight.</td></tr>
<tr><td rowspan="2">Disinfection or sterilization and drying</td><td>High level thermal disinfection</td><td>High level chemical disinfection</td><td>Sterilization</td></tr>
<tr><td>1. Using a certified hot water disinfection system, soak the disinfectable mask components using a temperature-time combination:
• 167°F (75°C) for 30 minutes
• 176°F (80°C) for 10 minutes
• 194°F (90°C) for 1 minute.
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.</td><td>1. Fully immerse and soak the disinfectable mask components in a commercially available solution according to the manufacturer's instructions:
• ortho-phthalaldehyde 0.55% (eg, CIDEX OPA) for 12 minutes at room temperature (approx. 68°F or 20°C).
2. Rinse the mask components 3 times in drinking quality water (5 liters per mask).
3. Allow the mask components to air dry out of direct sunlight.</td><td>1. Package the mask components prior to sterilization as described in the manufacturer's instructions for the STERRAD Sterilization System. ResMed masks have been validated using the tray method.
Note: The use of pouches is not recommended.
2. Sterilize the mask following the manufacturer's instructions for the STERRAD Sterilization System.
Note: Drying is achieved as part of the sterilization process.</td></tr>
<tr><td>Inspection</td><td colspan="3">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.</td></tr>
<tr><td>Reassembly</td><td colspan="3">Reassemble the mask according to the instructions in the User Guide.</td></tr>
<tr><td>Packaging and storage</td><td colspan="3">Store in a dry, dust-free environment away from direct sunlight.
Storage temperature: -4°F to 140°F (-20°C to 60°C).</td></tr>
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⚠ 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 sterilization.
- When using detergents, disinfectants or sterilization agents, always follow the manufacturer's instructions.
- Do not iron the headgear as the material is heat sensitive and will be damaged.

MANUFACTURER
ResMed Ltd
1 Elizabeth Macarthur Drive
Bella Vista NSW 2153 Australia

DISTRIBUTED BY
ResMed Corp 9001 Spectrum Center Boulevard
San Diego CA 92123 USA
EC REP ResMed (UK) Ltd 96 Jubilee Ave Milton Park
Abingdon Oxfordshire OX14 4RW UK

ResMed.com