

## AirSense 10 and AirCurve 10 reprocessing guide

This guide is intended for multipatient use of the AirSense™10 and AirCurve™10 devices.

When the device is used for multiple patients, for example, in a sleep lab, clinic, hospital or at a health care provider, the cleanable water tub, air outlet and air tubing should be reprocessed between each patient use.

If the cleanable water tub or the air tubing are being used for a single user in the home, refer to the cleaning instructions in this guide or in the User Guide.

Described here are ResMed's recommended and validated procedures for cleaning and disinfecting the cleanable water tub, air outlet and air tubing. However, the steps for disinfection vary regionally and each healthcare facility should consult its own procedures before carrying out those within this guide.

**Note:** The standard water tub cannot be disinfected. If contaminated, it must be discarded and replaced with a new water tub.

### WARNING

- ResMed cannot give any assurance that deviations from the procedures listed in this guide, and their effect on the performance of the product, will be acceptable.
- When using detergents, disinfectants or sterilization agents, always follow the manufacturer's instructions.
- Beware of electrocution. Do not immerse the device, power supply or power cord in water. If liquids are spilled into or onto the device, unplug the device and let the parts dry. Always unplug the device before cleaning and make sure that all parts are dry before plugging it back in.

### Surface disinfection

1. Wipe the exterior of the device including display, externally accessible ports, side cover, power supply unit and accessories with a disposable cloth and mild detergent or alcohol disinfectant (see list below).
2. Remove any excess disinfectant with a disposable dry cloth.

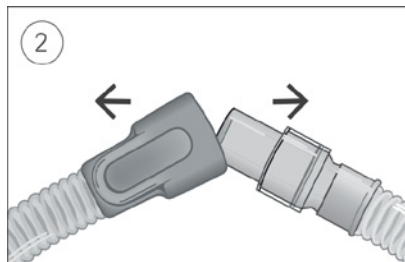
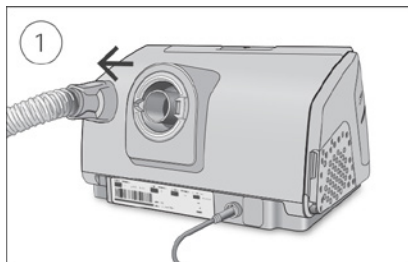
Agents recommended for surface disinfection and cleaning:

- Warm water and mild detergent eg, Teepol™ multipurpose detergent
- Window cleaner or other premixed surface detergent
- Methyl alcohol solution
- 70% Ethyl alcohol solution
- 70-90% Isopropanol solution
- 10% Bleach solution
- Isopropyl wipes
- CaviCide™
- Mikrozyd®
- Actichlor™ Plus
- Terralin®.

**Note:** Agents may not be available in all regions.

## Reprocessing the air tubing and Air10 tubing elbow

### Disconnecting



1. Hold the cuff of the air tubing and gently pull it away from the device.
2. Hold both the cuff of the air tubing and the swivel of the mask, then gently pull apart.

### Decontaminating

Before the disinfection process, each component must be cleaned and rinsed so no visible contamination is present.

1. Clean all components with a soft bristled brush for one minute while soaking in detergent solution (see table below). Pay particular attention to all crevices and cavities.
2. Run the detergent solution through the air tubing repeatedly until no contamination is visible.
3. Thoroughly rinse each component according to the detergent manufacturer's instructions.

ResMed has tested the following detergents according to the manufacturer's instructions:

Detergent	Water temperature	SlimLine / Standard	ClimateLineAir	ClimateLineAir Oxy	Air10 tubing elbow
Alconox™ (diluted at 1%)	Hot water (approx 140°F or 60°C) Warm water (approx 113 to 140°F or 45 to 60°C) Room temperature water (approx 70°F or 21°C)	✓	✓	✓	✓

### Disinfecting

In the procedures below, only one disinfection process needs to be performed.

#### High level thermal disinfection

Part	Validated number of cycles Hot water: 167°F (75°C) for 30 minutes.
SlimLine	100
ClimateLineAir	26
ClimateLineAir Oxy	20
Standard	20
Air10 tubing elbow	26

1. Immerse the air tubing in a water bath.  
Take care that no air bubbles are trapped inside the air tubing.
2. Increase the water bath temperature to 167°F (75°C) for 30 minutes. Higher temperatures may damage the tubing.
3. Air dry out of direct sunlight and/or heat.

## High level chemical disinfection

Part	Validated number of cycles	
	CIDEX® OPA Ortho-phthalaldehyde 0.55% at room temperature (approx. 69.8°F or 21°C) for 12 minutes	
SlimLine	100	
ClimateLineAir	26	
ClimateLineAir Oxy	20	
Standard	100	
Air10 tubing elbow	26	

1. Soak the air tubing/Air10 tubing elbow in a commercially available solution of a chemical sterilant. Take care that no air bubbles are trapped inside the air tubing.
2. Thoroughly rinse the air tubing/Air10 tubing elbow in drinking quality water (five liters per assembly) by immersing it completely for a minimum of one minute in duration.
3. Repeat the rinse procedure two additional times using fresh water for a total of three rinses.
4. Air dry out of direct sunlight and/or heat.

## Sterilization

Part	Validated number of cycles	
	Sterrad NX Standard and Advanced cycles	Sterrad 100S Short cycle
ClimateLineAir	26	26
ClimateLineAir Oxy	20	20

1. Sterilize the air tubing using Sterrad by following the manufacturers instructions.
2. Rinse and agitate the air tubing in drinking quality water, 5 liters per component at 59°F-68°F (15°C-20°C) for 1 minute.
3. Shake the air tubing to remove excess water.
4. Allow the air tubing to air dry out of direct sunlight.

## Inspecting

Perform a visual inspection of the components. If any visible deterioration is apparent (holes, tears or cracks etc), the components should be discarded and replaced. Slight discoloration may occur and is acceptable.

## Reconnecting the air tubing

When the air tubing is dry, you can reconnect it to the device.

1. Connect the air tubing firmly to the air outlet located on the rear of the device.
2. Connect the free end of the air tubing firmly onto the assembled mask.

## Packaging and storage

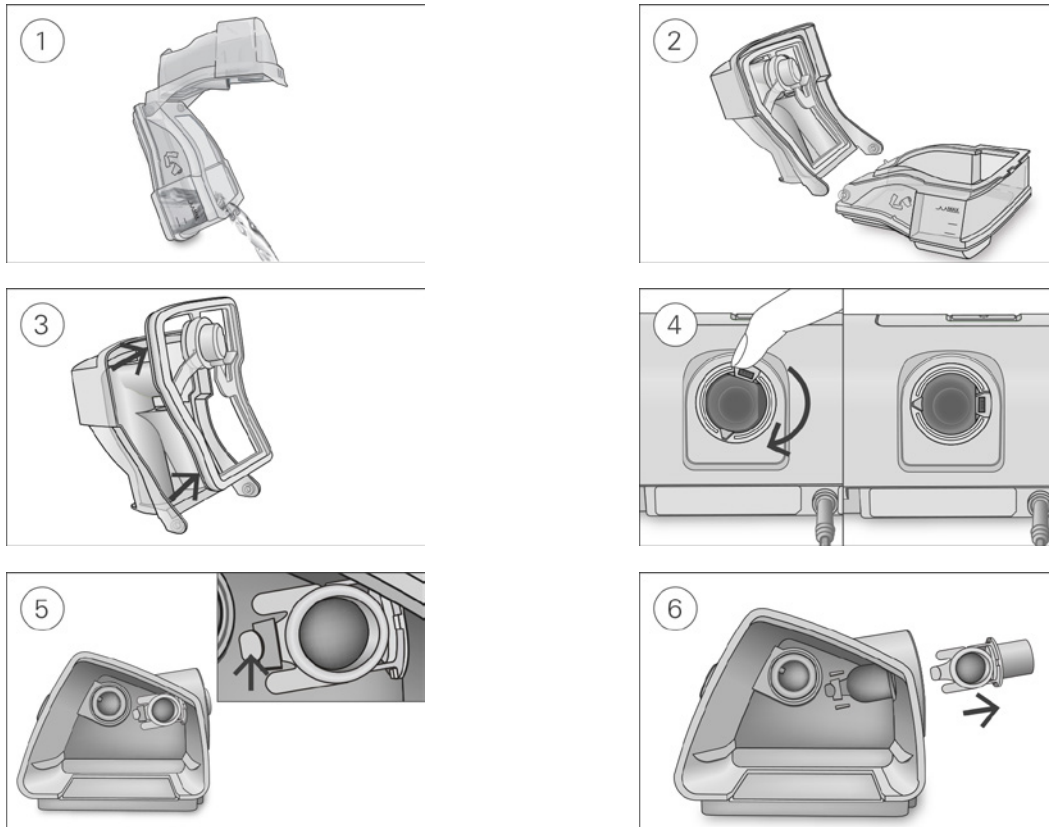
Store in a dry, dust-free environment away from direct sunlight.

Storage temperature: -4°F to 140°F (-20°C to 60°C).

## Reprocessing the water tub and air outlet

### Disassembling

The following instructions provide guidance on how to correctly disassemble the cleanable water tub and the air outlet.



1. Remove the water tub from the device, open it and discard any remaining water.
2. Hold the water tub base and then fully open the water tub lid and pull it away so that it easily detaches from the base.
3. Remove the water tub seal from the water tub lid by pulling it away.
4. Align the swivel so that the connector port is on the right. If the swivel is not in this position you will not be able to remove the air outlet.
5. Locate the air outlet on the inside of the device and release it by pressing the clip firmly.
6. Remove the air outlet by pulling it out through the air outlet socket at the rear of the device.

### Reprocessing the air outlet

If the device is used with the side cover, reprocessing of the air outlet is not required when a recommended antibacterial filter is installed in-line between the device and air tubing.

The antibacterial filter must be discarded and replaced between each patient.

If the device and side cover are used without the recommended antibacterial filter, then the air outlet must be reprocessed before re-use with another patient.

### Decontaminating

Before the disinfection process, each component must be cleaned and rinsed so no visible contamination is present.

1. Clean all components with a soft bristled brush for one minute while soaking in detergent solution (see table below). Pay particular attention to all crevices and cavities.
2. Thoroughly rinse each component according to the detergent manufacturer's instructions.

ResMed has tested the following detergents according to the manufacturer's instructions:

Detergent	Water temperature	Cleanable water tub	Air outlet
Alconox (diluted at 1%)	Hot water (approx 140°F or 60°C) Warm water (approx 113 to 140°F or 45 to 60°C) Room temperature water (approx 70°F or 21°C)	✓	✓

## Disinfecting

In the procedures below, only one disinfection process needs to be performed.

### High level thermal disinfection

Part	Validated number of cycles
	Hot water: 194°F (90°C) for 1 minute OR 167°F (75°C) for 30 minutes.
Cleanable water tub	130
Air outlet	130

1. Soak the disassembled components in a hot water bath at pasteurizing temperature.  
Take care that no air bubbles are trapped against the components.
2. Air dry out of direct sunlight and/or heat.

### High level chemical disinfection

Part	Validated number of cycles
	CIDEX OPA Ortho-phthalaldehyde 0.55% at room temperature (approx. 69.8°F or 21°C) for 12 minutes
Cleanable water tub	130
Air outlet	130

1. Soak the disassembled components in a commercially available solution of a chemical sterilant.  
Take care that no air bubbles are trapped against the components.
2. Thoroughly rinse the cleanable water tub in drinking quality water (five liters per assembly) by immersing it completely for a minimum of one minute in duration.
3. Repeat the rinse procedure two additional times using fresh water for a total of three rinses.
4. Air dry out of direct sunlight and/or heat.

### Sterilization

Part	Validated number of cycles		
	<table border="0"> <tr> <td style="padding-right: 20px;">Sterrad NX Standard and Advanced cycles</td> <td>Sterrad 100S Short cycle</td> </tr> </table>	Sterrad NX Standard and Advanced cycles	Sterrad 100S Short cycle
Sterrad NX Standard and Advanced cycles	Sterrad 100S Short cycle		
Air Outlet	130		

1. Sterilize the air outlet using Sterrad by following the manufacturers instructions.
2. Rinse and agitate the air outlet in drinking quality water, 5 liters per component at 59°F-68°F (15°C-20°C) for 1 minute.
3. Shake the air outlet to remove excess water.
4. Allow the air outlet to air dry out of direct sunlight.

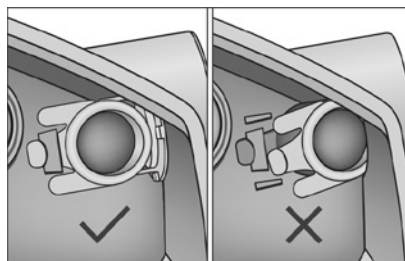
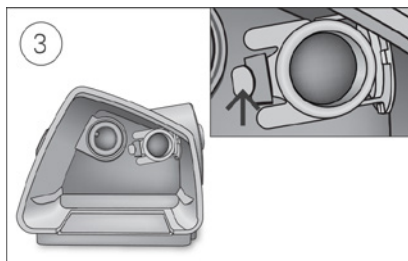
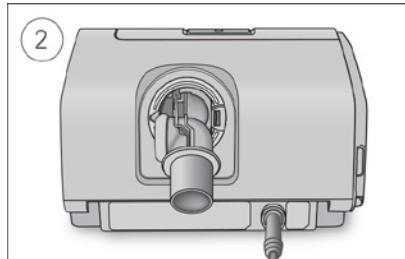
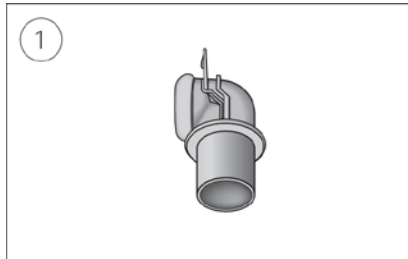
## Inspecting

Perform a visual inspection of all components. If any visible deterioration is apparent (cracking, crazing, tears, etc), the water tub should be discarded and replaced. Slight discoloration of the silicone components may occur and is acceptable.

## Reassembling

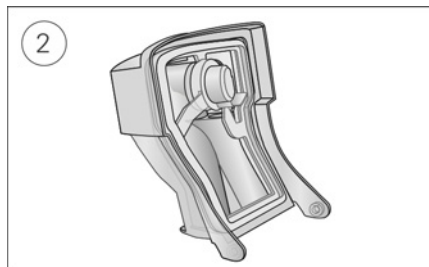
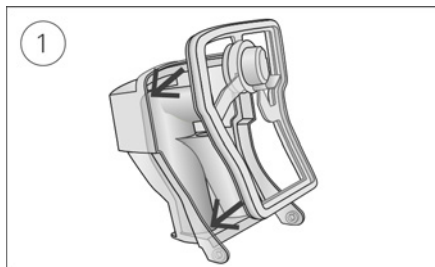
The following instructions provide guidance on how to correctly reassemble the air outlet and the water tub.

### To reassemble the air outlet



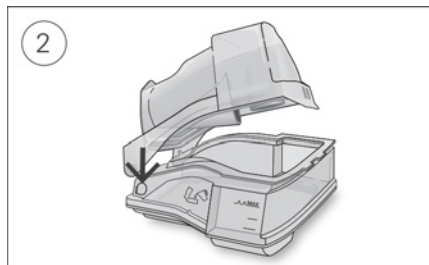
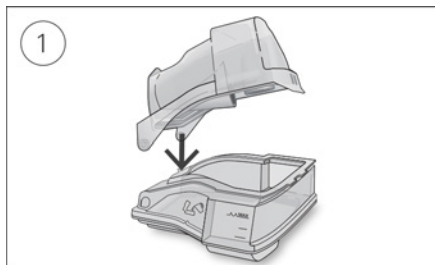
1. Hold the air outlet with the seal pointing to the left and the clip pointing forward.
2. Make sure that the air outlet is correctly aligned and insert the air outlet into the socket. It will click in place.
3. Check if the air outlet is inserted correctly as shown.

### To insert the water tub seal:



1. Place the seal into the lid.
2. Press down along all edges of the seal until it is firmly in place.

### To reassemble the water tub lid:



1. Insert one side of the lid into the pivot hole of the base.
2. Slide the other side down the ridge until it clicks into place.

## 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).



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