

Cleaning and maintenance of homecare devices during the period of Covid-19

Covid19 epidemic period

• The purpose of this guide is to provide instructions for cleaning, disinfection and use of bacterial filters on ResMed home devices (Astral, Stellar, Lumis, AirSense, Elisee150, VSIII)

 For more information, please refer to the clinical guides for each of these devices

ResMed Statement



ResMed Technical Services

Tech note March 2020 Distribution: Global

Coronavirus (COVID-19) and the handling of ResMed products

Details

As described by the World Health Organisation "Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). A novel coronavirus (nCoV) is a new strain that has not been previously identified in humans."

With the spread of the coronavirus (COVID-19) worldwide, it should be noted that no change is required in the handling of ResMed devices.

→ Extracts from clinical guides available at the end of this PPT

Refer to the appropriate device Clinical guide regarding the use of antibacterial filters and the processing of devices used by multiple patients.

When a device is returned for service, or is being used within a loan pool, no additional steps beyond current cleaning and disinfection processes are recommended. The handling of contaminated devices (including those with

Coronavirus concerns) should be managed by each Service Centres' existing safe handling procedures. For each ResMed device, cleaning and disinfection procedures are provided in the associated device Clinical Guide, User Guide or Service Manual, and are developed in accordance with global ISO standards, including 80601-2-79 and 80601-2-80, addressing requirements for basic safety and essential performance of ventilator support equipment.

Extracts from clinical guides

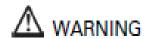


Astral – Single patient use

Cleaning and maintenance

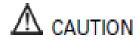
The cleaning and maintenance described in this section should be carried out regularly.

Refer to the user guides for the patient interface, humidifier and other accessories in use for detailed instructions for care and maintenance of those devices.



- A patient treated by mechanical ventilation is highly vulnerable to the risks of infection. Dirty or contaminated equipment is a potential source of infection. Clean the Astral device and its accessories regularly.
- Always turn off and unplug the device before cleaning and be sure it is dry before plugging back in.
- Do not immerse the device, pulse oximeter or power cord in water.

The Astral device can be cleaned using an anti-bacterial solution on a clean, non-dyed disposable cloth. After replacing any accessory in the patient circuit, ResMed recommends you perform a Learn Circuit.



Clean only exterior surfaces of the Astral device.

The following cleaning solutions are compatible for use on a weekly basis (except as noted) when cleaning the external surfaces of the Astral device:

- Actichlor Plus
- Bleach (1:10) (May also be known as 'dilute hypochlorite').
- Isopropanol
- Cavicide*
- Mikrozid*

*Suitable for cleaning on a monthly basis only.

Single patient use

For all circuit components, follow the manufacturer's recommendations for cleaning and maintenance.

Weekly

- Wipe the exterior of the device with a damp cloth using a mild cleaning solution.
- Inspect the condition of the circuit adapter for entry of moisture or contaminants. Replace as necessary, or at regular intervals not less than once every six months.
- Test the alarm sounders, refer to Testing the alarm sounders (see page 109).

Monthly

- Inspect the condition of the air filter and check whether it is blocked by dirt or dust. With normal use, the air filter needs to be replaced every six months (or more often in a dusty environment).
- Check the charge level of the internal battery by:
 - removing external power and operating the device on internal battery for a minimum of 10 minutes.
 - reviewing the remaining battery capacity, refer to Using the Internal battery (see page 63).
 - restoring external power once the test is complete.

Astral – Multi-patient use and hospital

Multi-patient use



⚠ WARNING

- To prevent the risk of cross-contamination, an antibacterial filter, placed on the inspiratory port is mandatory if the device is to be used on multiple patients as under some fault conditions, expired gas may be returned through the inspiratory port.
- . The expiratory module, internal antibacterial filter, expiratory flow sensor and blue membrane come into contact with exhaled gases but do not form part of the inspiratory pathway.

In addition to the cleaning and maintenance instructions for single patient use, you must perform the following before the device is provided to a new patient.

Component	Cleaning/ Maintenance method
Device	Refer to Cleaning and maintenance (see page 130).
Double limb adapter (used with Double limb circuits)	For general hygiene the Double limb adapter should be replaced or protected with an antibacterial filter.
Mask	Masks should be reprocessed when used between patients. Refer to the User guide provided with the mask in use.
Patient circuits	Replace or sterilise. Refer to the manufacturer's recommended cleaning instructions.
Humidifier	Refer to the User Guide provided with the humidifier in use.
Internal battery	Check the charge level by removing the external power and operating the device on internal battery for a minimum of ten minutes. Review the remaining battery capacity and restore external power.

Additional considerations for hospital or healthcare facilities

Component	Hospital or healthcare facility
Device	Follow the cleaning and maintenance protocol and schedule of the hospital/healthcare facility.
Double limb adapters	For general hygiene, the double limb adapter should be replaced between patients or protected with an antibacterial filter.
Air filter	Replace every six months (or more if necessary).
Mask	Masks should be reprocessed or replaced between patients. Cleaning, disinfection and sterilisation instructions are available from the ResMed website, www.resmed.com/downloads/masks. If you do not have internet access, please contact your ResMed representative.
Patient circuits	Follow the protocol of the hospital/healthcare facility and the recommendations of the manufacturer.
Humidifier	Follow the protocol of the hospital/healthcare facility and the recommendations of the manufacturer.
Antibacterial filter	Replace as required and between patients.

Astral 150 – Connection of an antibacterial filter on the patient circuit - inspiratory side

Attaching an antibacterial filter



WARNING

- Regularly check the antibacterial filter and expiratory valve for signs of moisture or other contaminants, particularly during nebulisation or humidification. Failure to do so could result in increased breathing system resistance and/or inaccuracies in expired gas measurement.
- Only use antibacterial filters that comply with the relevant safety standards, including ISO 23328-1 and ISO 23328-2.



CAUTION

The antibacterial filter must be used and replaced according to the manufacturer's specifications.

To attach an antibacterial filter:

- 1. Fit the antibacterial filter to the inspiratory port of the device.
- 2. Connect the air tubing to the other side of the filter.
- 3. Perform the Learn Circuit function.
- 4. Attach the patient interface to the free end of the air tubing.

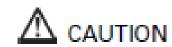


NB: according to the recommendations, it is possible to double the protection by using filters on the outlet of the device and on the patient side (see below). Performing the Learn Circuit will allow to recognize and compensate the increased resistances brought by these additional filters



Astral 150 – Replacing the expiratory flow sensor and antibacterial filter

Replacing the expiratory flow sensor and antibacterial filter (Astral 150 only)



- Regularly check the double limb adapter (expiratory valve) for moisture and contaminants.
 Particular care should be taken when using nebulisers or humidifiers.
- When replacing the expiratory flow sensor and antibacterial filter also replace the blue membrane and adapter.

A CAUTION

Following the replacement of the Expiratory flow sensor, you must run a Learn Circuit to calibrate the new sensor and ensure accurate therapy and monitoring.

To calibrate the Expiratory flow sensor, connect a double limb circuit. Prior to performing the Learn Circuit, ensure double circuit is selected on the Circuit sub-menu.

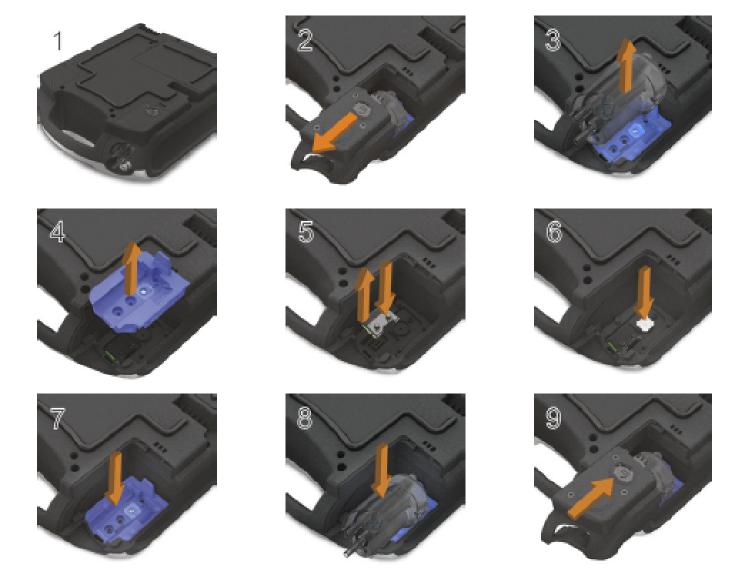
Double limb adapter (used with Double limb circuits)

For general hygiene the Double limb adapter should be replaced or protected with an antibacterial filter.

To remove and replace the expiratory flow sensor and antibacterial filter:

Before replacing the expiratory flow sensor, turn off the device and remove mains power and/or external battery.

- Turn over the device and place on a soft surface (to protect the LCD screen).
- 2. Press and hold the eject button. Pull the cover out towards you.
- Lift out the adapter and discard.
- Remove the blue membrane (including the white antibacterial filter) and discard.
- Remove and insert a new expiratory flow sensor.
- Insert a new antibacterial filter.
- Insert a new blue membrane ensuring the rear tab and surrounds sit flush in the enclosure.
- 8. Insert a new adapter, gently pushing down so it sits firmly in place.
- Place the cover over the enclosure, ensuring the runners on the device and the cover are aligned. Slide the cover back into place until the latch clicks.



Stellar – Single patient use

Cleaning and maintenance

The cleaning and maintenance described in this section should be carried out regularly. This also helps to prevent the risk of cross contamination. Refer to the mask, humidifier and other accessories user guide for detailed instructions for care and maintenance.



WARNING

- Beware of electric shock. Do not immerse the device, pulse oximeter or power cord in water. Turn off the device, unplug the power cord from the power socket and the device before cleaning and be sure that it is dry before reconnecting.
- The mask system and air tubing are subject to normal wear and tear. Inspect them regularly for damage.



CAUTION

The Stellar 150 cannot be sterilized.

Daily

Disconnect the air tubing from the device (and humidifier, if used) and hang it in a clean, dry place until next use. If the device is visibly soiled, wipe the exterior surfaces of the device and the pulse oximeter (if used) with a damp cloth and mild detergent.



CAUTION

- Do not hang the air tubing in direct sunlight as the tubing may harden over time and eventually crack.
- Do not use bleach, chlorine, alcohol or aromatic-based solutions (including all scented oils), moisturizing or antibacterial soaps to clean the air tubing or the device on a daily basis (other than the approved cleaning agents Mikrozid® AF or CaviCide®). These solutions may cause hardening and reduce the life of the product.
 The use of cleaners and disinfecting solutions containing alcohol (other than the approved cleaning agents) is acceptable for periodic cleaning of the device, such as for cleaning between patients or especially for service periods, but not recommended for daily use.

Weekly

- 1 Remove the air tubing from the device and the patient interface.
- Wash the air tubing in warm water using mild detergent.
- 3 Rinse thoroughly, hang and allow to dry.
- 4 Reconnect the air tubing to the air outlet and patient interface.
- If the device is visibly soiled, wipe the exterior surfaces of the device and the pulse oximeter (if used) with a damp cloth and mild detergent.

Monthly

- 1 Wipe the exterior of the device and the pulse oximeter (if used) with a damp cloth and mild detergent.
- Visually inspect the air filter to check if it is blocked by dirt or contains holes.

Replacing the air filter

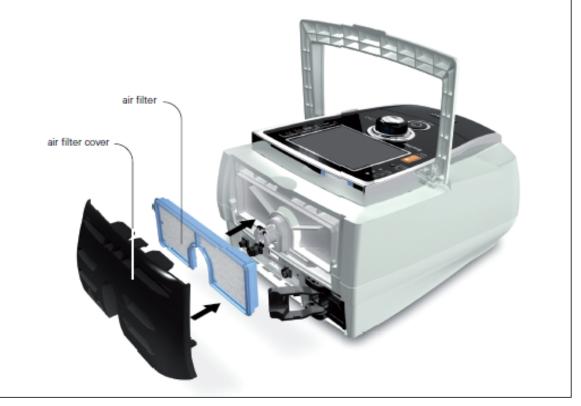
Replace the air filter every six months (or more often if necessary).



WARNING

Do not wash the air filter. The air filter is not washable or reusable.

- Remove the air filter cover at the back of the device.
- Remove and discard the old air filter.
- 3 Insert a new filter
- Refit the air filter cover



Stellar – Multi-patient use

Multipatient use



WARNING

· An antibacterial filter is mandatory if the device is used on multiple patients.

 In a mulitpatient use environment, you must perform the following before the device is provided to a new patient:

Mask Reprocess; Cleaning, disinfection and sterilization instructions are

available from the ResMed website, www.resmed.com/masks/

sterilization/americas. If you do not have Internet access, please contact

your ResMed representative.

Air tubing Replace the air tubing. Alternatively, consult the air tubing instructions for

cleaning and disinfection information.

Device Disinfect the Stellar 150 as follows:

Use an anti-bacterial cleaning/disinfectant solution such as Mikrozid[®] AF or CaviCide[®] with a clean non-dyed disposable cloth to clean and disinfect the exterior surfaces of the device. Wipe all accessible surfaces of the device, including the air outlet (avoid liquid entering any openings in the device). Follow the manufacturer's recommended cleaning instructions.

Humidifier As instructions for humidifiers vary, see the user guide for the humidifier

in use. For multipatient use environment, use the H4i water chamber

(disposable) in place of the H4i reusable water chamber.

Stellar – Attaching an antibacterial filter

An antibacterial filter is mandatory if the device is used on multiple patients.

Attaching an antibacterial filter

The use of an antibacterial filter can be recommended as per facility policy. An antibacterial filter can be purchased separately from ResMed.

Regularly check the filter for entry of moisture or other contaminants. The filter must be replaced according to the manufacturer's specifications.

Note: ResMed recommends using a filter with a low impedance (less than 2 cm H_2O at 60 L/min, eg, PALL BB 50 filter).

(Î)

WARNING

- · An antibacterial filter is mandatory if the device is used on multiple patients.
- · Do not use the antibacterial filter (product code 24966) with the H4i.



- 1 Fit the antibacterial filter to the air outlet of the device.
- 2 Attach the air tubing to the other side of the filter.
- 3 Attach the mask system to the free end of the air tubing.
- Perform the Learn Circuit function (see "Setup menu: Options" on page 45). From the Setup menu, select Options. This enables the device to compensate for the impedance introduced by the filters.

Lumis / AirSense – Single patient use

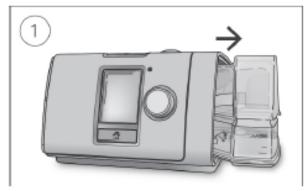
Cleaning and Maintenance

It is important that the Lumis device is cleaned regularly to ensure optimal therapy. The following sections will help with disassembling, cleaning, checking and reassembling the device.

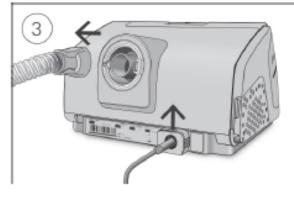
⚠ WARNING

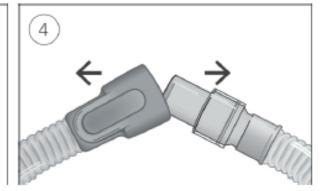
Regularly clean the tubing assembly, humidifier and mask for optimal therapy and to prevent the growth of germs that can adversely affect the patient's health.

Disassembling









- 1. Hold the humidifier at the top and bottom, press it gently and pull it away from the device.
- Open the humidifier and discard any remaining water.
- Hold the cuff of the air tubing and gently pull it away from the device. Grip the retention clip and pull up to release the power cord.
- 4. Hold both the cuff of the air tubing and the swivel of the mask, then gently pull apart.

Cleaning

You should clean the device weekly as described. Refer to the mask user guide for detailed instructions on cleaning the mask.

- Wash the humidifier and air tubing in warm water using mild detergent.
- 2. Rinse the humidifier and air tubing thoroughly and allow to dry out of direct sunlight and/or heat.
- Wipe the exterior of the device with a dry cloth.

Notes

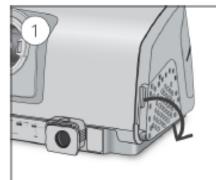
- The humidifier may be washed in a dishwasher on the delicate or glassware cycle (top shelf only). It should not be washed at temperatures higher than 65°C.
- Do not wash the air tubing in a dishwasher or washing machine.
- Empty the humidifier daily and wipe it thoroughly with a clean, disposable cloth. Allow to dry out
 of direct sunlight and/or heat.

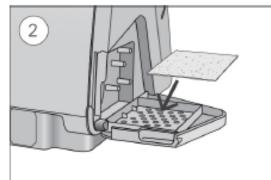
Checking

You should regularly check the humidifier, air tubing and the air filter for any damage.

- 1. Check the humidifier:
 - Replace it if it is leaking or has become cracked, cloudy or pitted.
- Replace it if the seal is cracked or torn.
- Remove any white powder deposits using a solution of one part household vinegar to 10 parts water.
- 2. Check the air tubing and replace it if there are any holes, tears or cracks.
- Check the air filter and replace it at least every six months. Replace more often if there are any holes or blockages by dirt or dust.

To replace the air filter:





- Open the air filter cover and remove the old air filter.
 The air filter is not washable or reusable.
- Place a new air filter onto the air filter cover and then close it.Make sure the air filter is fitted at all times to prevent water and dust from entering the device.

Reassembling

When the humidifier and air tubing are dry, you can reassemble the parts.

- 1. Connect the air tubing firmly to the air outlet located on the rear of the device.
- Open the humidifier and fill it with room temperature water up to the maximum water level mark.
- 3. Close the humidifier and insert it into the side of the device.
- 4. Connect the free end of the air tubing firmly onto the assembled mask.

Reprocessing

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

If the cleanable humidifier 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 humidifier, 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.

⚠ 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 sterilisation 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

- 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).
- Remove any excess disinfectant with a disposable dry cloth.

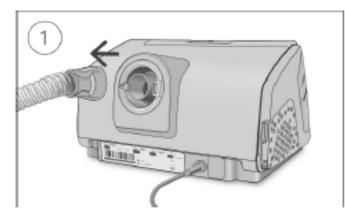
Agents recommended for surface disinfection and cleaning:

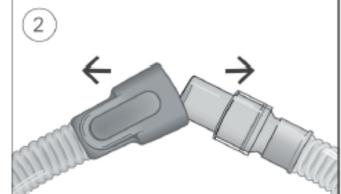
- Warm water and mild detergent eg, Teepol[™] multipurpose detergent
- Window cleaner or other premixed surface detergent
- Methyl alcohol solution
- 70% Ethyl alcohol solution
- 70-90% Isopropanol solution
- 10% Bleach solution
- Isopropyl wipes
- CaviCide"
- Mikrozid[®]
- Actichlor[™] Plus
- Terralin[®]

Note: Agents may not be available in all regions.

Reprocessing the air tubing and Air10 tubing elbow

Disconnecting





- 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.

- 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.
- 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 60°C) Warm water (approx 45 to 60°C) Room temperature water (approx 21°C)	✓	✓	✓	√	
Neodisher MediZyme (diluted at 2.0%)	Warm water (approx 45 °C)	✓				
Gigazyme® (diluted at 1.0%)	Room temperature water (approx 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: 75°C for 30 minutes OR 70°C for 100 minutes.			
SlimLine	100			
ClimateLineAir	26			
ClimateLineAir Oxy	20			
Standard	100			
Air10 tubing elbow	26			

- Immerse the air tubing in a water bath.
- Take care that no air bubbles are trapped inside the air tubing.
- Increase the water bath temperature to 70°C for 100 minutes, or a maximum of 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% for 12 minutes	Gigasept FF® 5% for 15 minutes		
SlimLine	100	-		
ClimateLineAir	26	26		
ClimateLineAir Oxy	20	20		
Standard	100	-		
Air10 tubing elbow	26	26		

- 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.
- Thoroughly rinse the air tubing/Air10 tubing elbow in drinking quality water (five litres 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.

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

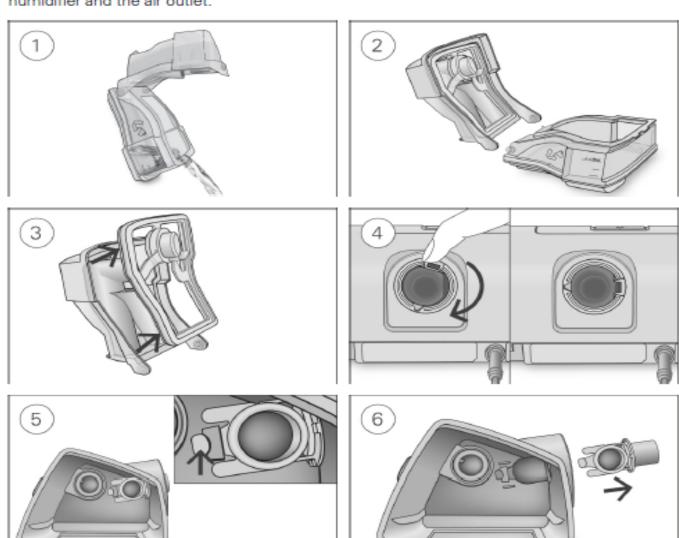
When the air tubing is dry, you can reconnect it to the device.

- 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.

Reprocessing the humidifier and air outlet

Disassembling

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



- 1. Remove the humidifier from the device, open it and discard any remaining water.
- Hold the humidifier base and then fully open the humidifier lid and pull it away so that it easily detaches from the base.
- 3. Remove the humidifier seal from the humidifier lid by pulling it away.
- 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.
- 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.

Decontaminating

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

- 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.
- 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 humidifier	Air outlet
Alconox (diluted at 1%)	Hot water (approx 60°C) Warm water (approx 45 to 60°C) Room temperature water (approx 21°C)	✓	✓
Gigazyme (diluted at 1.0%)	Room temperature water (approx 21°C)	✓	✓
Aniosyme DD1		✓	

Disinfecting

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

High level thermal disinfection

Part	Validated number of cycles
	Hot water: 90°C for 1 minute OR 75°C for 30 minutes OR 70°C for 100 minutes.
	Due to specific regional requirements, ResMed cleanable humidifiers have been tested for disinfection (100 cycles) at 93°C for 10 minutes
Cleanable humidifier	130
Air outlet	130

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

High level chemical disinfection

Part	Validated number of cycles		
	CIDEX OPA Ortho-phthalaldehyde 0.55% for 12 minutes Gigasept FF 5% for 15 minutes	Anioxide	
Cleanable humidifier	130	130	
Air outlet	130		

© 2020 Resolublicat Air outlet 13

- Soak the disassembled components in a commercially available solution of a chemical sterilant.
 Take care that no air bubbles are trapped against the components.
- Thoroughly rinse the cleanable humidifier in drinking quality water (five litres per assembly) by immersing it completely for a minimum of one minute in duration.
- 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.

Inspecting

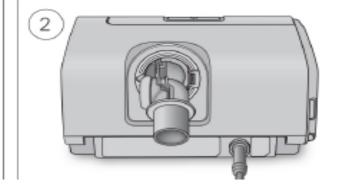
Perform a visual inspection of all components. If any visible deterioration is apparent (cracking, crazing, tears, etc), the humidifier should be discarded and replaced. Slight discoloration of the silicone components may occur and is acceptable.

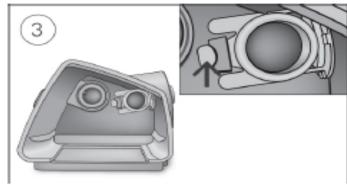
Reassembling

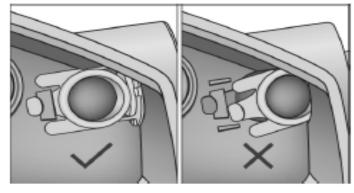
The following instructions provide guidance on how to correctly reassemble the air outlet and the humidifier.

To reassemble the air outlet



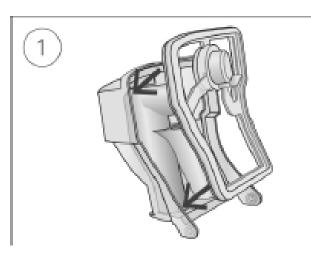


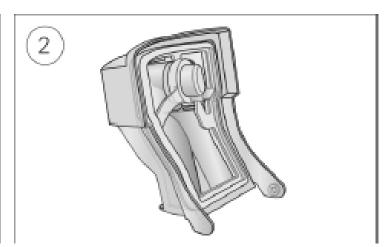




- 1. Hold the air outlet with the seal pointing to the left and the clip pointing forward.
- Make sure that the air outlet is correctly aligned and insert the air outlet into the socket. It will click in place.
- 3. Check if the air outlet is inserted correctly as shown.

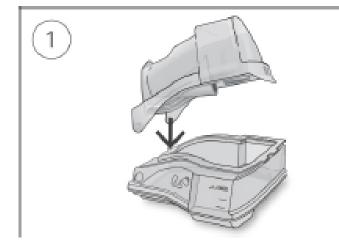
To insert the humidifier seal:

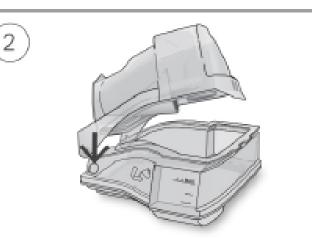




- Place the seal into the lid
- 2. Press down along all edges of the seal until it is firmly in place.

To reassemble the humidifier lid:





- 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: -20°C to 60°C.

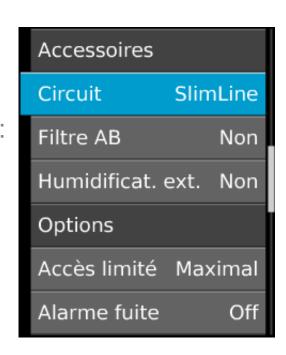
Antibacterial filters

Antibacterial filters increase resistance in the air circuit and may affect accuracy of displayed and delivered pressure, particularly at high flows.

ResMed recommends using an antibacterial filter with a low impedance [eg, 2 cm H₂O (2 hPa) at 60 L/min], such as PALL (BB50T), GVS Filter without Luer Port (4222/702) or GVS Filter with Side Port 24966 (4222/701). If using the GVS Filter with Side Port, an Oxygen Connector Port is required.

Note: When using the SlimLine air tubing above 20 cm H₂O (20 hPa), the device optimum performance may not be reached if used with an antibacterial filter. The device performance must be checked prior to prescribing the SlimLine air tubing for use with an antibacterial filter.

Caution, when adding an antibacterial filter, it must be specified in the settings menu: Accessories section AB filter: YES



Accessories

Parameter	Description	Range
Tube	Select the type of air tubing used by the patient. ClimateLineAir air tubing is automatically detected when connected to the device.	SlimLine / Standard / 3m
AB filter	Select Yes if you attach an antibacterial filter.	No / Yes
Ext. humidifier	Select Yes if you connect an external humidifier.	No / Yes
View oximeter	Displayed at all times when an oximeter is connected.	18-300 BPM 0-100% SpO ₂

Elisée 150 – Maintenance and disinfection

6 Maintenance and disinfection



CAUTION

- ResMed recommends the use of an antibacterial filter with the ventilator. This will help avoid cross-contamination when the device is used by a new patient.
- The device should be cleaned and disinfected before it is used for the first time, and also between patients.
- After cleaning or replacing any accessory in the patient circuit, always perform a manual test.

Note: In a hospital environment, we recommend the ventilator be disinfected regularly and also whenever contamination occurs.

Elisée 150 – Filters

4.4 Other accessories

To obtain the best results from this ventilator, a humidification system and/or antibacterial filters may be used.

Any circuit can be used with the Elisée 150, whether single or double, with or without water traps, reusable or single-use, as long as it has the same technical specifications as the recommended circuit (see "Technical specifications for accessories" on page 101).

Remember that the manual test must be repeated each time the circuit configuration is modified (see "Manual test (while ventilation is stopped)" on page 50).

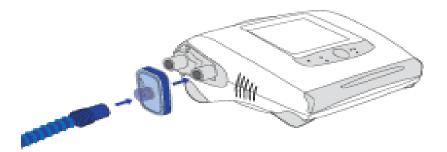
Antibacterial filter and HME filter (heat and moisture exchange filter)

An antibacterial filter, a heat and moisture exchange filter (HME), or a combination HME/ antibacterial filter, can all be used with the Elisée 150.

An antibacterial filter is commonly placed:

- At the point where the inspiratory limb connects to the ventilator, or
- Adjacent to the Y-connector, in a double circuit.

However, an HME filter or a combination HME/antibacterial filter can only be placed adjacent to the Y-connector.



- Connect the filter to the inspiratory limb of the patient circuit, following the filter installation instructions.
- Connect the filter to the insufflation outlet of the ventilator.

Note: This filter also offers protection against dust and common allergens present in the air.

Figure 4.13: Connecting an antibacterial filter



WARNING

The antibacterial filter must be installed in compliance with the manufacturer's recommendations.

For further details, refer to the user guide for this accessory.

5 Antibacterial filter



Follow the protocol of the hospital/health care facility and the manufacturer's recommendations.

If the antibacterial filter is used to protect against bacteria and viruses, it should be inserted in the inspiratory limb of the patient circuit. It should be changed as directed by the manufacturer.

Note: ResMed recommends the use of a proximal antibacterial filter in accordance with the practice of the home care facility or hospital.

If the antibacterial filter is being used to protect against bacteria and viruses, follow the filter manufacturer's instructions on replacement frequency. However, if the filter is being used to filter dust, it should be replaced weekly.

New patient

The antibacterial filter must be changed for each new patient.

NB: according to the recommendations, it is possible to double the protection by using filters on the outlet of the device and on the patient side. The execution of the manual test will allow to recognize and compensate the increased resistances brought by these additional filters.

Elisée 150 – summarising cleaning and replacement tasks

6.3 Summary table

Key: ✓: Yes; ➤: No

Table 6.1: Table summarising cleaning and replacement tasks

		Cleaning		ı	Replacement	
Equipment	Hospital/ health care facility	At home	New patient	Hospital/ health care facility	At home	New patient
Mask	Manufacturer's protocol	Manufacturer's protocol	(it must be replaced)	Hospital and manufacturer's protocol	Manufacturer's protocol	✓
Rousable patient circuit	Manufacturer's protocol	Manufacturer's protocol	(it must be replaced)	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	✓
Disposable patient circuit	*	*	*	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	✓
Double circuit support	Disinfection	Wash with soapy water and leave to dry on a paper towel	Hospital/health care facility and manufacturer's protocol	*	*	*

		Cleaning			Replacement	
Equipment	Hospital/ health care facility	At home	New patient	Hospital/ health care facility	At home	New patient
Double circuit clapper	(it must be replaced)	(it must be replaced)	(it must be replaced)	Every time the double circuit support is cleaned	Every time the double circuit support is cleaned	✓
O ₂ sensor	(it must be replaced)	(it must be replaced)	(it must be replaced)	Hospital/health care facility protocol or see the expiry date on the packaging	See expiry date on the packaging	√
Antibactorial filter	*	*	*	Manufacturer's protocol if used for antibacterial protection, or weekly if used to filter dust	Manufacturer's protocol if used for antibacterial protection, or weekly if used to filter dust	~
Humidifior (Washable chamber)	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	Manufacturer's protocol	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	✓
Humidifier (Disposable chamber)	*	*	*	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	✓
Dust filter	*	*	*	Whenever visibly contaminated or at least every 6 months	Whenever visibly contaminated or at least every 6 months	✓
Cassing	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	Manufacturer's protocol	(unloss damaged)	(unless damaged)	*

Elisée 150 – Double circuit support and expiratory valve clapper

3 Double circuit support and expiratory valve clapper 🔊 🛇



Follow the protocol of the hospital/health care facility and the manufacturer's recommendations.

As a general rule, replace the valve clapper each time the double circuit support is cleaned. The valve clapper cannot be disinfected or autoclaved.

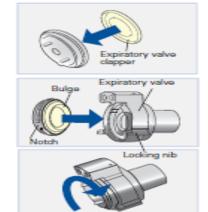
Assembly/disassembly

To disassemble the double circuit support:



- Hold the support in one hand. Place the index finger and thumb of your other hand on the two centring nibs.
- Press down on the centring nibs and pull out the clapper holder by twisting in an anti-clockwise direction.

To reassemble the double circuit support:



1. Place the new valve clapper in its holder, with the bulge facing outwards



- 2. Line up the three notches with the locking nibs and push
- Lock the support together by turning the clapper holder clockwise as far as you can

Figure 6.2: Assembling the double circuit support

Hospital/health care facility

Cold disinfection protocol

ResMed recommends the disinfection of the double circuit support according to the following protocol. This protocol allows cleaning, pre-disinfection and complete cold disinfection through two cycles. Proceed as follows:

- Disassemble the double circuit support and throw away the valve clapper.
- Disinfection Cycle A (using a pre-disinfecting cleaning solution: HEXANIOS G+R or Salvanios
- · Immerse all parts (except the clapper) for 15 minutes in the pre-disinfecting detergent, i.e. HEXANIOS G+R diluted to 0.5%, or Salvanios pH 7 diluted to 0.5%.
- During immersion, gently remove any visible dirt with a soft brush.
- Rinse under running water.
- Dry on a paper towel.
- 3. Disinfection Cycle B (using ANIOXYDE 1000, a high-performance disinfecting solution):
- · Immerse fully for 30 minutes in the activated, high-performance disinfecting solution ANIOXYDE 1000
- Rinse under running water.
- Dry on a paper towel.
- Reassemble the double circuit support using a new valve clapper.

Note: After the twentieth cycle, fine whitish lines may appear on the valve. These will not affect its

Do not use a high-pressure air generator to dry the valve more rapidly, as this would damage its honeycomb structure.

Autoclaving

If required by your hospital protocol, the double circuit support can be sterilised by autoclave. Prior to autoclaving, the valve must be dismantled and cleaned in a detergent bath. Proceed as follows:

- Disassemble the expiratory support and throw away the valve clapper.
- · Immerse all parts (except the clapper) for 15 minutes in the pre-disinfecting detergent, i.e. HEXANIOS G+R diluted to 0.5%, or Salvanios pH 7 diluted to 0.5%.
- During immersion, gently remove any visible dirt with a soft brush.
- Rinse under running water.
- Dry on a paper towel.
- To autoclave:
- Put the disassembled parts of the double circuit support in an autoclave at a temperature of 134°C (273°F) for 18 minutes.
- Reassemble the double circuit support using a new valve clapper.

Note: Autoclaving can affect the appearance of the accessory without affecting its performance.

At home

The double circuit support may be cleaned with soapy water and rinsed thoroughly. It must then be placed on a paper towel and left to air dry to remove all traces of water before reassembly.

New patient

For every new patient, the double circuit support must be cleaned and its clapper valve replaced.

VS III – Maintenance and disinfection

7 Maintenance and disinfection



CAUTION

ResMed recommends the use of an antibacterial filter with the ventilator. It safeguards the ventilator from contamination by the patient, thereby protecting the next patient to use the ventilator.

7.1 Hospital/Health care facility, Home use and New patient

The disinfection of the ventilator must be carried out as stated in the manufacturer's instructions. and in accordance with the current protocol of the home care facility or hospital.

Service personnel must be familiar with cleaning and disinfection protocols as well as the precautions required for certain materials.

3 Double circuit support and expiratory valve clapper 🍊 🤍



Follow the protocol of the hospital/health care facility and the manufacturer's recommendations.

Hospital

The expiratory valve clapper must be replaced for every patient and every time the double circuit support is autoclaved or decontaminated.

Autoclaving

Only the removable part of the double circuit support may be autoclaved (the expiratory valve; see the next figure). It may be autoclaved at a temperature of 134°C (273°F) for 18 minutes. Make sure you remove the clapper from inside the valve before autoclaving.

Note: Autoclaving can affect the appearance of the accessory without affecting its performance.

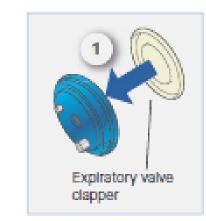
Hospital/health care facility

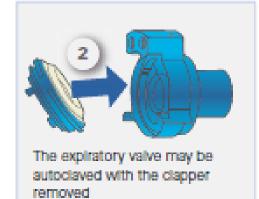
Decontamination

Cold immersion decontamination (expiratory valve only) may also be performed using a bactericidal, fungicidal and virucidal solution.

After cleaning, to reassemble the double circuit support (before attaching to the ventilator):

- Place the new valve clapper in its holder.
- Place the holder inside the double circuit support.
- Reattach the expiratory valve to the double circuit support.





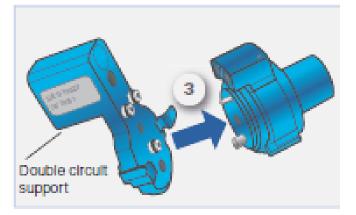


Figure 7.2: Assembling the double circuit support

At home

The double circuit support may be washed with soapy water and rinsed thoroughly. Leave it to air dry. It must be completely dry before reassembly.

As a general rule, we recommend the expiratory valve clapper be replaced every time the valve is cleaned.

New patient

The expiratory valve clapper must be replaced for every new patient.

VS III – Filtres

6.6 Antibacterial filter

Description

An antibacterial filter like the one shown in the next figure can be placed in the inspiratory limb and/or the expiratory limb of the patient circuit, as instructed by the clinician.

Note: ResMed recommends the use of a proximal antibacterial filter, to be used in accordance with the practice of the home care facility or hospital.

For the recommended specifications for using an antibacterial filter with the ventilator, see "Antibacterial filter" on page 99.

Antibacterial filter

The recommended antibacterial filter is the Intersurgical Filta-Guard, Ref. 1944.

- Filter: antibacterial / antiviral
- Connector: 22 female and 22 male / 15 female
- Bacterial and viral retention > 99.999%
- Resistance at 60 L/min: 2.3 cm H₂O
- · Compressible volume: 66 mL
- Internal volume: 200 mL
- Duration of use: 24 hours.

VS III – at hospital or at home

7.3 Summary table

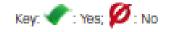


Table 7.1: Table summarising cleaning and replacement tasks

		Cleaning		Replacement		
Equipment	Hospital/ health care facility	At home	New patient	Hospital/ health care facility	At home	New patient
Mask F	Manufacturer's protocol	Manufacturor's protocol	(it must be replaced)	Hospital and manufacturer's protocol	Manufacturer's protocol	*
Reusable patient circuit	Manufacturer's protocol	Manufacturer's protocol	(it must be replaced)	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	•
Disposable patient circuit	Ø	Ø	(it must be replaced)	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	•
Double circuit support	Autoclaving or decontamination	Wash with scapy water and leave to air dry	Hospital/health care facility and manufacturer's protocol	Ø	Ø	Ø
Double circuit dapper	Ø	Ø	(it must be replaced)	Every time the double circuit support is autoclaved or decontaminated	Every time the double circuit support is cleaned	
O ₂ sensor	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	Manufacturer's protocol	Hospital/health care facility protocol or see the expiry date on the packaging	See expiry date on the packaging	•

	Cleaning			Replacement		
Equipment	Hospital/ health care facility	At home	New patient	Hospital/ health care facility	At home	New patient
Antibactorial filter	Q.	Q.	Ø.	Manufacturer's protocol if used for antibacterial protection, or weekly if used to filter dust	Manufacturer's protocol if used for antibacterial protection, or weakly if used to filter dust	•
Humidifier (Washable chamber)	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	Manufacturer's protocol	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	*
Humidifier (Disposable chamber)	Ø.	Ø.	Ø	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	•
Dust filter	Q	Ø	Q	Whenever visibly contaminated or at least every six months	Whenever visibly contaminated or at least every six months	•
Casing	Hospital/health care facility and manufacturer's protocol	Manufacturer's protocol	Manufacturer's protocol	(Unless damaged)	(Unless damaged)	Ø



WARNINGS

- The ventilator may be decontaminated using the current procedures approved by your service centre.
- If other products are used, they must comply with the conditions set by the
 pharmacopoeia of your country, must be known not to leave any residue and must not
 affect the operation of the ventilator. Alternative procedures must not conflict with safety
 measures recommended by the manufacturer.

Note: In leak ventilation, the ventilator is designed to contain any contamination from the air exhaled by the patient almost entirely within the patient circuit.

- While the patient is actively exhaling at the start of the expiratory phase, an influx of clean air (through the patient circuit) acts as a buffer between the ventilator and the patient.
- During the passive part of the expiratory phase, a constant airflow pushes exhaled air out through the mask vents (flushing). However, the only way to guarantee optimal protection is to use an antibacterial filter (particularly in a hospital setting).

We recommend you change the patient circuit for each new patient. This does not apply to the air supply components and foam pieces inside the ventilator, which are not exposed to the same conditions.

Mentions & disclaimer

24/03/20

COVID-19

Cleaning and maintenance of homecare devices during the period of Covid-19

This document is based on information available at the time of publication

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