

User's Manual

SERVO-air Ventilator System
Cleaning and Maintenance

MAQUET
GETINGE GROUP



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1 Introduction

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1.1 Introduction

Unless otherwise stated, the information in this User's Manual is valid for the SERVO-air ventilator system.

Here you will find the information needed to safely clean and maintain the ventilator system.

1.2 General information

As cleaning practices vary widely among health care institutions, it is not possible for Maquet to specify particular practices that will meet all needs, or to be responsible for the effectiveness of cleaning procedures carried out in the patient care setting.

Maquet recommends methods that have been validated using the specified equipment and procedures outlined in this manual. Other methods may work but are not covered by the warranty unless Maquet has given written permission.

1.3 Safety guidelines

WARNING! Indicates critical information about a potential serious outcome to the patient or the user.

CAUTION: Indicates instructions that must be followed in order to ensure the proper operation of the equipment.

Important: Indicates information intended to help you operate the equipment or its connected devices easily and conveniently.

Note: Indicates information requiring special attention.

CAUTIONS:

- All personnel should be aware of the risk of parts being infected when disassembling and cleaning the ventilator system.
- The expiratory channel and expired gas from the exhaust port may be contaminated.
- All disposable parts must be discarded according to hospital routines and in an environmentally safe way.

Important:

- Follow your hospital's routines for handling infectious material when handling any part of the ventilator system.
- If possible, cleaning should be performed immediately after use and always before steam autoclaving/disinfection. Blood or other residues should not be allowed to dry onto the devices.
- Water quality affects cleaning/disinfection. Maquet recommends drinking water quality as the minimum quality level.
- Maquet recommends the use of Servo Duo Guard bacterial filter or equivalent to reduce the transmission of bacteria from the patient via the expiratory cassette to the ambient air. This reduces the risk of infection spread and prolongs the life of the expiratory cassette due to reduced cleaning requirements.
- The use of a washer-disinfector for cleaning/disinfection is recommended if bacterial filters are not used.
- Steam autoclaving is normally not necessary for the expiratory cassette, as it is not an invasive instrument, but when applied, use processes recommended by Maquet.

Notes:

- Single use (i.e. disposable) items shall not be reused. Cleaning of single use items can damage the item and compromise its intended use. Reuse of single use items increases the risk of spreading infections and compromises the durability of the item.
- Maquet recommends that the equipment is inspected regularly.
- A preventive maintenance must be performed by authorized personnel at least once every year as long as the unit is not used more than normal. Normal operation during one year is estimated to correspond to approximately 5000 hours of operation. The current operating time and time to next preventive maintenance is presented in *SERVICE & SETTINGS/BIOMED/STATUS/General* on the user interface.

1.4 Symbols



Hazardous waste The device contains parts which must not be disposed of with ordinary waste.



Special waste This product contains electronic and electrical components. Discard disposable, replaced and left-over parts in accordance with appropriate industrial and environmental standards.

2 Patient unit and user interface

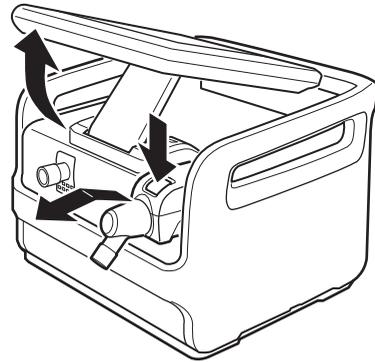
2.1 Preparations

Note: Cleaning should be done after each patient or according to hospital routines.

- Switch off the ventilator system using the on/off switch on the patient unit.
- Disconnect the ventilator system from the mains power and gas supply.
- Disconnect any optional equipment from the mains power and from the ventilator system.
- Discard disposable items according to hospital routines and environmental regulations.
 - Servo Duo Guard viral/bacterial filter
 - SERVO humidifier/HME
 - disposable patient tubing
 - disposable airway adapter
 - Aerogen Solo nebulizer
- Remove the expiratory cassette.

2.1.1 Remove the expiratory cassette

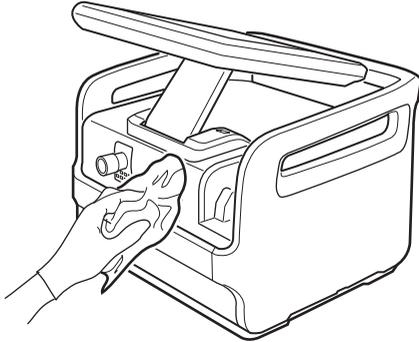
Important: The expiratory cassette is a precision instrument and must be handled carefully.



- Tilt the user interface backwards.
- Press the button on the expiratory cassette.
- Tilt the cassette upwards and remove.

Important: After removing the expiratory cassette, do not pour any fluid into the expiratory cassette compartment. Avoid contact with electrical connectors.

2.2 Wiping and discarding



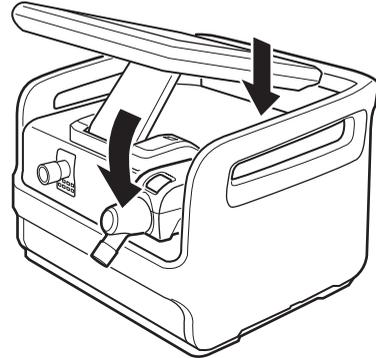
Wipe all parts with cleaning wipes or a soft lint-free cloth moistened in soap & water or detergent-based disinfectant.

In case of more contaminated surfaces, use ethyl alcohol (70%) or isopropyl alcohol (70%). Avoid contact with electrical connectors.

Important: Do not use abrasive or sharp tools to clean the user interface.

2.3 Assembling

2.3.1 Insert the expiratory cassette



- Hinge a clean expiratory cassette and press it firmly down into lock position.

Important: Make sure that the cassette clicks into position. Check that it cannot be moved upwards and that the button on top of the cassette is completely ejected.

- Note on a log sheet that a routine cleaning has been performed. Refer to hospital routines.

2.3.2 Pre-use check

After cleaning, always perform a pre-use check.

Refer to the ventilator system User's Manual.

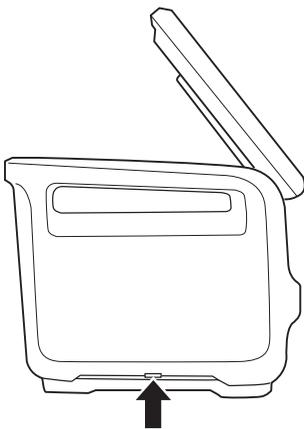
If the pre-use check fails:

- Carefully shake/tilt the cassette (5-7 times).
- Run the cassette in a ventilator system with a test lung for 10 minutes.
- Re-do the pre-use check.

2.4 Preventive maintenance

2.4.1 Check fan filters

Regularly check that the fan filter on both sides looks clean (i.e. black). If dusty, remove (snap off/snap on) and rinse in water. Shake out, ensuring that the filter is free from excess water.



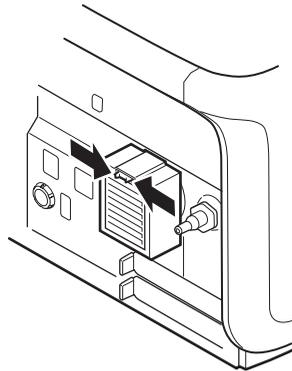
2.4.2 Check air inlet filter

The air inlet filter must be exchanged once a year during preventive maintenance or more often when necessary.

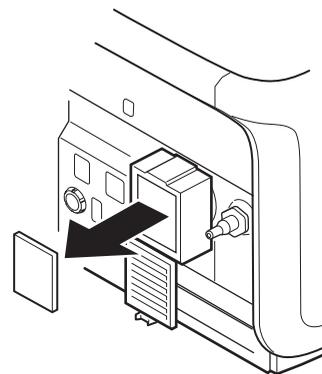
2.4.3 Replace the dust filter

Check the dust filter and replace it once a month or more often when necessary.

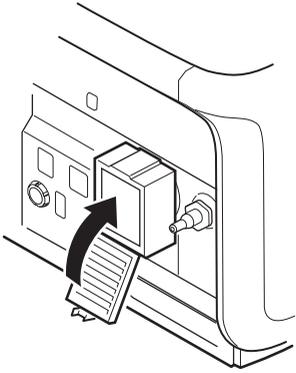
Note: The dust filter must be replaced. If it is washed it will lose its characteristics.



- Open the air inlet filter lid by pressing the two latches towards each other.



- Replace dust filter.



- Close the lid.

3 Expiratory cassette

3.1 Preparations

- Remove the expiratory cassette

Refer to section Remove the expiratory cassette on page 7.

3.2 Disinfection

There are two disinfection procedures for the expiratory cassette and associated parts when no bacterial filter is used:

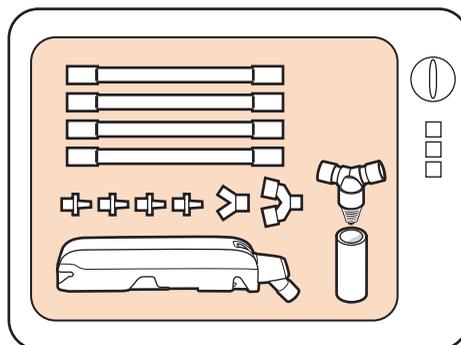
- Washer-Disinfector (ISO 15883-1) (recommended)
- Disinfectant

3.2.1 Washer-disinfector

If rinsing before disinfection is not included in the washer disinfector program:

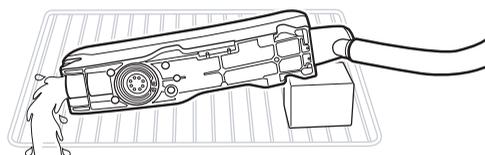
- Rinse the parts thoroughly in water (<35°C/95°F).
- Let the water flow through the parts.

Important: Immediate rinsing in water (<35°C/95°F) can remove particles and reduces the risk of cross-contamination between patients.



- Wash the parts with water only in a washer-disinfector at a temperature of 85-95°C (185-203°F).

Refer to section Recommended intervals and disinfectants on page 24.

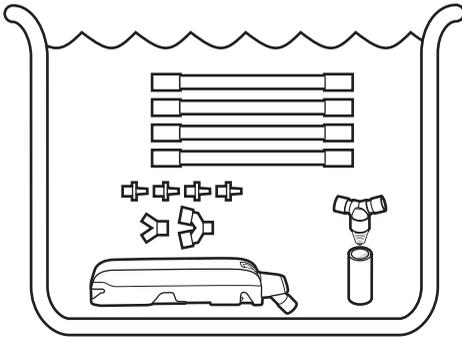


- Place the expiratory cassette on its side with the electrical connector uppermost.

Notes:

- The water pressure in the washer-disinfector should not exceed 1.5 bar.
- The maximum water flow should not exceed 10 l/min.
- The water must have free passage through the cassette.

3.2.2 Disinfectant



- Let the parts soak in disinfectant. Refer to section Recommended intervals and disinfectants on page 24.

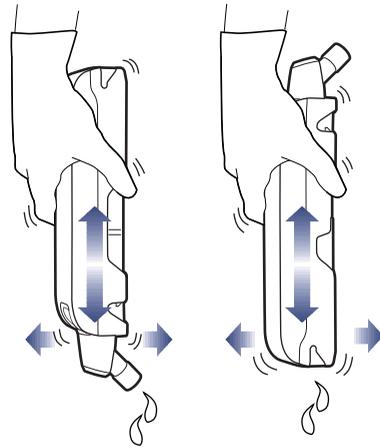
Important: Follow the disinfectant manufacturer's recommendations and instructions, otherwise the cassette may be damaged or not disinfected properly.

Rinse after disinfection

Important:

Follow the disinfectant manufacturer's recommendation and instructions regarding rinsing.

Mineral deposits from disinfectant on the expiratory cassette affect the function. It is important to rinse the expiratory cassette thoroughly. Residues from chemicals can affect the patient, cause leakage and extra stress on the material.



- Rinse the parts thoroughly in water to remove all traces of disinfectant. Let the water flow through the parts.
- **Carefully** shake and tilt the cassette, turn upside down and repeat at least 5-7 times.

3.3 Drying alternatives

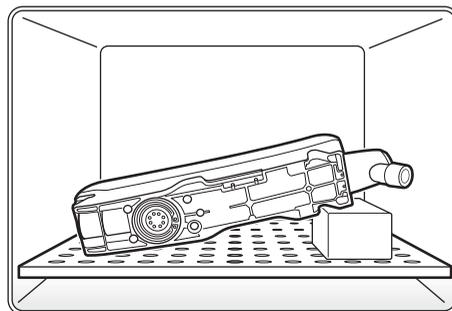
Important: The expiratory cassette must be dried before use (if not dry, the expiratory cassette may not pass the pre-use check).

Always shake/tilt the cassette carefully (5-7 times).

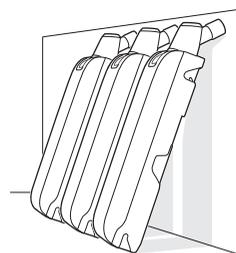
There are several drying alternatives for the expiratory cassette:

- Drying cabinet 1 hour in maximum 70°C (158°F); if available, connect a 22 mm air hose to the expiratory cassette for extra drying effect, or
- Drying the cassette in room air 12-24 hours, depending on surrounding conditions.

3.3.1 Recommended position in a drying cabinet



3.3.2 Recommended position in room air



If the pre-use check is not passed after drying then:

- Run the cassette in a ventilator system with a test lung for 10 minutes, or
- Dry the cassette in room air (if no drying cabinet is available) 12-24 hours, depending on surrounding conditions.

Notes:

- Never dry the cassette by applying high-pressure air as the internal tubing may be damaged.
- Drying may not be necessary if the washer-disinfector has a drying phase.

3.4 Steam autoclaving

Note: Steam autoclaving procedures are not recommended.

Steam autoclaving will reduce the lifetime of the expiratory cassette and is not recommended as a cleaning method.

Steam autoclaving is normally not necessary for the expiratory cassette, as it is not an invasive instrument, but when applied, use validated processes only.

Refer to section Recommended intervals and disinfectants on page 24.

3.4.1 Cleaning

- Clean before steam autoclaving.

Refer to section Washer-disinfector on page 11.

3.4.2 Rinse

- Rinse the parts thoroughly in water (<35°C/95°F).
- Let the water flow through the parts.

3.4.3 Drying before steam autoclaving

Before placing the expiratory cassette in a steam autoclave, make sure that no water remains inside the cassette.

Refer to section Drying alternatives on page 13.

3.4.4 Steam autoclave

Refer to section Recommended intervals and disinfectants on page 24.

3.4.5 Drying after steam autoclaving

Refer to section Drying alternatives on page 13.

3.5 Assembling

Refer to section Assembling on page 8.

4 O₂ cell (maintenance)

4.1 Preventive maintenance

Regularly check the cell status in quick menu *SYSTEM STATUS/O₂ cell*. The O₂ cell should be exchanged if <10% estimated remaining capacity is indicated.

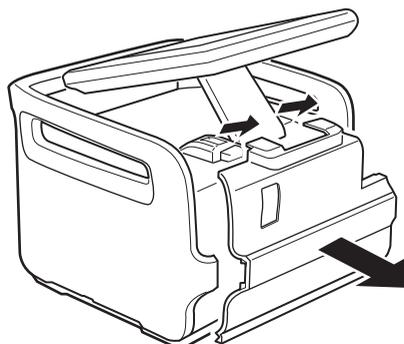
Refer to the ventilator system User's manuals for O₂ cell adjustment.

4.2 Preparations

WARNING! The sealed unit of the O₂ cell contains a caustic liquid which may cause severe burns to the skin and eyes. In case of contact, immediately wash the affected area continuously with water for at least 15 minutes and seek medical attention, especially if the eyes are affected.

Important:

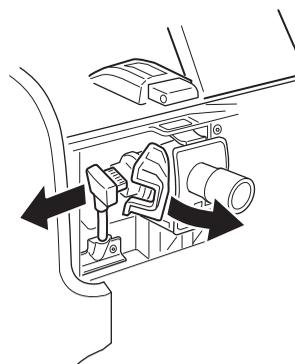
- Make sure the O₂ cell is for the intended ventilator model.
- Replacement of the O₂ cell and filter and extended cleaning must only be performed by trained personnel.
- Unpack the O₂ cell at least 15 minutes before replacement. Turn the ventilator system off using the on/off switch on the patient unit.
- Disconnect the ventilator system from the power and gas supply.



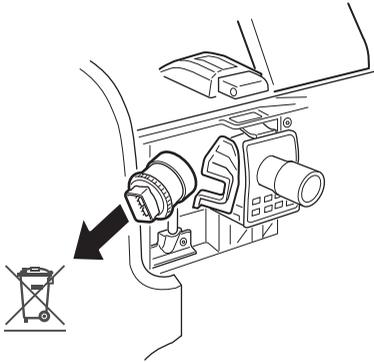
- Remove the expiratory cassette.
- Remove the front cover.
- Remove the O₂ cell.

WARNING! The inspiratory channel cover shall be kept in place once maintenance has been performed. Otherwise the gas modules can be affected and deliver the wrong flow.

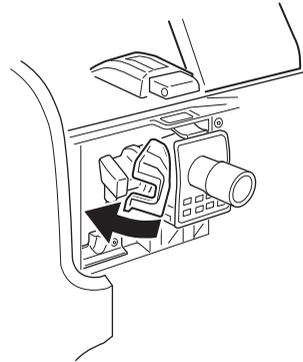
4.2.1 Remove the O₂ cell



- Unfasten and turn out the locking latch.
- Disconnect the O₂ cell connector.



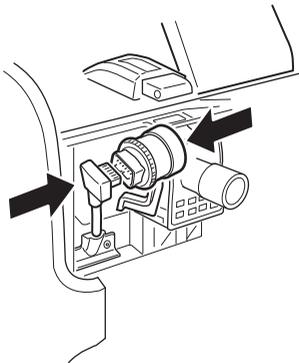
- Remove the O₂ cell.



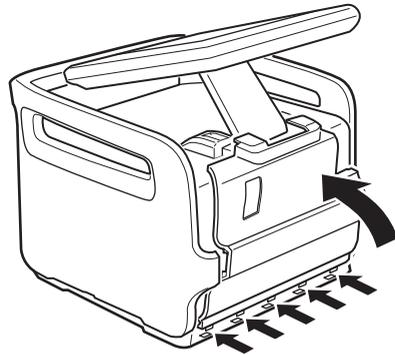
- Fasten the locking latch.

4.3 Assembling

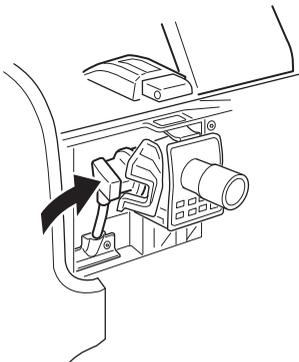
4.3.1 Insert the O₂ cell



- Connect the O₂ cell connector.



- Put the lower part of the front cover in position.
- Press the upper part of the front cover into position.
- Perform a pre-use check.



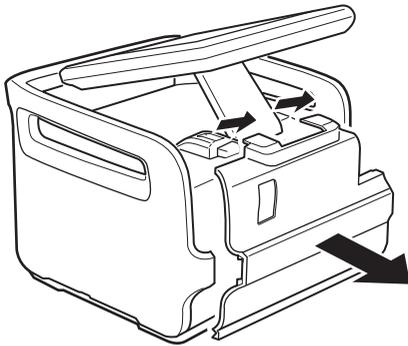
- Put the O₂ cell in position.

5 Inspiratory channel (maintenance)

5.1 Preventive maintenance

Important: It is recommended that a regular cleaning and an extended cleaning of the inspiratory channel should be performed before carrying out preventive maintenance.

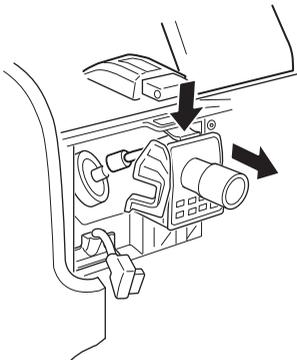
5.2 Preparations



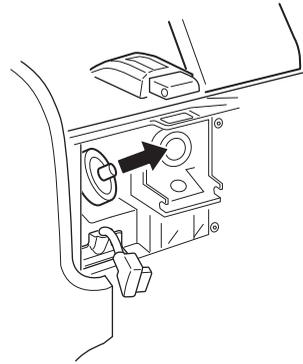
- Remove the expiratory cassette.
- Remove the front cover.
- Remove the O₂ cell.

Refer to section Remove the O₂ cell on page 15.

5.2.1 Remove inspiratory channel and tube



- Press the latch and gently pull out the inspiratory channel.



- Disconnect the tube and remove the bacterial filter. Discard the filter to hazardous waste.

5.3 Disinfection

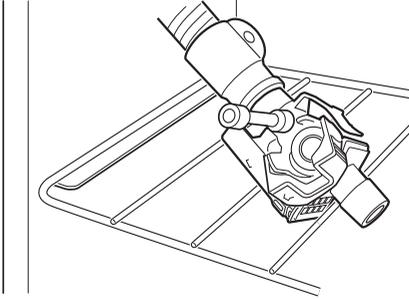
5.3.1 Rinse before disinfection

If rinsing before disinfection is not included in the washer disinfector program:

- Rinse the parts thoroughly in water (<35°C/95°F).
- Let the water flow through the parts.

Important: Immediate rinsing in water (<35°C/95°F) can remove particles and reduces the risk of cross-contamination between patients.

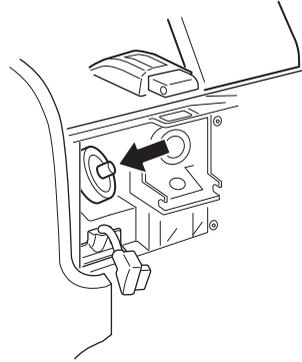
5.3.2 Washer-disinfector



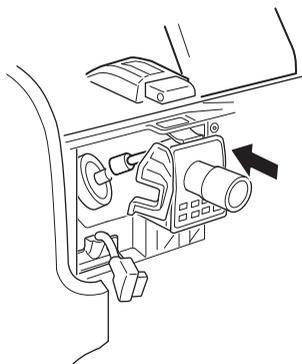
- Place the inspiratory channel so that the water flows through it.
- Clean the inspiratory channel and tube the same way as the expiratory cassette.
- Refer to section Disinfection on page 11.

5.4 Assembling

5.4.1 Insert inspiratory channel and tube



- Put a new bacterial filter in position and connect the filter to the tube.



- Push the inspiratory channel until it clicks into locked position.
- Re-insert the O₂ cell.
Refer to section Insert the O₂ cell on page 16.
- Mount the front cover.
Refer to section Assembling on page 16.
- Note on a log sheet that an extended cleaning of the inspiratory channel has been performed.
- Insert the expiratory cassette.
- Perform a pre-use check.
Refer to the ventilator system User's Manual.

6 Aerogen Pro nebulizer

6.1 Preparation

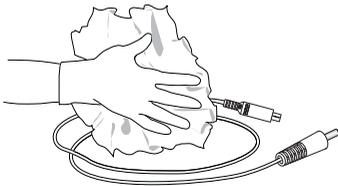
Important: Do not use abrasive or sharp tools to clean the nebulizer unit.

Note: The Aerogen Solo nebulizer unit is intended for single patient use only, do not re-use, clean or sterilize.

Cleaning should be done after each patient or according to hospital routines.

Disconnect the nebulizer unit from the control cable, and remove the nebulizer unit, T piece and adapters from the patient circuit or mask.

6.2 Wiping and discarding



- Wipe the control cable with a damp cloth. Do not autoclave.
- Check for exposed wiring, damaged connectors, or other defects and replace if any are visible.

Note: In case of more contaminated surfaces, use ethyl alcohol (70%).

6.3 Disinfection

6.3.1 Cleaning

- Ensure there is no medication remaining in the nebulizer.
- Disassemble the nebulizer unit and adapters into individual components.
- Remove the filler cap from nebulizer unit.
- Clean all parts with warm water and mild liquid detergent.
- Rinse all parts in sterile water.
- Shake excess water from parts and allow parts to air dry.
- Assemble the nebulizer.
Refer to the ventilator system User's Manual.

6.3.2 Washer-disinfector

Two different washing cycles are validated for the Aerogen Pro nebulizer:

- Liquid alkaline cleaner (diluted as per manufacturer instruction) and mains water.
 - Load the components in the washer-disinfector.
 - Pre-rinse the components for 3 minutes.
 - Clean the components with liquid alkaline cleaner at 55 °C (131 °F) for 10 minutes.
 - Rinse for 1 minute.
 - Rinse using thermal disinfection cycle at 93 °C (199.4 °F) for 10 minutes.
- Mains water and without the use of a detergent.
 - Load the components in the washer-disinfector.

- Wash components for 10 minutes at 91 °C (195.8 °F).
- Drain the machine for 40 seconds.
- Rinse at 90 °C (194 °F) for 1 minute.
- Drain the machine for 40 seconds.
- Rinse at 90 °C (194 °F) for 1 minute.
- Drain the machine for 40 seconds.
- Dry at 90 °C (194 °F) for 15 minutes.

6.3.3 Disinfectant

- Immerse the parts in appropriate disinfecting agent.

Refer to section Recommended intervals and disinfectants on page 24.

Important: Follow the disinfectant manufacturer's recommendations and instructions.

6.4 Steam autoclaving

- Disassemble the nebulizer unit and adapters into individual components.
- Remove the filler cap from the nebulizer unit.
- Clean all parts with warm water and mild liquid detergent. Rinse thoroughly and air dry.
- Check for cracks or damage and replace if any defects are visible.
- Place the disassembled components into appropriate sterilization wrapping.

Note: Do not reassemble parts prior to steam autoclaving

Only the Aerogen Pro nebulizer unit, T piece and neonate adapters can be autoclaved.

Refer to section Recommended intervals and disinfectants on page 24.

Note: Sterilization using the long autoclave cycle may cause some areas of the nebulizer to become discolored. This does not affect the performance of the nebulizer unit.

To sterilize with hydrogen peroxide gas plasma, place wrapped parts in a STERRAD[®] System, and use the long cycle.

Note: Users should refer to the product labelling for the STERRAD[®] 100S Sterilization System for specific instructions regarding its proper operation.

6.5 Assembling

Assemble the nebulizer.

Perform a function test of the Aerogen Pro nebulizer after the cleaning.

Refer to the ventilator system User's Manual.

7 Accessories

7.1 Hardware accessories

Hardware accessories are:

- Mobile cart
- Humidifier holder
- Support arm 179
- Water bag/IV pole
- Drawer
- Cabinet
- Gas cylinder restrainer kit
- Shelf base
- Hook and Y piece holder
- Cable holder

Refer to section Recommended intervals and disinfectants on page 24.

7.2 Patient circuits

Note: Discard the disposable patient circuits. The disposable patient circuits are for single patient use only.

Refer to the cleaning routines in the operating manual for the patient circuit.

7.3 Humidifier

Fisher & Paykel Humidifier MR850/MR810

Refer to the cleaning routines in the operating manual for the Fisher & Paykel Humidifier.

8 Recommended intervals and disinfectants

Patient unit and user interface

Surface cleaning	<ul style="list-style-type: none"> • 3M Respirator Cleaning Wipes • Clorox Bleach Germicidal Wipes (may cause discoloration) • Super Sani-Cloth Germicidal Wipes (may cause discoloration) • Virkon S • Accel TB (Virox 5) • In case of more contaminated surfaces, use ethyl alcohol (70%) or isopropyl alcohol (70%) together with lint free cleaning wipes.
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Expiratory cassette

Pre-disinfectant	<ul style="list-style-type: none"> • Aniosyme DD1 • Gigazyme Plus • Salvanios pH7 <p>Follow the disinfectant manufacturer's recommendation and instructions.</p>
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Disinfectant	<ul style="list-style-type: none"> • Alcohol (ethyl or isopropyl alcohol 70%) • Anioxyde 1000 • Cidex OPA • Actanios HLD (prion decontamination agent), may cause discoloration <p>Follow the disinfectant manufacturer's recommendation and instructions.</p>
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Number of immersion cycles	at least 100 cycles
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Cleaning agent	<ul style="list-style-type: none"> • neodisher® MediClean forte • Getinge MIS Detergent
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Number of cycles in washer-disinfector	at least 200 cycles.
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Steam autoclave	<ul style="list-style-type: none"> • Instrument parts should be steam autoclaved in a validated process, at a temperature of 134°C (273°F) for 3 minutes. • Rubber parts should be steam autoclaved in a validated process, at a temperature of 121°C (250°F) for 15-20 minutes.
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Number of cycles in steam autoclave	<p>The expiratory cassette will last at least:</p> <ul style="list-style-type: none"> • 100 autoclaving cycles with 3 minutes sterilization time at 134°C (273°F). • 30 autoclaving cycles with 18 minutes sterilization time at 134°C (273°F).
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O₂ cell

O ₂ cell	Replace the O ₂ cell when it is requested by the ventilator system.
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Inspiratory channel

Pre-disinfectant	<ul style="list-style-type: none"> • Aniosyme DD1 • Gigazyme Plus • Salvaios pH7 <p>Follow the disinfectant manufacturer's recommendation and instructions.</p>
Disinfectant	<ul style="list-style-type: none"> • Alcohol (ethyl or isopropyl alcohol 70%) • Anioxyde 1000 • Cidex OPA • Actanios HLD (prion decontamination agent), may cause discoloration <p>Follow the disinfectant manufacturer's recommendation and instructions.</p>
Number of immersion cycles	at least 10 cycles
Cleaning agent	<ul style="list-style-type: none"> • neodisher® MediClean forte • Getinge MIS Detergent
Number of cycles in washer-disinfector	at least 20 cycles.
Number of cycles in steam autoclave	The inspiratory channel will last at least 10 autoclaving cycles with 3 minutes sterilization time at 134°C (273°F).

Aerogen Pro nebulizer

Pre-disinfectant	<ul style="list-style-type: none"> • Hexanios G+R <p>Follow the disinfectant manufacturer's recommendation and instructions.</p>
Disinfectant	<ul style="list-style-type: none"> • Isopropyl alcohol (70 %) • CIDEX • NU-CIDEX • Cidex OPA
Number of cycles in steam autoclave	at least 26 cycles
Steam autoclave	<p>Steam autoclaving can be performed using the following three methods:</p> <ul style="list-style-type: none"> • Autoclave wrapped parts using steam autoclaving pre-vacuum cycle, a minimum of 134°C (270°F - 275°F) for 3.5 minutes with drying cycle (134°C wrapped cycle). • Autoclave wrapped parts using steam autoclaving pre-vacuum cycle, a minimum of 121°C (250°F) for 20 minutes with drying cycle (121°C wrapped cycle). • Autoclave wrapped parts using steam autoclaving pre-vacuum cycle, a minimum of 134°C (270°F - 275°F) for 20 minutes with drying cycle (sometimes referred to as a "Prion cycle"). <p>Note: This cycle may cause some areas of the nebulizer to become discolored. This does not affect the performance of the nebulizer.</p>

Accessories

Surface cleaning

Wipe the surface with a soft cloth moistened in soap and water or in disinfectant.

In case of more contaminated surfaces, use ethyl alcohol (70%) or isopropyl alcohol (70%) together with lint free cleaning wipes.

MAQUET
GETINGE GROUP

Manufacturer: Maquet Critical Care AB
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GETINGE GROUP

Getinge Group is a leading global provider of innovative solutions for operating rooms, intensive-care units, hospital wards, sterilization departments, elderly care and for life science companies and institutions. With a genuine passion for life we build quality and safety into every system. Our unique value proposition mirrors the continuum of care, enhancing efficiency throughout the clinical pathway. Based on our first-hand experience and close partnerships, we are able to exceed expectations from customers – improving the every-day life for people, today and tomorrow.

