

Bonaduz, 10th February 2015

Reprocessing guide according to EN ISO 17664

Cleaning and disinfection of Aeroneb Pro system components

NOTE This is only a copy of the reprocessing guide of Aerogen. For the latest version or further questions contact Aerogen directly www.aerogen.com

It is important that Aeroneb Pro device components are cleaned and sterilized prior to first patient use.

The components are:

- Nebulizer unit (including filler cap)
- T-piece (including T-piece plug) for adult and pediatric
- Neonate adapters
- Control module*, control module cable*, and AC/DC adapter*
- Mounting bracket*

CAUTION Always clean, sterilize and disinfect in accordance with current hospital protocols.

To avoid damage to the nebulizer:

- Autoclave according to specified directions and temperature given in the “Cleaning, disinfection and sterilization” section of this Instruction Manual only. Any deviation from directions given in this Instruction Manual may cause damage to the nebulizer unit and render it inoperable.
- Do not apply undue pressure to the domed aperture plate in the center of the nebulizer.
- Do not push out the OnQ™ Aerosol Generator

Manual Cleaning

Cleaning nebulizer unit, T-pieces and neonate adapters

1. Ensure there is no medication remaining in the device.
2. Remove nebulizer unit from T-piece. Remove filler cap from nebulizer unit.
3. Clean all parts with warm water and mild liquid detergent in accordance with current hospital protocols.
4. Rinse parts with sterile water.
5. Shake excess water from parts and allow parts to fully air dry.

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

**Components not to be autoclaved.*

Automated Washing Cycle

The Aeroneb Pro Nebulizer System has been validated with the following automated washing cycles:

1. Automated Cycle One

Detergent Liquid alkaline cleaner (diluted as per manufacturers instruction)

Water Quality Mains water

Method

1. Load the components in the automated washer.
2. Pre-rinse the components for 3 minutes.
3. Clean the components with liquid alkaline cleaner at 55°C (131°F) for 10 minutes.
4. Rinse for 1 minute.
5. Rinse using thermal disinfection cycle at 93°C (199.4°F) for 10 minutes

2. Automated Cycle Two

Detergent The following cycle was validated without the use of a detergent

Water Quality Mains water

Method

1. Load the components in the automated washer.
2. Wash components for 10 minutes at 91°C (195.8°F).
3. Drain the machine for 40 seconds.
4. Rinse at 90°C (194°F) for 1 minute.
5. Drain the machine for 40 seconds.
6. Rinse at 90°C (194°F) for 1 minute.
7. Drain the machine for 40 seconds.
8. Dry at 90°C (194°F) for 15 minutes.

Disinfection of nebulizer unit, T-pieces and neonate adapters

1. Follow steps 1 through 3 in manual cleaning section on page 1.
2. Completely immerse parts in appropriate disinfecting agent in accordance with current hospital protocols and disinfectant agent manufacturer guidelines.

NOTE Aerogen approves the following disinfection solutions for use with its Aeroneb Pro Nebulization System regarding material compatibility. With respect to microbiological effectiveness, please ask the manufacturer. Refer to the product labeling for specific instructions regarding activation, safe use and disposal of these solutions.

- Isopropyl (70%)
- CIDEX®
- NU-CIDEX®
- CIDEX® OPA
- Hexanios G+R

Sterilization of nebulizer unit, T-pieces and neonate adapters

1. Disconnect the nebulizer unit from the control module, and then remove the nebulizer unit and adapters from the ventilator circuit, mask or mouthpiece.
2. Disassemble the nebulizer unit and adapters into individual components.
3. Remove the filler cap from the nebulizer unit
4. Clean all parts with warm water and mild liquid detergent in accordance with current hospital protocols. Rinse thoroughly and air dry.
5. Check for cracks or damage and replace if any defects are visible.
6. Place the disassembled components into appropriate sterilization wrapping.

CAUTION Do not reassemble parts prior to autoclaving.

Sterilize components

1. Steam sterilization can be performed using the following three methods:
 - a. autoclave wrapped parts using steam sterilization pre-vacuum cycle, a minimum of 134°C (270°F - 275°F) for 3.5 minutes with drying cycle (134°C wrapped cycle).
 - b. autoclave wrapped parts using steam sterilization pre-vacuum cycle, a minimum of 121°C (250°F) for 20 minutes with drying cycle (121°C wrapped cycle).
 - c. autoclave wrapped parts using steam sterilization 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").

NOTE Sterilization using the long autoclave cycle (c.) may cause some areas of the nebulizer to become discolored. This is not indicative of the performance of the nebulizer unit.

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

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

Prior to next use

- a. Check for cracks or damage and replace if any defects are visible.
- b. Perform a functional test as described in this manual.

Cleaning of mounting brackets

Wipe clean with a damp cloth and mild liquid detergent. Do not use abrasive or sharp tools.

Cleaning of control module, control module cable and AC/DC adapter

1. Wipe clean with an alcohol based disinfectant wipe or a quaternary ammonium compound based disinfectant wipe.
2. Check for exposed wiring, damaged connectors, or other defects and replace if any are visible.
3. Visually inspect for damage and replace the control module if any damage is observed.

CAUTION Do not autoclave.
Do not use abrasive or sharp tools.
Do not spray liquid directly onto the control module.
Do not immerse control module in liquid.

The Aeroneb Pro nebulizer unit contains active electronic components. Aerogen has validated the methods of cleaning, disinfection and sterilization above. The use of any other means of cleaning, disinfection or sterilization has not been validated and is likely to reduce the life of your nebulizer and will invalidate your warranty

With kind regards

Hamilton Medical AG



Melanie Obert

Product Manager
mobert@hamilton-medical.ch

☎ +41 58 610 18 86

📠 +41 58 610 00 20



Frederike Brüschwein

Senior Manager Regulatory Affairs