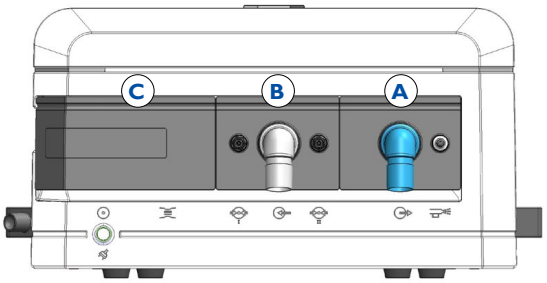
elisa 300 to 800 VIT –
Hygiene measures for critical pathogen spectra

1 Introduction

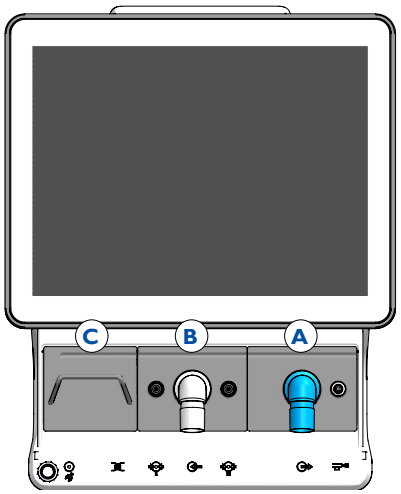
Routine reprocessing strategies are subject to intense scrutiny when it comes to critical pathogen spectra such as annually recurring influenza or coronavirus (SARS-CoV-2). We recommend supplementary measures for parts with and without direct contact with contaminated patient gas for hygienic reprocessing of elisa 300 to elisa 800 (VIT) devices.

2 Valve bar

The valve bar, comprising the inspiratory valve (A), expiratory valve (B) and expiratory flow sensor (C), includes all connections for nebulization, oesophageal pressure measurement and continuous cuff pressure monitoring. The valve bar is in direct contact with potentially contaminated patient gas and can be completely processed with a validated procedure. It makes sense to process the inspiratory valve separately since doing so effectively prevents smear and droplet contamination. The inspiratory valve is frequently touched in routine hospital activities, for example when connecting pneumatic nebulizers or changing tubes.



elisa 600 / elisa 800 (VIT)

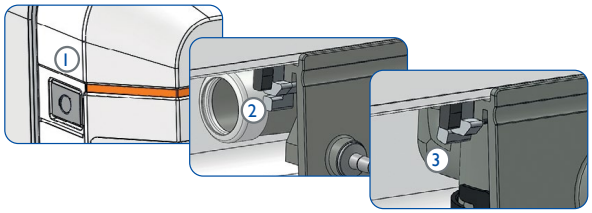


elisa 300 / elisa 500

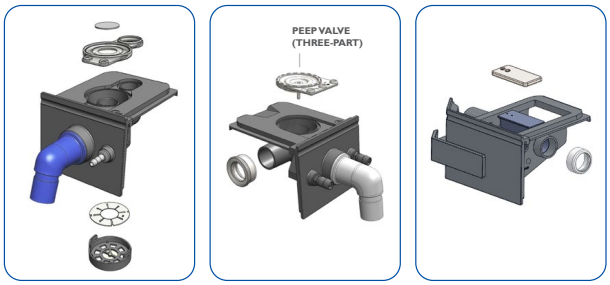
2.1 Procedure:

2.1.1. Remove valve bar components

1 Release lever for expiratory flow sensor
2 Release lever for expiratory valve
3 Release lever for inspiratory valve



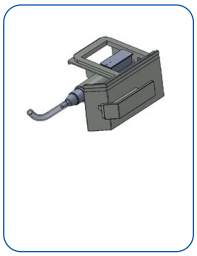
2.1.2 Disassemble valve bar components



Remove the silicone parts.
Do **NOT** disassemble the PEEP valve of the expiratory valve.

2.1.3 Attach cleaning adapters for machine cleaning



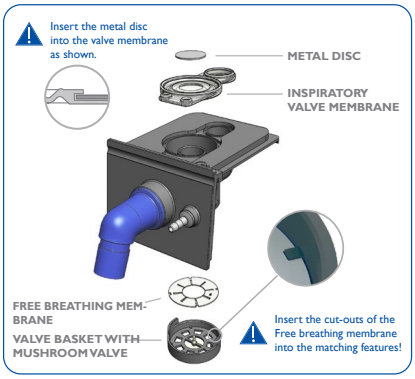


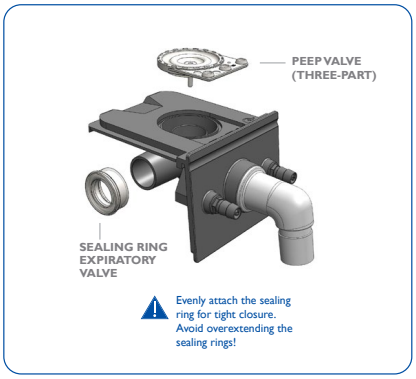
- Attach the cleaning adapters to the components of the valve bar as well as to the flushing nozzles of the washer disinfector.
- Position all elements on the cart for anaesthesia and ventilation accessories so that all interior spaces and surfaces are completely rinsed. Place the individual silicone parts in a separate preparation container for small parts.

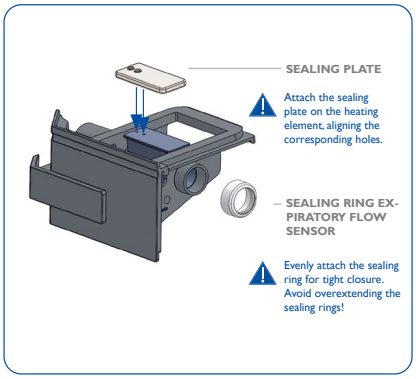
2.1.4 Perform cleaning or disinfection

- Place the elements in the washer disinfector.
- Use: "neodisher® MediClean forte" by Chemische Fabrik Dr. Weigert GmbH & Co. KG. or „thermosept® X·tra" by „Schülke & Mayr GmbH".
- Select a programme for anaesthesia accessories (e.g. Vario TD)
  - cleaning at 55°C (131°F) for at least 10 minutes
  - thermal disinfection at 93°C (199.4°F) for at least 5 minutes.
- Perform a final rinse with demineralised water.
- Carefully check all elements, especially the membrane contact surfaces, for damage (leakage!).
- Dry for at least 40 minutes or until the unit is sufficiently dry.

2.1.5 Assemble valve bar components







3 Cleaning and disinfection of the ventilator, the display unit, and the cart (if used)

Use a soft cloth and mild cleaning agent to clean the surface of the housing and of the control unit.

For disinfection of the surface, we recommend using the following products according to the manufacturers' instructions:

- "mikrozid® sensitive liquid" and "perform" by Schülke & Mayr GmbH
- "Dismozon plus" and "Mikrobac forte" by Bode Chemie GmbH
- "Bacillol AF" and "Bacillol 30" by BODE Chemie GmbH
- "Incidin™ OxyWipe" by EcoLab

Make sure to prevent moisture from penetrating the housing and carefully observe the exposure times specified by the corresponding manufacturers.

Dispose of all single-use products such as breathing circuits, Cuffscout lines or nebulizer heads in accordance with your hospital's hygiene regulations.

4 elisa 300 elisa 500: Turbine protection filter

The air entering the turbine is conducted through a HEPA quality fine filter. The filter efficiency of the fine filter meets the requirements of the HEPA H13 filter class, which means that 99.95% of all particles in the aspirated room air are captured. This guarantees that only ultra-clean air reaches the patient through the ventilator.

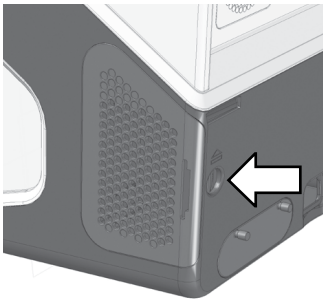
The applicable standards distinguish between EPA, HEPA and ULPA particle filtering levels, which are assigned to filter classes 1-17. "HEPA" refers to high-efficiency particulate separation as a quality characteristic. The following filter classes and particulate separation levels qualify as HEPA: H13:99.95% or H14: 99.995%.

The air filter cassette for the turbine inlet air needs to be replaced at regular intervals. The ward standards for this interval are defined at the configuration level.

The manufacturer recommends changing the turbine filter cassette:
- as part of reprocessing the ventilator after use with critical pathogen spectrum patients (e.g. CoVid-19, influenza,…)
- as part of annual maintenance
- in response to hygiene sensor alarms (e.g. gross filter material contamination)
- based on hospital standards (adjustable in Hygiene management → configuration level)

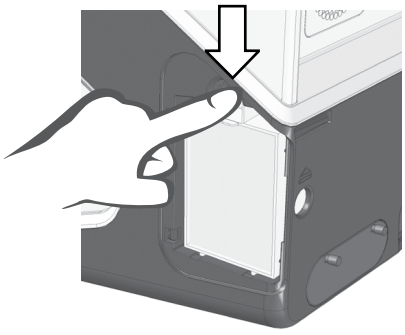
4.1 Exchanging the air filter cassette

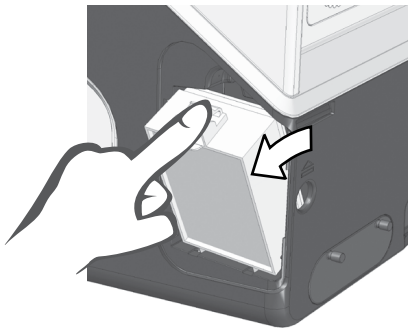
Open the cover of the turbine filter on the side of the device by pressing on the release button at the back of the device ⏏.



Remove the cover and put it aside.

Remove the turbine filter cassette. To do this, press on the tab at the top of the filter cartridge and tilt it forward.





Dispose of the turbine filter cassette in compliance with the hygiene policy of your facility.

Remove the new filter cartridge from its packaging and check it for integrity. Do not use the filter cartridge if damaged.

Install the cartridge in the device. To do this, introduce the cartridge into the device at an angle so that the hooks at the bottom engage in the recesses in the device. Then push the filter cartridge into the device until you feel it lock into place.
Finally introduce the snap arms of the turbine filter cover on the left and close it by pressing on the right side of the cover until you feel it lock into place.

5 Use of filters in clinical practice

A wide variety of filter systems is used in everyday clinical situations, ranging from conventional HMEs (heat-moisture-exchangers) to antiviral or antibacterial filters and device protection filters. We recommend the following procedure for use with critical pathogen spectrum patients:

Inspiratory limb

Due to the hygiene-optimized architecture of the inspiratory valve, the inspiratory limb does not require the use of filters. The inspiratory valve must be reprocessed together with the entire valve bar, using a validated procedure.

Use of filters at the patient connection end with non-humidified gas flow

Make sure to use so-called HME-F filters with integrated antiviral and antibacterial filter function. The filter class is specified on the product. Filtration efficiency of 99.99% or 99.999% is virus-impermeable

An additional filter attached to the expiratory valve does not generate any added safety value.

Use of filters with humidified gas flow

Device protection filters attached to the expiratory connection protect the flow sensor system from condensate. We recommend the following device protection filter:

1790000 Air Guard device protection filter. Manufacturer: Intersurgical	
Efficiency (antibacterial)	99.99999%
Efficiency (antiviral)	99.9999%
Period of use	24 hours

This hydrophobic device protection filter is not suitable for use at the patient connection end of the breathing system. The specified period of use may be significantly shorter if high levels of condensate are present.

Use of filters with drug nebulization

Device protection filters attached to the expiratory connection protect the flow sensor system from drug residue and condensate. We recommend the following device protection filter:

1790000 Air Guard device protection filter. Manufacturer: Intersurgical	
Efficiency (antibacterial)	99.99999%
Efficiency (antiviral)	99.9999%
Period of use	24 hours

This hydrophobic device protection filter is not suitable for use at the patient connection end of the breathing system. The specified period of use may be significantly shorter depending on the number of nebulization cycles, the patient's respiratory rate, and the osmolarity of the respective drugs.

Additional filter at the expiratory flow sensor

In the case of active humidification, respiratory gas is particularly saturated with water molecules, but
it is unclear whether respiratory gas at the expiratory flow sensor can potentially lead to infections. That would require a 1-40 µm aerosol to serve as a transport medium. The typical water vapour particle size in air-conditioning is 0.0001 µm (= 1 nm). Influenza viruses measure 120 nm, while coronaviruses have a size of 160 nm and bacteria, 0.2-10 µm. In addition, it should be noted that the volume, and accordingly, the sinking velocity increases in humidified air.
An additional filter attached to the expiratory filter therefore does not provide additional safety, but interferes significantly with volume measurement.

6 Period of use of breathing circuits

Independent of the recommendations by the Robert Koch Institute and the specifications of the respective hygiene specialists or medical hygiene officer, the breathing circuits for elisa intensive care ventilators have the following technical periods of use:

Disposable breathing circuits Löwenstein Medical	14 days
Disposable breathing circuits Deas	14 days
Disposable breathing circuits Fisher & Paykel without Evaqua	7 days
Disposable breathing circuits Fisher & Paykel with Evaqua	14 days

The replacement interval for hygiene reasons must be determined to match the respective patient population as specified by the responsible hygiene specialists or the medical hygiene officer.

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