

Exhalation valve cassette
bellavista 1000
bellavista 1000e
SKU: 302.679.000

Instructions for use

The integrated exhalation valve allows the use of dual limb breathing circuits (circuit type E) with bellavista and is part of the Integrated exhalation valve package as well (302.529.000).

Scope of Delivery

- a) Exhalation valve holder
- b) Exhalation valve cassette
 - b1) Membrane (2 pc, material: silicone, stainless steel)
 - b2) Valve body (material: POM-C)
 - b3) O-ring (material: VMQ, FEP)
 - b4) Locking ring (material: POM-C)
 - b5) Water trap (material: PC)
- c) Exhalation valve control tube 030.000.010

Spare parts

- b1) Membrane (1 pack = 5 pcs) 302.526.000
- b3) O-ring 030.000.009
- b5) Water trap 030.000.008

Safety Requirements

Please read these instructions for use carefully. They are a part of the device and have to be available at all times.

Clean and disinfect as described in "Hygienic Preparation". Inappropriate cleaning can lead to infection or contamination and impair the function of the exhalation system.

Replace immediately any part if visibly damaged, cracked or brittle.

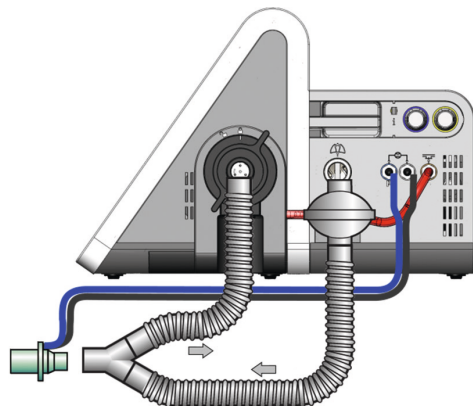
Prior to ventilating a patient, perform the Quick Check (see bellavista manual).

Symbols

MAX	Empty the water trap before the liquid level reaches the MAX mark (possible while ventilation is running).
	Flow direction of exhalation gases

Operation

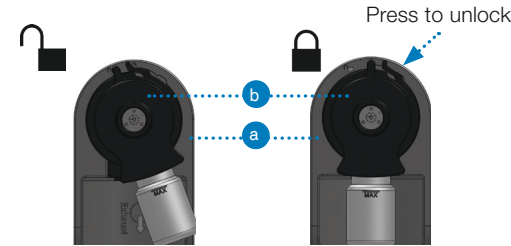
Connect the breathing circuit as indicated below (with or without humidifier and water trap in the circuit). Configure bellavista using the **Start Screen**.



Breathing Circuit E with Flow Sensor

Step 1: Disassembly

- Unlock cassette (b) counter clockwise to remove from valve body (a).
- Remove membrane (b1) and water trap (b5) from cassette (b).
- Disassemble fixation ring (b4) and remove O-ring (b3) from body (b2) in position .



Conduct hygienic preparation of the integrated exhalation valve cassette prior to each use.

Step 2: Clean

Remove any visible soiling on the surface of the items with a CaviWipe. Unfold the wipe and wipe the surface of the cassette items completely. Repeat the cleaning process until the device is visually clean.

Next, followed by either manual / thermal disinfection or Sterilization.

Step 3: Disinfect or Sterilize

Choose one of the following method as appropriate per the hospital protocol.

Manual Disinfection

1. Using a CaviWipe to disinfect the surface. (Disinfectant Agent: CaviWipes Surface Disinfectant Wipes (EPA REG. NO.: 46781-14)) The surface treated must remain visibly moist for three minutes. Use more wipes if necessary to keep the surface moist for three minutes.
2. Wipe the cassette items with a clean lint-free cloth dampened with purified water for one minute.
3. Allow to dry in the air.
4. Reassemble the exhalation valve cassette after it is dry.

Thermal Disinfection

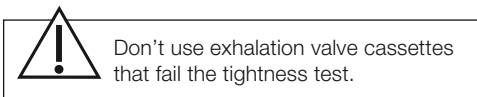
1. Wipe the cassette items with a clean lint-free cloth dampened with purified water for one minute.
2. Disinfect at 90°C / 194°F for 5 minutes.

Sterilization

Automated Cleaning to prepare for Sterilization

1. Rinse under running tap cold water (<35°C/95°F) for 1 minute to remove excess soil.
2. Prepare a detergent bath using Metrizyme solution at the manufacturer's recommendation of 1 oz per gallon using utility (tap) water 20°C/68°F – 30°C/86°F.
3. Immerse cassette items in detergent solution for one minute.
4. Brush the cassette items with clean soft bristled brush while immersed to assist in removing soil. Ensure the device is thoroughly cleaned prior to sterilization by thoroughly visually inspecting the device.
5. Remove the articles from detergent and rinse them under running tap water for one minute.
6. Repeat the rinsing for a total of three times.
7. Transfer the cassette items on to the 4-Level manifold rack accessory (or other appropriate rack system) contained inside the washer for processing.
8. Select the appropriate cycle as listed below:

Phase	Recirculation Time (Minutes)	Temperature	Detergent Type and Concentration (If applicable)
Pre-wash 1	02:00	Cold tap water	N/A
Wash 1	02:00	45°C/113°F Tap water (Set Point)	MetriZyme 1/2 oz per gallon or 4 ml per L (~1/2 oz per gallon)
Neutralization Wash	02:00	Warm tap water	MetriZyme 1/2 oz per gallon or 4 ml per L (~1/2 oz per gallon)
Rinse 1	01:00	Warm tap water	N/A
Dry Time	20:00	90°C / 194°F (Set Point)	N/A



- After the drying process, reassemble and package immediately for sterilization in packaging suitable for vapor sterilization. Ensure that packaging keeps dry before autoclaving.

Note: Articles must be individually single pouched in a qualified 7.5" x 13" pouch (e.g. Cardinal Health self sealing pouch CAT# 92713).

Autoclave, Steam Sterilize

Sterilization Cycle

Option 1:

Step 1: Set the autoclave with the following parameters

- 4 preconditioning pulses
- Steam cycle at 132°C/270°F for 4 minutes
- Dry cycle for 30 minutes

Step 2: Individually single pouch the cassette articles

Step 3: Autoclave the cassette articles using the cycle parameters in Step 1

Option 2:

Step 1: Set the autoclave with the following parameters

- 4 preconditioning pulses
- Steam cycle at 134°C/273°F for 3 minutes
- Dry cycle for 30 minutes

Step 2: Individually single pouch the cassette articles

Step 3: Autoclave the cassette articles using the cycle parameters in Step 1

Before use

Check the exhalation valve cassette and execute a circuit test as described in the ventilator's user manual. Replace defective cassettes (b) or replace after 30 sterilization cycles.

Assembly



- Assemble body (b2), O-ring (b3) and locking ring (b4) in position of the Marking:
- Insert water trap (b5).
- Snap membrane (b1) carefully into body (b2). Ensure the etching "top" is visible.
- Lock cassette (b) including membrane into valve body (a).
- Perform bellavista Quick Check (see bellavista manual).

Assembly of the Integrated exhalation valve body or the Dual Limb Holder

Two Types of exhalation valve holders can be assembled with bellavista:

- The Integrated exhalation valve body as part of the Integrated exhalation valve package. SKU: 302.529.000
- The dual limb holder for use of the single use exhalation valve. SKU: 301.522.000

For cleaning and disinfection instructions of the holders please refer to the section 11.5 "Reprocessing, cleaning, disinfection" of the bellavista User Manual.

Before assembling one of both holder types identify the two screw holes on the right side of the bellavista housing.



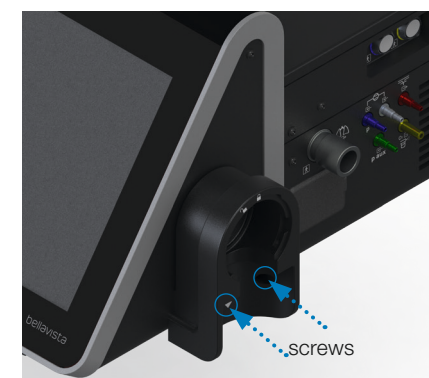
Screw holes for the montage of the different holder types.

The dual limb holder assembly package (301.522.000) is fitted with two allen bolts (M4) and a corresponding allen key. Please tighten the allen bolts through the holder firmly and attach the single use exhalation valve (302.231.000) to the holder. Connect the exhalation valve control tube with the pressure control port. Always perform a quick check and a circuit test before patient use.



bellavista with dual limb adapter

The Integrated exhalation valve body as part of the Integrated exhalation valve package (302.529.000) is fitted with two allen bolts (M4) and a corresponding allen key. Please tighten the allen bolts through the body firmly, connect the exhalation valve control tube (c) with the pressure control port and attach the exhalation valve cassette (302.679.000) correctly. Always perform a quick check and a circuit test before patient use.



bellavista with integrated exhalation valve body