EN Instructions for use Evone

CAUTION:
Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Device Information

Name: Evone

Document Information

Instructions for Use

Version: IESV01

Language: English

Date of issue: February 2023

Manufacturer Information

IES MEDICAL®
Bizkaia Science and Technology Park
Ibaizabal Street, Building 500
48160 Derio (Bizkaia), Spain

T +34 94 400 88 47
info@ventinovamedical.com

CE 0344

Table of contents

1 Safety

1.1 Introduction

Thank you for choosing Evone. This Instruction for Use accompanies Evone and is intended for users who operate Evone. Users must be trained.

Always read the Instructions for Use before use!
Refer to the website https://www.ventinovamedical.com for further information and training materials related to this product.

Ventinova Medical B.V. makes no claim for use of the product other than the intended use specified herein and disclaims any liability resulting from other uses. Observe all warnings, cautions and notes.

If, in relation to the use of this product, a death or a serious deterioration of health has / could have occurred, this should be reported to the manufacturer and the competent authority / local representative of your country.

1.2 Intended Use

Evone is a mechanical ventilator intended to be used for ventilation of patients requiring FCV® or jet ventilation modes.

Evone is intended to be used in elective procedures for less than 72 hours without the need to use inhaled anesthetic agents.

1.3 Operator

Evone is intended to be used by or under direct and undivided supervision of an anesthesiologist or intensivist in all settings.

For safe and effective use of the device, device specific training is required.

1.4 Patient Group

All patients >40 kg IBW

1.5 Use Environment

Evone is intended to be used in operating rooms and ICU environments in hospitals.

Warning: Correct functioning of Evone may be adversely affected by the operation of other equipment, such as high frequency electro-surgery equipment, short-wave therapy equipment, defibrillators, or MRI equipment. Risk on malfunction.

Warning: Make sure Evone is not used in an oxygen enriched environment. Risk on fire or explosion.

1.6 Benefits and Complications

1.6.1 Potential Benefits

The following benefits as compared to volume controlled ventilation (VCV) and pressure controlled ventilation (PCV) may be expected while ventilating patients in FCV® mode:

- Improved lung recruitment and less atelectasis [1–4]
- Better aeration of the lungs [1–5]
- Higher ventilation efficiency (oxygenation and CO_2 removal) [2–4,6]
- Lower energy dissipation in the lungs [3,7,8]
- Less applied mechanical power [9-11]

1.6.2 Potential Complications

- Use of tubes can result in mucosal damage due to cuff and tube contact.
- Use of Evone may result in mucosal damage due to dry air.
  Always use an HME filter in FCV® mode.
- Prolonged mechanical ventilation carries the risk of metabolic disturbances.
- Large negative intratracheal end expiratory pressures may result in harm to the patient.
  Prevent when possible (for more details see 6.5.3).

1.7 Generic warnings

Warnings
Before using Evone, make sure an alternative ventilation method is available for the specific patient. When using Tritube, the advised alternative is the use of Ventrain. Other alternatives may include balloon ventilation through a (laryngeal) mask or a conventional tube, preferably inserted parallel to Tritube. When using conventional tubes in combination with the Evone Conventional Tube Adapter, switch to the preferred conventional ventilation method (e.g. balloon).
Read all the Instructions for Use (if available) of used accessories before first use of the device.
Only use accessories specified within this Instructions for Use. Use of accessories, transducers and cables other than those specified in this manual could result in decreased performance, increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of Evone, including cables specified in this manual. Otherwise, it could result in degradation of the performance of this equipment.
Use of Evone close to other equipment, stacked with other equipment or covered with other materials should be avoided because it could result in improper operation. If such use is necessary, all equipment should be observed to verify normal operation.

Do not use Evone in combination with humidifiers or nebulizers. This creates a risk on blocked filters and insufficient ventilation.
Before using Evone, make sure prescribed maintenance (section 8.3) has been performed. Otherwise, there is a risk on malfunction or no ventilation.
Evone may not be modified, (partly) dissembled or opened at any time. This creates a risk on malfunction.
Regularly check $EtCO_2$ while ventilating with low inspiratory volumes. Rebreathing can occur. This creates a risk on insufficient ventilation.
Make sure alarm limits are appropriate for the patient and actual situation. Otherwise, there is a risk on harming the patient, which can occur since the range of alarm limit settings is broad.
In Jet Mode intratracheal pressures measured may be slightly underestimated as compared to actual pressure due to the venturi effect. This creates a risk of too high airway pressures.
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
To set alarm limits towards extreme values may render the alarm system useless.
Do not obstruct exhaust openings on the back side of Evone.
The operator shall not touch serial port or CO_2 sensor port simultaneously with the patient.
Do not spill any liquid on Evone, there is a risk on malfunction.

Table 1.1 List of applicable warnings

1.8 Generic cautions

Cautions
The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
The internal dead volume of Evone, excluding endotracheal tube, is 42 mL when using the Evone Breathing Tubing and 52 mL when using the Evone Conventional Tube Adapter, which may influence ventilation efficiency for patients with a low respiratory volume.
Evone is designed conforming the IEC 60601-1-2 EMC standard but non-conforming equipment can either be influenced by or may influence Evone.
The maximum achievable minute volume of Evone is 9 L/min - depending on patient characteristics - which should be taken into account for clinical situations that usually require higher minute volumes.
Keep Evone away from high capacity transformers, electric motors and other devices which may create strong electromagnetic fields. Please note that this medical equipment complies with the requirements of the applicable EMC-standards. Electronic equipment exceeding the radiation limits defined in the EMC-standards may affect the working of our equipment.

Table 1.2 List of applicable cautions

1.9 References

1 Schmidt, J. *et al.* Glottic visibility for laryngeal surgery: Tritube vs. microlaryngeal tube: A randomised controlled trial. *Eur J Anaesthesiol* **36**, 963–971 (2019).

2 Schmidt, J. *et al.* Improved lung recruitment and oxygenation during mandatory ventilation with a new expiratory ventilation assistance device: A controlled interventional trial in healthy pigs. *Eur J Anaesthesiol* **35**, 736–744 (2018).

3 Spraider, P. *et al.* Individualized flow-controlled ventilation compared to best clinical practice pressure-controlled ventilation: a prospective randomized porcine study. *Crit Care* **24**, 662 (2020).

4 Schmidt, J. *et al.* Flow-Controlled Ventilation Attenuates Lung Injury in a Porcine Model of Acute Respiratory Distress Syndrome: A Preclinical Randomized Controlled Study. *Crit Care Med* **48**, e241–e248 (2020).

5 Weber, J. *et al.* Flow-controlled ventilation (FCV) improves regional ventilation in obese patients – a randomized controlled crossover trial. *BMC Anesthesiology* **20**, 24 (2020).

6 Weber, J. *et al.* Flow-controlled ventilation improves gas exchange in lung-healthy patients— a randomized interventional cross-over study. *Acta Anaesthesiologica Scandinavica* **64**, 481–488 (2020).

7 Barnes, T. & Enk, D. Ventilation for low dissipated energy achieved using flow control during both inspiration and expiration. *Trends in Anaesthesia and Critical Care* **24**, 5–12 (2019).

8 Barnes, T. *et al.* Minimisation of dissipated energy in the airways during mechanical ventilation by using constant inspiratory and expiratory flows - Flow-controlled ventilation (FCV). *Med. Hypotheses* **121**, 167–176 (2018).

9 Wittenstein et al. Comparative effects of flow vs. volume-controlled one-lung ventilation on gas exchange and respiratory system mechanics in pigs. *Intensive Care Med Exp.* 2020 Dec 18;8(Suppl 1):24.

10 Grassetto et al. Flow-controlled ventilation may reduce mechanical power and increase ventilatory efficiency in severe coronavirus disease-19 acute respiratory distress syndrome. *Pulmonology* 2022

11 Spraider *et al.* Individualised flow-controlled ventilation versus pressure-controlled ventilation in a porcine model of thoracic surgery requiring one-lung ventilation: A laboratory study. *Eur J Anaesthesiol.* 2022 Nov 1;39(11):885-894.

12 Spraider, P. *et al.* A case report of individualized ventilation in a COVID-19 patient - new possibilities and caveats to consider with flow-controlled ventilation. *BMC Anesthesiol.* **21**:145 (2021)

13 Spraider P, *et al.* Individualized flow-controlled ventilation compared to best clinical practice pressure-controlled ventilation: a prospective randomized porcine study. *Crit Care* **24**, 662 (2020)

14 Enk, D *et al.* Dynamic compliance in flow-controlled ventilation. *Intensive Care Med Exp.* **9**(1):26 (2021)

2 System description

Evone consists of the Evone Control Unit and the Evone Breathing System.
The Evone Breathing System exists in two configurations and consists of the following parts:

- Evone Cartridge
- Evone Airway Adapter
- Humid-Vent Filter Pedi straight
- Evone Breathing Tubing or Evone Conventional Tube Adapter (CTA)

Evone's required additional materials:

- Tritube
- Conventional adult cuffed endotracheal tube (single lumen at least 5 mmID and double lumen at least CH35)
- Single lumen jet catheter
- Rigid bronchoscope
- Artificial lung

Warning: Do not use Evone on non-invasive ventilation accessories.

2.1 Evone Control Unit

The Evone Control Unit is shown in Figure 2.1 from four different sides. Detachable parts are presented in Figure 2.2. The numbered parts are described in the table 2.1.

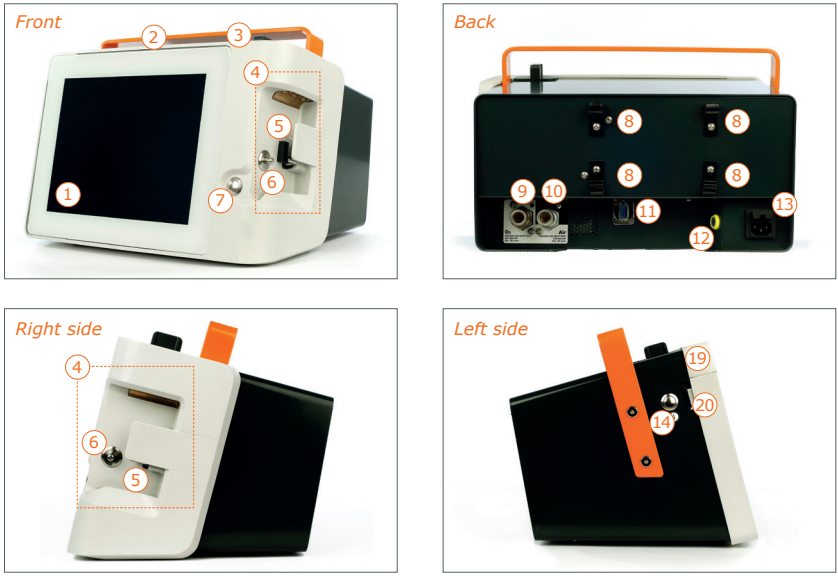

Figure 2.1 Evone Control Unit

Figure 2.2 The detachable parts of Evone Control Unit

Component	Description component
1	Touch screen
2	Handle to carry the device
3	Holder to place the mainstream CO_2 sensor when it's not being used
4	Area to place the Evone Cartridge
5	Exhaust valve, a rotating valve to pinch the silicone tube in order to switch between inspiration and expiration
6	Locking pin to keep breathing system in place during use
7	Release-button to release breathing system from control unit
8	CO_2 sensor cable holder
9	High pressure medical oxygen inlet
10	High pressure medical air inlet
11	Serial data port to transfer real-time data
12	CO_2 sensor port
13	Power cable connector
14	Stand-by button
15	Mainstream CO_2 sensor + connecting cable
16	Power Cable
17	High pressure oxygen tubing
18	High pressure air tubing
19	Alarm light indicator
20	SD-card holder

Table 2.1 Description of components indicated in Figures 2.1 and 2.2

2.2 Evone Breathing System

The Evone Breathing System exists in two configurations, which either include the Evone Breathing Tubing or the Evone Conventional Tube Adapter. All parts are shown below. Additionally, an artificial lung (not shown) is required to perform startup checks. Preferably, the artificial lung has a volume of 1 L and a compliance of 25 mL/cmH_2O. Materials are further explained in Table 2.2.

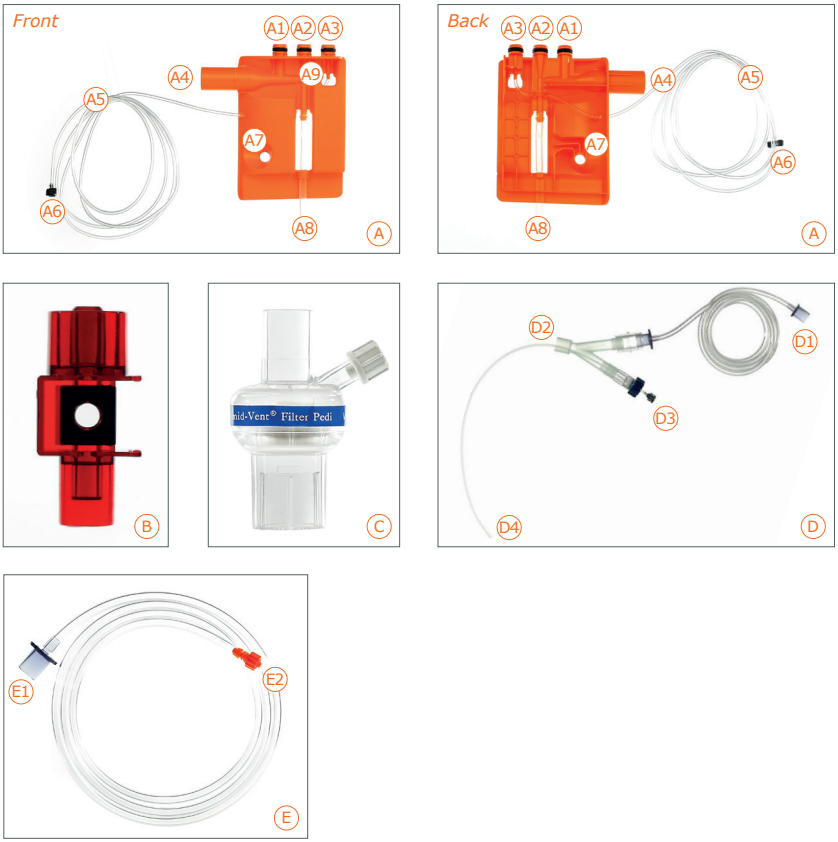

Figure 2.3 Evone Breathing System (A-E)

#	Evone Breathing System and additional material	
A	Evone Cartridge (Ventinova Medical B.V., single use)	
	A1	Jet inlet port
	A2	FCV® inlet port
	A3	Pressure lumen port
	A4	Patient outlet port
	A5	Pressure lumen
	A6	Pressure lumen connector for connection to pressure lumen (Tritube or Evone Conventional Tube Adapter (CTA))
	A7	Locking hole, enables fixation of control unit locking pin
	A8	(Exhaled) gas outlet
	A9	Handle to push cartridge upwards
B	Evone Airway Adapter (Ventinova Medical B.V.) to facilitate CO_2 measurement	
C	Humid-Vent Filter Pedi straight (Teleflex, single use, optional for jet mode)	
D	Evone Conventional Tube Adapter (CTA; Ventinova Medical B.V., single use)	
	D1	15 mm OD connector for connection to HMEF
	D2	15 mm OD connector for connection to conventional adult endotracheal tube
	D3	Pressure lumen connector for connection to the pressure lumen of the Evone Cartridge
	D4	Pressure lumen for intratracheal pressure measurements to be inserted in the conventional adult endotracheal tube
E	Evone Breathing Tubing (Ventinova Medical B.V., single use)	
	E1	15 mm OD connector for connection to HMEF
	E2	Male Luer lock to connect to Tritube ventilation lumen
F	Endotracheal Tube (Tritube, single lumen jet catheter, rigid bronchoscope or conventional adult endotracheal tube, single or double lumen)	
G	Trolley (optional)	

Table 2.2 Description of (subparts of) Evone Breathing System and accessories

2.3 Accessories

2.3.1 Tritube

Tritube can be used with Evone in combination with the Evone Breathing Tubing (Figure 2.3 E).

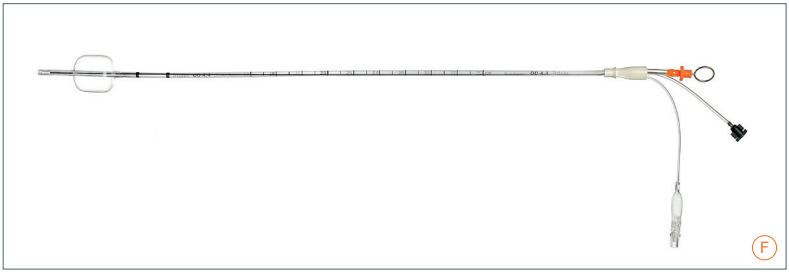

Figure 2.4 Tritube

A single lumen jet catheter or rigid bronchoscope can be used in combination with the Evone Breathing Tubing when using the single lumen jet function.

2.3.2 Conventional adult endotracheal tube

Conventional adult endotracheal tube (single lumen at least 5 mm ID and double lumen tube at least CH35) can be used with Evone in combination with the Evone Conventional Tube Adapter (CTA; Figure 2.3 D).

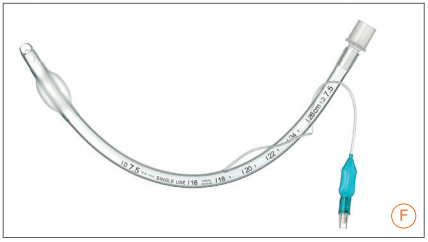

Figure 2.5 Conventional adult endotracheal tube

2.3.3 Trolley

Evone can be placed on a trolley (G) which is an optional accessory. See Figure 2.6 A and B.

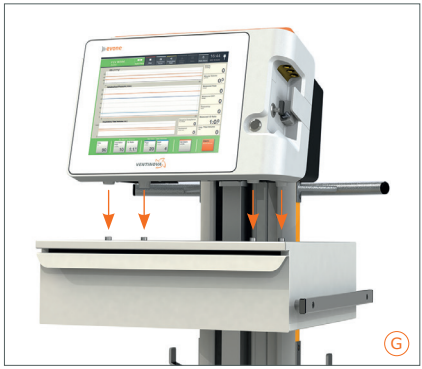

Figure 2.6 A
Example how to place Evone on the trolley

Figure 2.6 B
Evone on the Trolley

2.4 Distributed Information System

Evone facilitates being part of a Distributed Information System. Information including alarm statuses, setting changes and measured clinical data is send via the serial port and may be available to the user for information purposes. In the Device settings menu 'Basic hospital Data' shall be chosen as the data output format (see also section 6.1). Be aware that exported information shall not be used in a distributed alarm system as the device needs undivided attention of the user. Contact Ventinova Medical B.V. for information on the data protocol and the possibilities.

Exported data:

- Clinical event data
  - FCV® mode data
  - JET mode data
  - Alarm data
- Settings and alarm data
  - Ventilation Settings
  - Alarm settings
  - Alarm status
- Miscellaneous data
  - Charge Status
  - Alarm Mute
  - Ventilation status
  - User alarm confirm
  - Ventilation mode
  - JET mode take CO_2 sample
  - System to shut down

Connection:

- A standard RS232 cable can be used to make connection to a third 'communication' party.
- The third party shall write a 'driver' to interpret the transmitted data and supply it into the Patient Data Management System.
- The system software shall be at least version 2.14.0

3 Ventilation Principle

Evone is a mechanical medical ventilator, based on control of both inspiratory and expiratory flow (FCV®). Evone enables full ventilation of a patient using various endotracheal tubes (~2 mm ID to ~10 mm ID).

Ventilation is guided by intratracheal pressure measurements and controlled by a pressure compensated flow controller. Evone has two different operation modes:

1. FCV® Mode for full ventilation in elective situations for maximally 72 hours.
   To be used with all cuffed endotracheal tubes comprising a pressure lumen.
2. Jet Mode, to be used as traditional (High Frequency) Jet Ventilation, to be used during elective procedures or to gently liberate a patient from post-operative mechanical ventilation to spontaneous breathing.
   To be used with Tritube with deflated cuff, jet catheter or rigid bronchoscope.

Both methods are described in more detail in 3.1 and 3.2.

3.1 FCV® Mode

The FCV® Mode, applying FCV® ventilation, is used for full ventilation while controlling the flow in the whole ventilation cycle.
FCV® ventilation can only be applied when the cuff of the endotracheal tube is fully inflated, sealing off the trachea from the ambient atmosphere.

The FCV® ventilation cycle is governed by four operator settings only, as clarified in Figure 3.1:

- Inspiration Flow
- I:E ratio
- Peak pressure
- EEP (end expiratory pressure)

Note that Frequency, Minute Volume and Tidal Volume cannot be set directly.

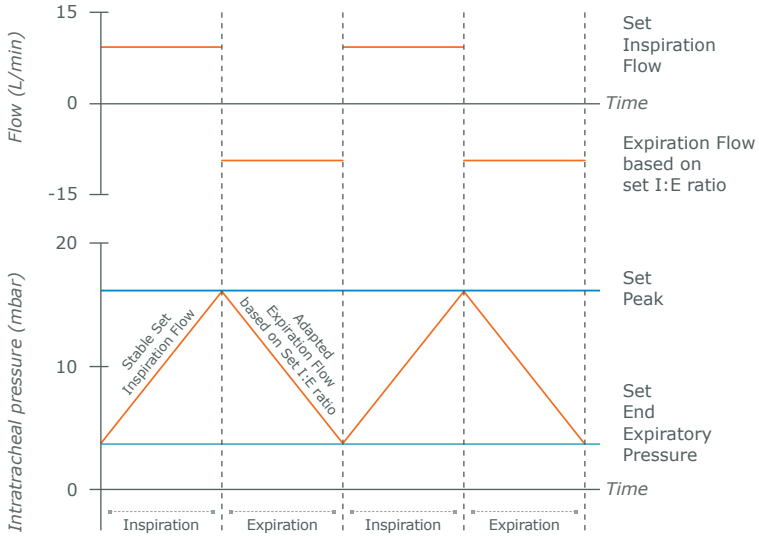

Figure 3.1 FCV® Mode intratracheal pressure profile

In Figure 3.1, a typical sequence of two FCV® breathing cycles is shown. In FCV® Mode the inspiration is performed with the set (constant) Inspiration Flow until the intratracheal pressure reaches the set Peak pressure. The device then starts the (assisted) expiration phase until EEP is reached. The expiration flow is controlled in order to:

A establish a (roughly) linearly reduction of the intratracheal pressure until the set EEP

B to ensure the set I:E ratio is reached.

In general, there are no periods without flow during FCV® ventilation: gasses flow either into or out of the lungs. Therefore only the set flow and I:E ratio determine a patients minute volume. Set Peak and EEP determine the inspiratory volume. Ventilation frequency is a result of parameter settings and does not affect minute volume.

In FCV® Mode, expiration is actively supported by Evone, resulting in a controlled decline in intratracheal pressure. A negative end expiratory pressure (NEEP; max -10 mbar) can be set. However, this is strictly limited to the clinical situation of hypovolemia/hemorrhagic shock (see 6.5.3).

Warning: Depending on the ventilation settings there might be a Peak/EEP overshoot of 1-2 mbar. Overshoot is often seen during tube-into-tube usage or in smaller airways. The resulting tidal volumes are correctly displayed on the right hand side of the main screen.

3.2 Jet Mode

The Jet Mode, can be used for jet ventilation during elective procedures and postoperatively to liberate the patient from mechanical ventilation and to stimulate spontaneous breathing. The maximum driving pressure is 1.5 Bar. Jet mode shall only be used with Tritube, jet catheter or a rigid bronchoscope, not with conventional endotracheal tubes, with the cuff of Tritube fully deflated to enable expiratory gases to freely egress.

Warning: The cuff must be deflated before Jet Mode can be started. Risk on barotrauma.

Warning: The cuff must be checked for accumulated debris before deflation. Risk on infection.

Warning: Do not use the Jet Mode in combination with the Evone Conventional Tube Adapter. Risk on barotrauma.

Warning: Do not use Jet Mode for longer than 30 minutes on a single patient. Risk on dehydration.

The Jet cycle is governed by 3 operator settings being:

- Frequency
- Inspiration Percentage
- Driving Pressure

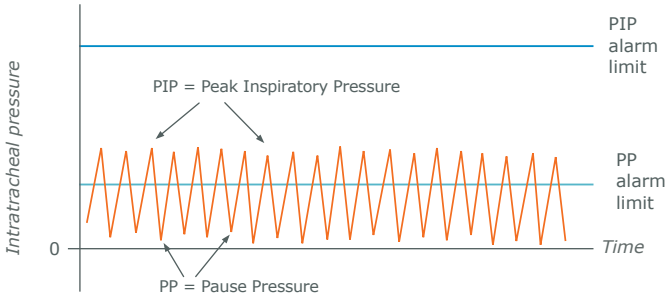

Figure 3.2 Jet Mode intratracheal pressure

In Figure 3.2, a typical sequence of Jet breathing cycles is shown. During the inspiration phase the device maintains a constant driving pressure on the tube. This set constant driving pressure is controlled by a set frequency and inspiration percentage. During inspiration Intratracheal pressure is expected to stay below the configured Peak Inspiratory Pressure (PIP) alarm limit.

During expiration, which is passive, the intratracheal pressure is expected to decrease below the operator configured Pause Pressure (PP) alarm limit, if not, the operator is notified by an alarm and the ventilation cycle is interrupted.

4 Preparation

Before switching on Evone, allow the control unit to acclimatize to ambient temperature.

4.1 System Assembly

Before the device can be used the Evone Cartridge has to be placed into the Control Unit (Figure 4.1).

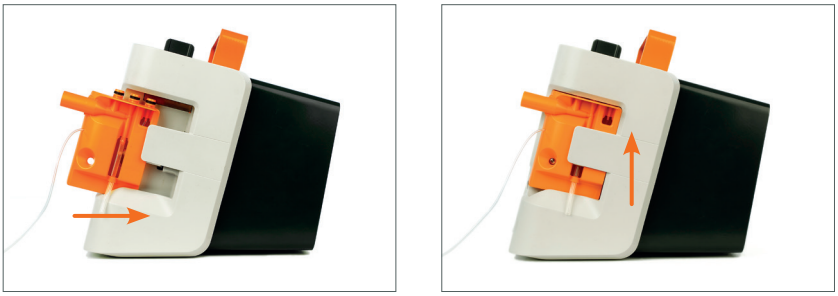

Figure 4.1 Cartridge placement steps

Upon placement of the Evone Cartridge, assemble the Evone Breathing System in combination with either Tritube (see Figure 4.2) or a conventional adult endotracheal tube (see Figure 4.3).

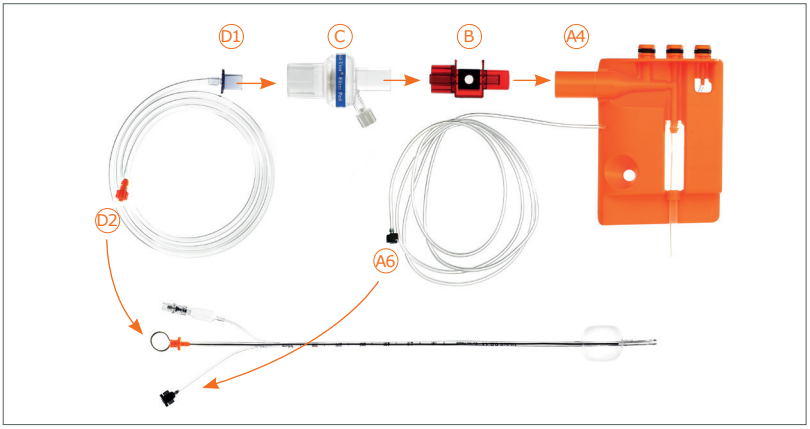

Figure 4.2 Assembly order of Evone Airway Adapter, HME filter (optional for jet mode), Evone Breathing Tubing and additional part Tritube, jet catheter or rigid bronchoscope. Parts are explained in Table 2.2.

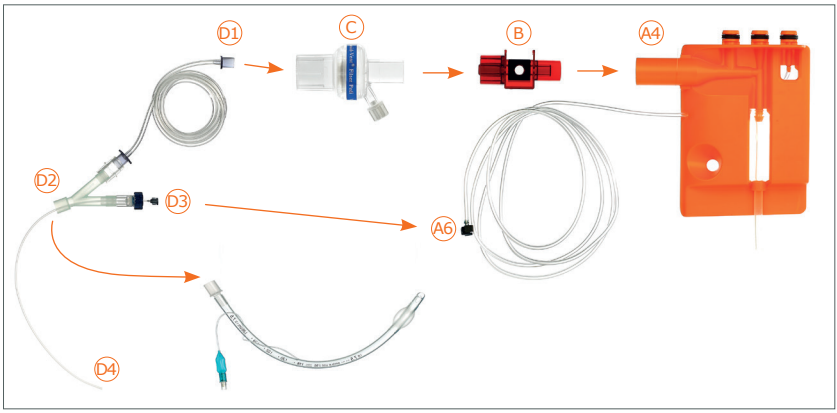

Figure 4.3 Assembly order of Evone Airway Adapter, HME filter, Evone Conventional Tube Adapter and additional part conventional adult endotracheal tube (example).
Parts are explained in Table 2.2.

Warning: In FCV® mode, always install an HME Filter between the Evone Airway Adapter and Breathing Tubing / Conventional Tube Adapter. Risk on contamination of the Control Unit

Warning: Make sure parts are connected tightly. Risk on leakage or disconnection of breathing system during ventilation.

Warning: Inspect the Airway Adapter for damage prior to use. Do NOT use the Airway Adapter if it appears to be dirty, damaged or broken.

4.2 Connecting Evone

Before use make sure that the following connections are made:

- Medical gases
- Electrical power
- CO_2 sensor

4.2.1 Medical Gases

Evone has two separate gas connections: one for medical air and one for medical oxygen. Before use, ensure proper connection of the gas tubing (Figure 2.2, component 17 and 18) to the high pressure gas supplies. A pressure of 5.0 bar is recommended, but shall always be between 3.0 and 6.0 bar.

Warning: Do not use Evone in combination with flammable gases or volatile anesthetics. Risk on fire or explosion.

Warning: Do not use Evone in combination with helium or helium mixtures. Risk on incorrect measurements and insufficient ventilation.

4.2.2 Electrical Power

Connect Evone to a mains power supply of between 115 and 230 Volt AC using the power cable (component 16).

Warning: Always use a protective earthed socket for the mains power plug of Evone.

Warning: Whenever possible, connect the device to the mains power supply since the battery lifetime of Evone is limited. The expected battery operating time is 1 hour. Evone provides an alarm when the remaining battery power provides less than 5 minutes of ventilation. Risk on no ventilation.

Warning: Disconnection from mains power supply can only be done by unplugging the mains power cord and therefore the mains power plug needs to be easily accessible at any time.

4.2.3 Mainstream CO_2 Sensor

Connect the CO_2 sensor to the Control Unit and place the sensor (Figure 2.2, component 15) onto the Evone Airway Adapter (Figure 2.3 B).

5 Operation

5.1 Switching On and Starting Up

Switch on Evone, using the hard button at the left hand side of the Control Unit. This results in lighting up of the screen, the alarm indicator LED turns white, an auditory signal is given and the exhaust valve will calibrate. After several seconds, the first screen will be shown. In order to ensure reliable performance, Evone has a number of automatic checks and a number of optional startup checks, which require interaction of the user.

5.1.1 Self-Check

Immediately after switching on Evone, a Self-Check will start, while showing the screen of Figure 5.1. During the Self-Check, basic proper functioning of the valves, sensors, alarm controller signals and internal communication are checked.

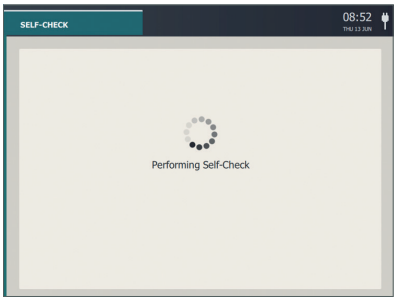

Figure 5.1 Self-Check screen

After performing the Self-Check successfully Evone will automatically continue to the 'Startup Check' (section 5.1.2). A failing Self-Check (on one or more topics) will be indicated by an alarm message and error code (Figure 5.2). The user shall only continue by shutting down and restarting the system or proceeding to the device settings menu. If the problem remains, the user should contact the service supplier. If a power failure is detected during the Self-Check, Evone will shut down automatically and and inform the supplier on the error code.

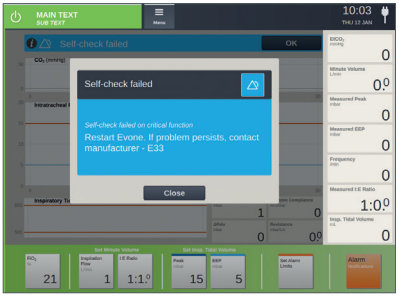

Figure 5.2 Self-Check failed screen

5.1.2 Startup Check

After a successful Self-Check the Startup Check menu will appear automatically (Figure 5.3). The user can select tests to perform. It is strongly recommended to perform all tests of the Startup Check once a day prior to starting ventilation.

This Startup Check requires a fully assembled Evone, i.e. including Evone Breathing System, and connection to Tritube or endotracheal tube, which is connected to an artificial lung.

In the Startup Check screen the actual values for the oxygen and air gas supply pressures are displayed and should be between 3.0 and 6.0 bar.

The Startup Check involves three tests which cover the following test items:

- Alarm Indication
  - Alarm sound and light signals are generated.
  - User needs to confirm low, medium and high priority alarm signals when indicated.
- FCV® Mode System
  - User needs to assemble the Evone Breathing Tubing and Tritube or otherwise the Evone CTA with an conventional endotracheal tube.
  - User needs to use an artificial lung and inflate cuff if applicable.
  - The following items are tested:
    - Pressure vessel and sensor
    - Valve warming-up
    - Mass flow controllers
    - Pressure lumen purge pulse
    - Pressure lumen sensor
    - Exhaust valve
    - Leakage

- Jet Mode System
  - User needs to assemble the Evone Breathing Tubing and Tritube or otherwise the Evone CTA with an conventional endotracheal tube.
  - User needs to keep tip of Tritube or endotracheal tube in ambient air when indicated.
  - The following items are tested:
    - Pressure vessel (10 Jet pulses are generated (1.5 bar, 60 bpm))
    - Jet valves
    - Inspiration %
    - Jet port pressure sensor

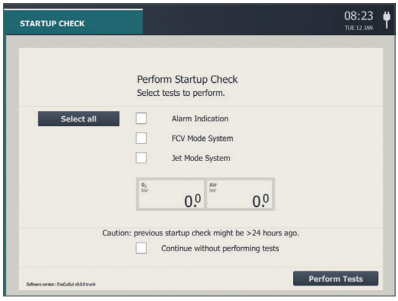

Figure 5.3 Startup Check test selection

Test outcomes ('succesfull' or 'failed') are indicated to the user including an error code. If the problem remains inform the manufacturer on the error code.

Warning: Tritube is considered 'non-sterile' after use during the startup check. Do not use in a patient afterwards. Risk on infection.

5.1.3 Additional Checks

Additional checks are recommended to perform manually to test specific alarms. First, choose random patient settings and start ventilation in FCV® mode with the artificial lung before generating the following alarms:

- High Pressure Alarm: Hit artificial lung at end of inspiration.
- Disconnection Alarm (Leakage respiratory circuit alarm): Disconnect the Evone airway adapter from the Evone Cartridge.
- Obstruction Alarm: Kink the Evone Breathing Tubing. Kink the ventilation line between filter and Tritube during Inspiration phase.
- Power Indication: Unplug power cord from mains and check if power icon in the top right corner of the main screen changes from 'plug' towards 'battery', indicating that the device is running on battery'.
- CO_2 Alarm: Add CO_2 gas into ventilation line via HMEF Luer port or via test lung. After triggering the high $EtCO_2$ alarm, remove CO_2 flow to trigger low $EtCO_2$ alarm.

5.1.4 Table of error codes

Self-check error codes			
Error	**Description**	**Possible Cause**	**Action**
E31	Valves status not ok	- Valve defect	- 'Shut Down and Power On' - If fail persists, contact Ventinova
E32	Communication between controllers failed	- Communication line defect	- 'Shut Down and Power On' - If fail persists, contact Ventinova
E33	Pressure sensor test failed	- Pressure sensor defect	- 'Shut Down and Power On' - If fail persists, contact Ventinova

Startup Check error codes			
Error	**Description**	**Possible Cause**	**Action**
E01	Low priority alarm blue light or sound is not generated	- (1) Incorrect user action pressing accidentally 'No' when there is no malfunction of visible and audible signals is present - (2) Correct user action pressing 'No' when malfunction of visible and audible signals is present	- If (1) Redo test, follow instructions - If (2) fail persists, contact Ventinova
E02	Medium priority alarm yellow light or sound is not generated	- (1) Incorrect user action pressing accidentally 'No' when there is no malfunction of visible and audible signals is present - (2) Correct user action pressing 'No' when malfunction of visible and audible signals is present	- If (1) Redo test, follow instructions - If (2) fail persists, contact Ventinova

Error	Description	Possible Cause	Action
E03	High priority alarm red light or sound is not generated	- (1) Incorrect user action pressing accidentally 'No' when there is no malfunction of visible and audible signals is present - (2) Correct user action pressing 'No' when malfunction of visible and audible signals is present	- If (1) Redo test, follow instructions - If (2) fail persists, contact Ventinova
E04 FCV/ JET	Disposable pressure too low after ventilation lumen purge	- Exhaust valve is not calibrated correctly - Leakage disposable circuit - Supply pressure too low	- Check supply pressure and if not correct redo test - Take out Cartridge and check for proper fixation silicon tubing and position back correctly (silicon 'exhaled gas outlet' positioned between rubber block and hook) and check for leaks in disposable circuit and test lung and redo test - Calibrate exhaust valve and redo test - If fail persists, contact Ventinova
E05 FCV	Pressure in pressure vessel is out of the expected range after increase of gas	- Leakage vessel valve	- Redo test - If fail persists, contact Ventinova
E06 FCV	Pressure in pressure vessel is out of the expected range after decrease of gas	- Leakage vessel valve	- Redo test - If fail persists, contact Ventinova

Error	Description	Possible Cause	Action
E07 FCV	Takes too long for test lung to be filled to 5 mbar	- Leakage disposable circuit - Leakage test lung - Pressure lumen not connected	- Check for leaks in disposable circuit and test lung and redo test - Take out Cartridge and check for proper fixation silicon tubing and position back correctly ('exhaled gas outlet' positioned between rubber block and hook) and redo test - If fail persists, contact Ventinova
E08 FCV	Pressure mis-match between Jet port and pressure lumen port after test of test lung to be filled to 5 mbar	- Obstructed pressure lumen - Pressure sensor out of calibration - Pressure sensor defect	- Check for obstructions pressure lumen and redo test - If fail persists, contact Ventinova
E09 FCV	Takes too long for test lung to be filled to 15 mbar	- Leakage disposable circuit - Leakage test lung	- Check for leaks in disposable circuit and test lung and redo test - Take out Cartridge and check for proper fixation silicon tubing and position back correctly ('exhaled gas outlet' positioned between rubber block and hook) and redo test - If fail persists, contact Ventinova
E10 FCV	Pressure mis-match between Jet port and pressure lumen port after test of test lung to be filled to 15mbar	- Obstructed pressure lumen - Pressure sensor out of calibration - Pressure sensor defect	- Check for obstructions pressure lumen and redo test - If fail persists, contact Ventinova
E11 FCV	Pressure drop vessel after 5 purges is out of expected range	- Malfunctioning purge valve - Leakage vessel valve	- Redo test - If fail persists, contact Ventinova

Error	Description	Possible Cause	Action
E12 FCV	Negative lung pressure during FCV mode test	- Exhaust valve is not calibrated correctly - Loose or leaking 'exhaled gas outlet'	- Take out Cartridge and check for proper fixation silicon tubing and position back correctly ('exhaled gas outlet' positioned between rubber block and hook) and redo test - Calibrate exhaust valve and redo test - If fail persists, contact Ventinova
E13 JET	Incorrect I/E ratio in Jet mode	- Sticky Jet valve	- If not have been done before, perform FCV test and redo test - Use Tritube or Jet catheter and redo test - If fail persists, contact Ventinova
E14 JET	Injection pressure after 5 cycle is not stable and not in range	- Leakage disposable circuit	- Use Tritube or Jet catheter and redo test - Take out Cartridge and check for proper fixation silicon tubing and position back correctly ('exhaled gas outlet' positioned between rubber block and hook) and redo test - If fail persists, contact Ventinova
E15 JET	Injection pressure is stabilized but not in range.	- Leakage disposable circuit	- Use Tritube or Jet catheter and redo test - Take out Cartridge and check for proper fixation silicon tubings and position back correctly ('exhaled gas outlet' positioned between rubber block and hook) and redo test - If fail persists, contact Ventinova
E16 JET	Pressure exceed PIP	- Obstruction in artificial airway - Cuff is inflated	- Make sure that artificial airway is not obstructed and make sure that cuff is deflated and redo test - If fail persists, contact Ventinova
E17 FCV/ JET	General SW error during test	- General error	- 'Shutdown and Power On' - If fail persists, contact Ventinova

5.2 Setting New Ventilation Parameters

5.2.1 Patient Setup

After the startup procedure, the screen Figure 5.4 will appear. Patient gender and length need to be entered to calculate the ideal body weight to set an inspiration volume in the first ventilation cycle and for the initial setting of the volume limits.

The first ventilation cycle in FCV® mode shall:

- Confirm equal pressure values while independently measured via the ventilation lumen and via the pressure measurement lumen.
- Achieve the desired inspiratory volume in a graduate and safe way.
- Detect leakage.

Figure 5.4 Patient setup screen

The gender should be selected, indicated by a color change. Furthermore, the patient's length can be chosen by the slider on screen.

At the bottom of the screen the user may choose to start with default ventilation settings to be based on the entered patient settings, i.e. 'patient data' or with settings from last use. Default choice is 'patient data'.

5.3 Clinical Workflow FCV® Mode

5.3.1 Ventilation with Tritube

1 Induce total intravenous anesthesia (TIVA).
2 Intubate patient with Tritube according to manufacturer's instructions.
3 Connect Tritube to Evone (ventilation lumen and pressure lumen).
4 Optional: start ventilation with the cuff deflated to allow deepening of anesthesia (Jet mode).
Note that the airway is open (risk on aspiration).
5 Start ventilation with the cuff inflated (25-30 mbar) in FCV® mode when anesthesia is deepened. A triangular pressure curve appears on the screen (Fig 5.5).

Figure 5.5 Active FCV® mode

6 If needed adapt ventilation settings:
- FiO_2 as preferred
- EEP as preferred
- Peak to adjust Tidal Volume
- Inspiratory Flow to adjust Minute Volume.

7 FCV® may be individually optimized based on patient compliance [11-13] as further explained in application notes available on the website https://www.ventinovamedical.com

5.3.2 Ventilation with conventional tubes

1 Induce total intravenous anesthesia (TIVA).
2 Intubate patient as usual with tube of choice.
3 Oxygenate patient as preferred to allow deepening of anesthesia.
4 Connect tube to Evone CTA when anesthesia is deepened.
5 Start ventilation in FCV® mode. A triangular pressure curve appears on the screen (Fig 5.5).
6 If needed adapt ventilation settings:
- FiO_2 as preferred
- EEP as preferred
- Peak to adjust Tidal Volume
- Inspiratory Flow to adjust Minute Volume.

Note that spontaneous breathing is not possible when the Evone CTA is connected to the conventional adult endotracheal tube.

5.3.3 Handling obstructions

1 Stop ventilation.
2 Fiercely flush the pressure lumen and/or ventilation lumen with 2-5 mL saline followed by ~15 mL air.
3 In case secretions are still present in ventilation lumen, remove secretions using a suction catheter.
Note that the airway needs to be open.
4 Purge lumen again with 2 mL saline followed by air.
5 In case of Tritube: slightly turn Tritube to avoid any tracheal wall contact and inflate cuff.
6 Re-start ventilation.

Warning: Do not use a closed suction catheter in combination with Evone.

5.3.4 Sedation and relaxation

Because of the small lumen (high resistance) of the breathing circuit, coughing may result in tube dislocation and spontaneous breathing is not possible.

In case of light anesthesia (indicated by e.g. irregular pressure curves, increased/decreased compliance, coughing, BIS>60, TOF>90%):

- Start awakening the patient OR optimize anesthesia.

5.3.5 Liberate patient from ventilator

1 Set FiO_2 as preferred.

Tritube

Wake patient using one of the two ventilation options:

2 With inflated cuff (e.g. in case of aspiration risk) in FCV® mode.
3 Gently wake patient (no shaking). Deflate cuff and extubate when patient awakes.
Or
2 With deflated cuff in Jet mode (risk on aspiration).
3 Open airway required.
4 Adapt settings if required (e.g. lower driving pressure with higher frequency may reduce tracheal stimuli).

Conventional tubes

Wake the patient:

1 Disconnect Evone CTA from tube allow waking up using preferred method of oxygenation.
Note that spontaneous breathing is not possible when the Evone CTA is connected to the conventional adult endotracheal tube.

Warning: Use Jet mode or alternative ways to deal with (prolonged) liberation procedures and periods of spontaneous breathing.

5.3.6 Effective aggregate alveolar pressure swing (ΔP_{alv})

FCV® is a dynamic ventilation mode with a continuous and stable gas flow. Therefore, the intratracheal pressures (P_{trach}) always include a resistive pressure part and are not equal to the effective aggregate alveolar pressures (P_{alv}). The intratracheal driving pressure is always larger than the effective aggregate alveolar pressure swing. [11,14]

To determine the pressure reaching the alveoli (= effective alveolar pressure distending the alveoli) and the pressure needed to overcome total resistance (= resistive pressure) a no-flow measurement maneuver is initiated at the end of inspiration and at the end of expiration, both every 20 cycles (see figure 5.6).

The effective aggregate alveolar pressure swing (ΔP_{alv}) is indicated by two dotted lines and a value on Evone's screen. Note that the resistive pressure, and thus the discrepancy between the tracheal and the effective aggregate alveolar pressure, increases by higher flows and / or higher airway resistance. Therefore, upon adapting flow or pressure settings, the two dotted lines showing the lower and upper P_{alv} disappear from Evone's screen and are again displayed after the next measurement maneuvers.

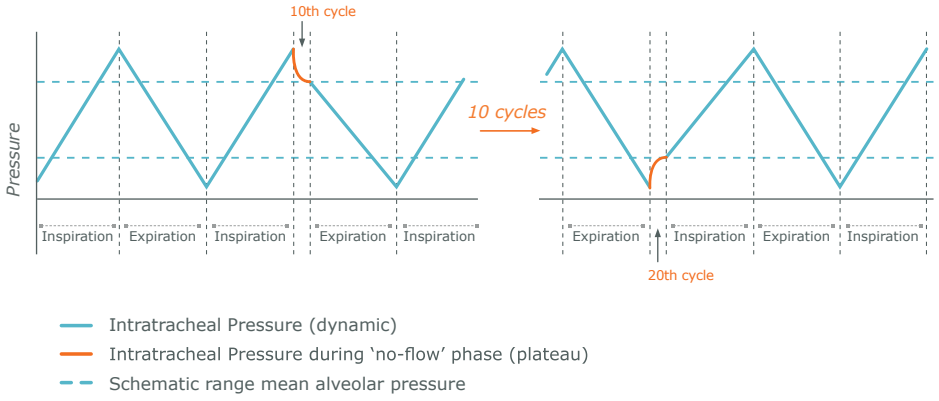

Figure 5.6 Dynamic tracheal pressures and schematic range of effective aggregate alveolar pressure swing (ΔP_{alv})

5.4 Clinical workflow Jet mode

1 Assemble and prepare Evone for using Tritube, jet catheter or rigid bronchoscope (HME filter is optional as this adds resistance to the Evone breathing system, which may make it necessary to adjust PP alarm limit in order to utilize maximal ventilation settings).
2 Induce Total Intravenous Anesthesia (TIVA).
3 Oxygenate patient as preferred to allow deepening of anesthesia.
4 Intubate patient as usual with Tritube, jet catheter or rigid bronchoscope.
5 Connect Evone Breathing tubing to the ventilation lumen.

In case of Tritube:
6 Connect pressure lumen.
7 Start ventilation.

In case of single lumen jet catheter or rigid bronchoscope:
6 Select 'Single lumen'.
7 Start ventilation.

8 If needed adapt ventilation settings.

6 Configuration

Within this section the main aspects of the user interface are explained.

6.1 Device settings

The general device settings may be adjusted from the idle FCV® mode and idle Jet mode screens by tapping the 'menu' button. Upon clicking, a pop-up screen will appear like shown in Figure 6.1.

Figure 6.1 Device settings menu, 'General' tab

6.1.1 General settings

The 'General' tab allows the user to see the current settings for the User Interface Language, the date and time, as displayed on the screen, the serial data output format and the current alarm sound level. If necessary, the date and time may be adjusted by tapping the 'Change' button. Similarly, the preferred User Interface language may be changed into one of the available languages, the serial data output format may be changed into one of the available formats and the alarm sound level may be set to the desired level. The gas standard can be chosen to display the volumes and flows at the desired conditions, i.e. ATPD or BTPS.

If the auditory alarm sound level is set to a level less than the ambient sound level, it may impede the user from recognizing an alarm condition.

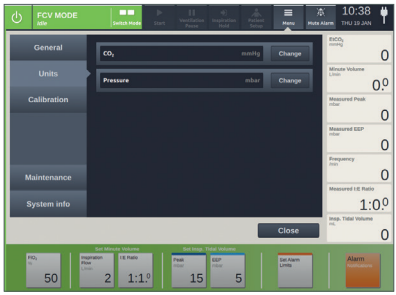

Figure 6.2 Device settings menu, 'Units' tab

6.1.2 Unit settings

The 'Units' tab allows the user to see the current settings for 'CO_2 partial pressure' and 'Pressure' units (Figure 6.2). The units for pressure may be chosen from the options: mBar, kPa and cmH_2O. The units for CO_2 partial pressure that are available are kPa, mmHg and vol%.

When units are changed, automatically graphs, displayed values and (alarm) limits will be adjusted to the new unit choice.

6.1.3 Calibrations

6.1.3.1 CO_2 sensor zeroing

The 'Calibration' tab allows the user to zero the CO_2 sensor or calibrate the exhaust valve. Only perform a zeroing process when the baseline signal is not zero or $EtCO_2$ values are at doubt. When zeroing the CO_2 sensor make sure of the following:

- Always use a clean and undamaged airway adapter when performing the zeroing process.
- This test will zero the baseline of the CO_2 sensor.
- User needs to put CO_2 sensor onto the Evone airway adapter and keep both in ambient air when indicated.
- The zeroing process may vary in duration from a few seconds up to 2 minutes depending on sensor temperature.
- A 'Fail' outcome of this test most likely is due to a too low sensor temperature, wait a minute and try again.

6.1.3.2 Exhaust valve calibration

During the calibration the optimized closing angle is determined for the exhaust valve pin. Only perform an exhaust valve calibration process at first installation of the device or at yearly maintenance (Chpt. 8). When calibrating the exhaust valve:

- Make sure the Evone Cartridge is placed inside Evone without accessories attached to the patient outlet port (Figure 2.3 A4).
- Make sure the Patient outlet port is sealed airtight (e.g. use a thumb).
- Perform the calibration by pressing 'Continue'.
  - If the calibration is successful select 'Close'.
  - If the calibration fails, select 'Retry' and repeat calibration until calibration is successful.
  - If calibration keeps failing contact the manufacturer.
- Always perform a startup check after calibration.

6.1.4 Maintenance menu

The maintenance menu is currently not available for users, it is only accessible for the manufacturer.

6.1.5 System info

The System info menu contains information about the current software version and the cumulative operating hours of the Evone, displayed per ventilation mode.

6.2 FCV® Mode User Interface

The FCV® Mode screen is shown in Figure 6.3. The user interface aspects are explained in Table 6.1.

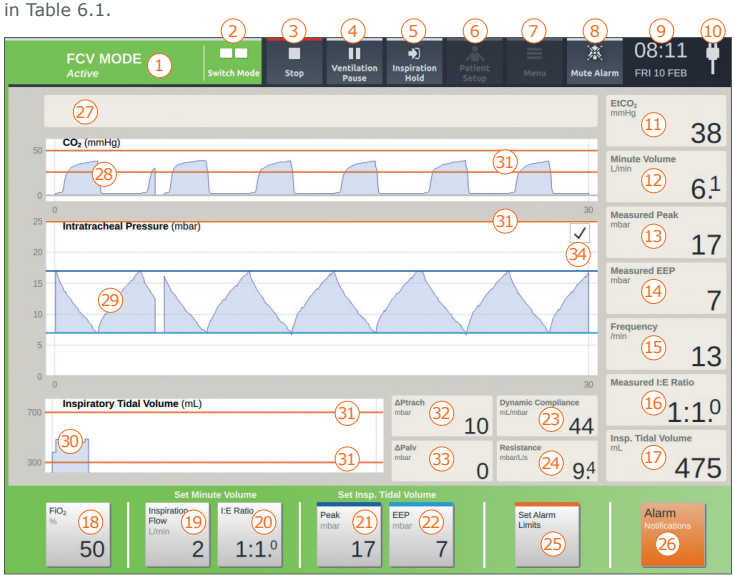

Figure 6.3 User interface aspects in FCV® Mode

UI ID	Function	Description
1	Mode indicator	Indication if the system is operating in FCV® (green) or Jet (purple) Mode and if the system is in idle or active mode.
2	Switch Mode	Button used to switch between FCV® and Jet Mode.
3	Stop/Start	Stop/Start button to switch between active ventilation and idle mode.
4	Ventilation Pause	Pauses active ventilation, while intratracheal pressure passively drops to set EEP level. Ventilation is resumed automatically after 60 seconds or by action of the user.
5	Inspiration Hold	Holds the inspiration phase at set Peak, so intratracheal pressure is maintained at Peak level in the patient. Normal ventilation is resumed automatically after 60 seconds or by action of the user.
6	Patient Setup	Button to Start-up check menu (see section 5.2.1). Only accessible when Evone is in idle state.
7	Menu	Button to enter device settings menu.
8	Mute Alarm	Button to mute the active alarm(s).
9	Time and Date	Showing current time and date.

UI ID	Function	Description
10	Power Supply Status	Indicating battery level, only showing full battery or low battery level. A full battery level always ensures 30 minutes of ventilation. When 30 minutes of ventilation cannot be guaranteed the low battery-level is indicated. A power plug indicates that the device is connected to mains power (see table appendix 1.1).
11	$EtCO_2$	Measured end tidal CO_2 level.
12	Minute Volume	Measured Minute Volume, averaged over 3 ventilation cycles.
13	Measured Peak	Measured intratracheal Peak pressure.
14	Measured EEP	Measured intratracheal end expiratory pressure.
15	Frequency	Breathing Frequency, averaged over 3 ventilation cycles.
16	Measured I:E Ratio	Measured Inspiration: Expiration ratio, averaged over 3 ventilation cycles.
17	Inspiratory Volume	Measured inspiration volume, averaged over 3 ventilation cycles.
18	FiO_2	Set inspiratory O_2 percentage.
19	Inspiration Flow	Set inspiration flow.
20	Set I:E Ratio	Set Inspiration: Expiration ratio.
21	Set Peak	Set Peak pressure.
22	Set EEP	Set end expiratory pressure.
23	Dynamic Compliance	Measured dynamic compliance.
24	Resistance	Measured resistance.
25	Set Alarm Limits	Button to change (alarm) limit settings for pressures, maximum and minimum $EtCO_2$ levels and volumes.
26	Alarm Notifications	Alarm notification and alarm history.
27	Alarm Bar	Appearance of alarm messages.
28	CO_2 graph	Measured CO_2 level during the past 30 seconds.
29	Intratracheal Pressure graph	Measured intratracheal pressure during the past 30 seconds. Also the corresponding P_{alv} pressures are displayed with dotted lines
30	Inspiratory Volume graph	Indicates trend of measured inspiratory volume.
31	Alarm Limits	Graphical representation of the set alarm limits by orange lines.
32	ΔP_{trach}	Calculated difference in measured Peak and EEP.
33	ΔP_{alv}	Effective aggregate alveolar pressure swing, which is the calculated difference in P_{alv} at Peak and P_{alv} at EEP.
34	Check-box	Activates dotted lines in pressure graph of P_{alv} values.

Table 6.1 Explanation user interface buttons FCV® mode screen of Figure 6.3

In the text in this Instructions for Use pressures are communicated in mbar or bar and $EtCO_2$ in mmHg. In table 6.2 and 6.3 setting ranges for all adjustable parameters and alarms are displayed and calculated for the various units.

Parameter	Unit	Setting		Resolution	Default
		Min (Rounded)	**Max** (Rounded)		(Rounded)
Peak	mbar	5	100	1	15
	kPa	0.5	10.0	0.1	1.5
	cmH_2O	5	102	1	15
EEP	mbar	-10	30	1	5
	kPa	-1.0	3.0	0.1	0.5
	cmH_2O	-10	31	1	5
I:E Ratio	-	1:1.0 – 1:2.5		0.1E	1 : 1.0
Inspiration Flow	L/min	2 – 20		1	12
FiO_2 Percentage	%	21 – 100		5 starting from 25	50

Table 6.2 Setting ranges of parameters in FCV® mode

The (alarm) limits can be adapted manually before starting and during ventilation as indicated in Table 6.3.

Parameter	Unit	Setting		Resolution	Default
		Min (Rounded)	**Max** (Rounded)		(Rounded)
Trach. Pressure Max. alarm	mbar	10	105	1	25
	kPa	1.0	10.5	0.1	2.5
	cmH_2O	10	107	1	25
Trach. Pressure Min. alarm	mbar	-100	-2	1	-20
	kPa	-10.0	-0.2	0.1	-2.0
	cmH_2O	-102	-2	1	-20
$EtCO_2$ High alarm	mmHg	20	70	1	50
	kPa	2.7	9.3	0.1	6.7
	vol%	2.6	9.2	0.1	6.6
$EtCO_2$ Low alarm	mmHg	5	50	1	26
	kPa	1.0	6.7	0.1	3.4
	vol%	1.0	6.6	0.1	3.4
Inspiratory Volume High	mL	150 – 1500		50	10 mL/kg IBW
Inspiratory Volume Low	mL	150 – 1000		50	4 mL/kg IBW

Table 6.3 Setting ranges and default values of (alarm) limits in FCV® mode

After adjusting ventilation settings of alarm limits, changes need to be confirmed.

Warning: Do not set the volume limits too wide from each other. Risk on barotrauma. It is recommended to set limits about 150 mL upper and lower of the expected tidal volume.

6.3 Jet Mode User Interface

The Jet Mode screen is shown in Figure 6.4. The numbered references are explained in Table 6.4.

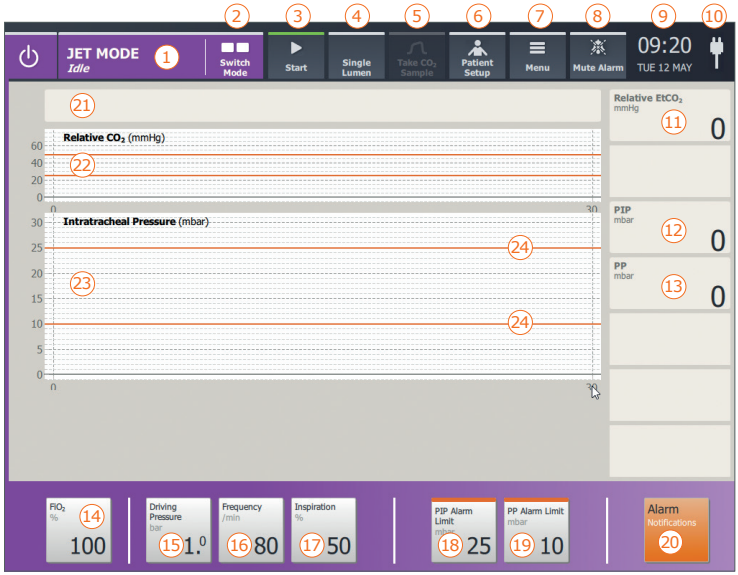

Figure 6.4 User interface aspects Jet mode

UI ID	Function	Description
1	Mode Indicator	Indication if the system is operating in FCV® (green) or Jet (purple) mode and if the system is in idle or active mode.
2	Switch Mode	Button used to switch between FCV® and Jet Mode.
3	Stop/Start	Stop/Start button to switch between active ventilation and idle state.
4	Single Lumen	Single lumen jet function.
5	Take CO_2 Sample	Pushing the button will result in a 2 second inspiration phase at 12 L/min, followed by an active expiration phase of 8 seconds using an expiration flow of approximately 3 L/min in order to measure an (end tidal) CO_2 concentration.
6	Patient Setup	Button to startup check menu (see section 5.1.2, 5.2.1). Only accessible when Evone is in idle mode.

UI ID	Function	Description
7	Menu	Button to enter device settings menu.
8	Mute Alarm	Button to mute the active alarm(s).
9	Time and Date	Showing current time and date.
10	Power Supply Status	Indicating battery level, only showing full battery or low battery level. When 30 minutes of ventilation cannot be guaranteed the low battery-level is indicated. A power plug indicates that the device is connected to mains power (see table appendix 1.1).
11	Relative $EtCO_2$	Measured relative end tidal CO_2 level. Be aware this value is an estimation, because of the open airway during Jet mode.
12	Measured PIP	Measured Peak Inspiratory Pressure value.
13	Measured PP	Measured pause pressure value.
14	FiO_2	Set inspiratory O_2 percentage.
15	Driving Pressure	Pressure supplied by Evone onto Tritube.
16	Frequency	Breathing frequency.
17	Inspiration %	Percentage of inspiration time relative to total cycle time.
18	Set PIP Alarm Limit	Button to change Peak inspiratory pressure alarm limit.
19	Set PP Alarm Limit	Button to change pause pressure alarm limit.
20	Alarm Notifications	Number indicates number of active alarms and pushing the button will show the complete list of alarms that have occurred.
21	Alarm Bar	Appearance of alarm messages.
22	Relative CO_2 graph	Measured relative CO_2 level over the past 30 seconds.
23	Intratracheal Pressure	Measured intratracheal pressure over the last 30 seconds (not visible in single lumen mode).
24	Alarm Limits	Graphical representation of the set alarm limits by orange lines.

Table 6.4 Explanation user interface buttons Jet mode screen of Figure 6.4

In the text in this Instructions for Use pressures are communicated in mbar or bar and $EtCO_2$ in mmHg. In table 6.6 setting ranges for all alarms are displayed and calculated for the various units.
In Table 6.5 the ranges are given for all adjustable ventilation parameters including the step size.

Parameter	Range	Setting Resolution	Default Value
Inspiration Percentage	20% – 50%	5%	1:1
FiO_2	21 – 100%	5%	100%
Frequency	60 – 150 BPM	5 BPM	60 BPM
Driving Pressure	0.3 – 1.5 bar	0.1 bar	1.0 bar

Table 6.5 Setting ranges of parameters in Jet Mode

The alarm limits can be adapted manually before starting and during ventilation as indicated in Table 6.6.

Parameter	Unit	Setting		Resolution	Default
		Min (Rounded)	**Max** (Rounded)		(Rounded)
PIP alarm	mbar	10	40	1	25
	kPa	1.0	4.0	0.1	2.5
	cmH_2O	10	41	1	25
PP alarm	mbar	5	35	1	10
	kPa	0.5	1.5	0.1	1.0
	cmH_2O	5	15	1	10

Table 6.6 Setting ranges and default values of alarm limits in Jet Mode

Jet ventilation is initiated by pushing the start button.

6.4 Alarm Interface

Alarm messages appear as a pop-up in the alarm bar. Alarms are audible and visible by means of the alarm indicator LED on the Evone Control Unit. Alarm sounds can be muted for 120 seconds by pressing the 'Mute Alarm'- button (Figure 6.3, number 8). Every new activated alarm will be muted too. More detailed alarm information may be obtained by clicking the alarm bar during an active alarm. An extended pop-up appears which can be closed again by clicking 'Close'.

Alarm notifications and alarm history are displayed after tapping the 'Alarm Notifications'- button (Figure 6.3, number 26). Alarms are logged starting from powering on Evone until powering off Evone. Note that the alarm history is not stored on Evone during power down situations. The capacity for alarm messages to be logged is 100. When a higher number of alarm messages will occur the oldest one will be deleted in favor of the newest one.

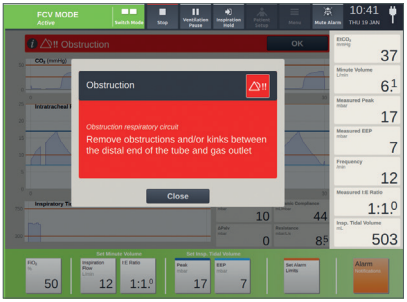

Figure 6.5 Example extended alarm pop-up

Alarm priority is indicated by four different colors, which are explained in Table 6.7.

Color	Alarm Level	Description
Red	High priority alarm with red blinking light and sound.	The system has detected a situation in which the patient is in immediate danger. Take direct actions to minimize the impact on the patient.
Yellow	Medium priority alarm with yellow/ orange blinking light and sound.	The system has detected an error that could indicate either a situation with the patient or a problem with the device. Check and take appropriate actions.
Blue	Low priority alarm with blue blinking light and sound.	The system has detected a situation that is outside the normal ranges, which could indicate an undesired situation. Check and take appropriate actions.
None	Obsolete/resolved Alarm.	No current alarm. This is the list of previous alarms that have been resolved or are no longer valid. Use this list to check on regularities in alarms and take appropriate actions when needed.

Table 6.7 Explanation of colors to indicate alarm priority

6.5 Special Functions

During ventilation in FCV® and/or Jet Mode the following special functions are available:

6.5.1 Ventilation Pause

The function of the 'Ventilation Pause'- button (Figure 6.3, number 4) is to set all active FCV® ventilation processes on hold. The 'Ventilation Pause'- button can be accessed from the active FCV® screen. Upon clicking, a pop-up screen will appear, like the one depicted in Figure 6.6. The user is asked to resume ventilation by clicking on the 'resume' button or to wait. In the screen, the FCV® device counts down from 60 seconds to 0 seconds. After this countdown, ventilation will automatically resume, using the settings identical to the settings just before the ventilation pause state was entered.

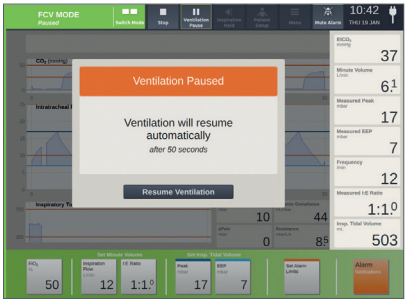

Figure 6.6 Ventilation pause screen

6.5.2 Safety State

The 'Safety State' is a state which cannot be chosen by the user, but will appear when the FCV® device has encountered an issue, large enough to restrict the user from using the device any further. The issue may be due to an irreversible technical defect or an external situation, leading to an immediate potentially hazardous situations for the patient. When the safety state becomes active, a pop-up screen will appear. The user has only one option: shut down the device. If the message occurs during ventilation the user should switch to alternative ventilation. The device may be restarted to perform a self-check and startup check.

In safety state there is an open connection between the patient's lungs and ambient air.

6.5.3 Negative End Expiratory Pressure

A negative end expiratory pressure (NEEP) can be set, but is strictly limited to be applied during hypovolemia/severe hemorrhage and concomitant hemodynamic instability. High intrathoracic pressures or PEEP levels prevent the return of venous blood to the heart, carrying a risk of metabolic acidosis. In contrast, lower intrathoracic pressures stimulate venous blood to return to the heart. In hypovolemic situations, the effects of intrathoracic pressures are more pronounced than in a normovolemic setting. A NEEP (of - 10 mbar maximally) may be considered during

hypovolemia/hemorrhagic shock in order to stimulate venous blood return, stimulate cardiac output and to create a possibility to maintain peripheral circulation.

The risk on metabolic acidosis (due to reduced venous return during PEEP ventilation), versus the risk on atelectasis (during NEEP ventilation) should be considered for each hypovolemic patient. After applying NEEP ventilation a recruitment maneuver should be considered once the patient is hemodynamically stable.

Warning: Negative end expiratory pressure may be considered to be applied only in hypovolemic/hemorrhagic shock situations. Risk on atelectasis.

6.5.4 Inspiration Hold

The function of the 'Inspiration Hold'- button (Figure 6.3, number 5) is to bring the intratracheal pressure to Peak level and keep it there for maximum 60 seconds to be used for clinical recruitment maneuvers. The 'Inspiration Hold'- button may be accessed from the active FCV® ventilation mode. Upon clicking, a yellow border appears around the button. Additionally, a timer, located below the top left FCV® mode indicator, will count down from 60 seconds to 0. After this countdown, ventilation will automatically resume starting with expiration, using the settings similar to the settings just before the inspiration hold state was entered.

6.5.5 Single Lumen Jet

The function of the Single Lumen - button (Figure 6.4, number 4) is to give the user the possibility to use single lumen jet catheter or rigid bronchoscopes. No pressure lumen can be connected, which has the consequence of not having an intratracheal pressure graph. Furthermore, the minimum breathing frequency will be 80 BPM and the PIP alarm will not be activated in this mode.

6.6 Shut Down

Evone shall be shut down by the shutdown option ⏻ on the screen.
A pop-up screen will appear, requiring confirmation of the shutdown by the user before termination. When shut down has been confirmed by the user an auditory signal is given.

Alternatively, Evone may be shut down by pressing the stand-by button on the left hand side of Evone. Pressing this button for more than 3 seconds results in immediate shut-down without warning.

7 Cleaning and Disposal

7.1 Switching Between Patients

When switching between patients the user shall always:

- Remove the Evone Cartridge by pressing the hard button ⏏, place a new Evone Cartridge, dispose the old unit.
- Replace the Evone Breathing Tubing or Evone Conventional Tube Adapter and dispose the old tubing/adapter.
- Replace the Evone Airway Adapter by a clean unit if necessary.
- Replace the Humid-Vent Filter Pedi straight and dispose the old filter.
- Replace endotracheal tube according to its Instructions for Use and dispose the old device.
- Reconnect all accessories and additional materials as described in section 1.6.

Treat all single use components in accordance with your institutional protocol for single use items.

⚠ **Warning:** Dispose the HME filter and endotracheal tube after each patient.
Risk on cross contamination.

⚠ **Warning:** Dispose the Cartridge after each procedure.
Risk on cross contamination.

7.2 General Cleaning Instructions

- Always dilute cleaning agents according to the manufacturer's instructions for use to the lowest possible concentration.
- Do not immerse any part of the control unit in liquid.
- Do not pour liquid on the control unit.
- Do not use abrasive material (such as steel wool or silver polish).
- Do not autoclave, steam sterilize, or ultrasonically clean the control unit or the CO_2 sensor and cable.
- Do not use cleaners on electrical contacts or connectors

7.3 Cleaning of the Control Unit

After removal of the Evone Cartridge, the Evone Control Unit must be cleaned with a damp cloth with mild cleaning agent using 70% alcohol solution or with 1000 ppm chlorine solution for disinfecting.

⚠ Make sure no cleaning fluids enter the Evone Cartridge under any condition.
Risk on intoxication.

7.4 Cleaning of the CO_2 Sensor

Cleaning the outside of the CO_2 Sensor and its cable:

- Make sure that the sensor is disconnected and cooled to room temperature for 30 minutes before cleaning.
- Use a cloth dampened with isopropyl alcohol (>70%) or a 10% aqueous solution of 6% chlorine bleach.
- Wipe down with a clean water-dampened cloth to rinse and dry before use. Ensure that the sensor windows are clean and dry before reuse.

⚠ Always disconnect the CO_2 Sensor before cleaning. Do not use if it appears to have been damaged. If damaged, refer servicing to qualified service personnel.

7.5 Reprocessing of the Airway Adapter

Treat Evone airway adapter in accordance with your institutional protocol for reusable items.

- Clean by rinsing in a warm soapy solution followed by soaking in either one of the following liquid disinfectants:
  - Isopropyl alcohol 70%
  - 10% aqueous solution of chlorine bleach
  - Glutaraldehyde 2.4% solution such as Cidex®
  - Peracetic Acid such as Perasafe or Steris System 1®
- Rinse thoroughly with sterile water and dry.
- Before reusing the adapter, ensure the windows are dry and residue free and that the adapter has not been damaged during handling or the cleaning/disinfecting process.

8 User Maintenance and Service

The first installation of Evone may be regarded as succeeded when the self-check and startup check are performed correctly.

8.1 Battery Charging

Evone must be connected to a grounded power supply, both when it is temporarily not in use and when it is in storage, to ensure a maximally charged battery.

8.2 Storage

Evone should be stored in a dry space at all times in environmental conditions as defined in Chapter 10 of these Instructions for Use.

8.3 Maintenance

8.3.1 Yearly maintenance

The 'Safety Preventive' maintenance needs to be performed every 12 months. Maintenance and service activities shall only be carried out by the legal manufacturer or by parties designated by the legal manufacturer. Do not open the device.

Battery condition check, and if needed replacement, can be done by a specialist who is trained by Ventinova Medical B.V. Further details on the maintenance and training can be acquired from Ventinova Medical B.V.

Perform an exhaust valve calibration (section 6.1.2).

8.3.2 User maintenance

When the power cord needs replacement, make sure these parts are replaced by identical parts of the same type. Furthermore, there are no replaceable parts inside the device, so the user shall not open the device by any means.

Warning: Do not perform maintenance on Evone while it is connected to a patient.

8.4 Warranty and Support

The expected service life for Evone is 5 years.

In case an issue is not resolved by following the instructions of the Alarm section, or if (parts of) Evone are damaged and need replacement or repair, please contact Ventinova Medical B.V. Furthermore, when necessary technical schemes can be requested by Ventinova Medical B.V.

Ventinova Medical B.V. provides one year of warranty on Evone, excluding the parts that suffer from natural wear and tear or which are single use. Warranty voids if, to the judgment of Ventinova Medical B.V., Evone or parts thereof are not used or maintained in accordance with these Instructions for Use.

8.5 Disposal of the Control Unit

Due to the complex nature of Evone, it is recommended to return the device to the supplier for disposal. When disposed by the user, please make sure all local laws are followed. This product contains a lead battery, electronics, metal and plastics.

8.6 Disposal of the accessories

The Evone breathing system parts and additional materials of Evone should be disposed similar to general hospital waste. Please make sure all local laws are followed.

8.7 Software Upgrade

When a new software version is available, the software of Evone can be upgraded by means of the SD-card port located on the left hand side of the device. Thereafter, an SD-card with the software update will become available and the following steps need to be carried out:

- Make sure the Evone is powered off
- Remove the SD-card with the outdated software version
- Insert SD-card containing software upgrade into SD-card port (make sure the flattened corner of the SD-card is at the upper side that goes into Evone first)
- Power on Evone
- Follow instructions on screen until software update is complete
- Shutdown Evone and wait for 3 minutes
- Evone is ready for use

Warning: Make sure sd-card is unlocked when placed into Evone.

Warning: Do never remove SD-card, except before upgrade procedure.

9 Alarms

The alarms generated by Evone may have a technical or physiological cause. The user always shall be in a position to notice audible and/or visual alarm signals of Evone directly.

Physiological alarms arise from monitored patient related variables (like CO_2 levels, intratracheal pressure, etc.). Technical alarms arise from product and interface related issues (like sensor failure, power failure, valve failure, no gas supply, catheter disconnection).

In table 9.1 all alarms are summed, including the priority level, alarm condition, and the device or user action.

Physiological Alarms				
Alarm Text	**Condition**	**Device Action**	**User Action**	**Priority**
Obstruction / obstruction respiratory circuit	Obstruction in the respiratory circuit, such that ventilation performance is reduced.	Ventilation pause with passive pressure release to EEP.	Remove obstructions and/ or kinks between the distal end of the tube and gas outlet.	High
Intratracheal pressure high / Intratracheal pressure higher than alarm limit	Intratracheal pressure is above the Peak pressure alarm limit.	Ventilation pause with passive pressure release to EEP until condition ceases. Cease delay: 2 s	Check level of sedation and (surgical) manipulations at patient. If alarm persists, consider to briefly deflate the cuff of Tritube or briefly disconnect CTA.	High
Intratracheal pressure low / Intratracheal pressure below EEP alarm limit	Intratracheal pressure comes below the EEP pressure alarm limit	Ventilation pause with passive pressure release to EEP until condition ceases. Cease delay: 2 s	Check level of sedation and (surgical) manipulations at patient. If alarm persists, consider to briefly deflate the cuff of Tritube or briefly disconnect CTA.	High

Alarm Text	Condition	Device Action	User Action	Priority
PIP high / PIP higher than alarm limit	The intratracheal pressure is above PIP alarm limit#.	Ventilation pause until intratracheal pressure is 40% of PIP alarm limit and below PP limit. Then alarm is reset and ventilation is continued.	Check for obstructions in the airway and if cuff is deflated.	High
PP high / PP higher than alarm limit	The intratracheal pressure does not reach a value below PP alarm limit#.	Ventilation pause until intratra-cheal pressure is 20% of PP alarm limit (0 is lowest value). Then alarm is reset and ventilation is continued.	Check for obstructions in the airway. Optionally, remove HME filter.	High
Inspiration volume low / Inspiration volume lower than alarm limit	Inspiratory volume does not reach the volume lower alarm-limit*, while Peak pressure is reached. Possible causes: compression of lungs by external cause unexpected compliance decrease.	Dual pressure measurements are compared. When check succeeds, ventilation is continued at first correct cycle.	Check patient.	Medium
Inspiration volume high / inspiration volume higher than alarm limit	Inspiratory volume exceeds the volume upper alarm limit*. Possible causes: • leakage • partly obstructed pressure lumen	Dual pressure measurements are compared. When check succeeds, ventilation is continued at first correct cycle.	Check for possible leaks in the repira-tory circuit. If problem persists, consider to adjust ventila-tion or alarm settings.	Medium
$EtCO_2$ high / The $ETCO_2$ is higher than the alarm limit	$EtCO_2$ value above alarm limit.	Alarm is reset when condition ceases.	Consider to adjust ventilation or alarm settings.	Medium

Alarm Text	Condition	Device Action	User Action	Priority
$EtCO_2$ low / The $ETCO_2$ is lower than the alarm limit	$EtCO_2$ value below alarm limit.	Alarm is reset when condition ceases.	Consider to adjust ventilation or alarm settings.	Medium
Minute Volume not reached / Minute volume lower than calculated minute volume (based on flow and I:E ratio settings).	Minute volume 10% lower than calculated minute volume (based on flow and I:E ratio settings). Possible obstruction in lumen.	Alarm is reset when condition ceases. Cease delay: 2 s	Consider to adjust ventilation settings as set I/E ratio cannot be reached.	Medium
Leakage detected / Leakage detected during first cycle	Leak detected during first cycle.	None	Check for leakage in respiratory circuit including cuff.	Medium
Leakage gas outlet / Leakage of exhaled gas outlet detected	Wrongly inserted cartridge or wrongly calibrated exhaust valve.	Ventilation stops.	Check proper placement of silicon gas outlet tube or perform exhaust valve calibration.	Medium

* The alarms will be triggered on relative volumes starting from EEP level.

\# The PP alarm is triggered by the pressure measured via the ventilation lumen and the PIP alarm is triggered by the pressure measured via the pressure lumen.

Technical Alarms				
Alarm Text	**Condition**	**Device Action**	**User Action**	**Priority**
30 s auditory alarm	Fatal alarm (total power loss, mains supply or battery / internal fatal error).	Move to safety state, device shuts down.	Start alternative ventilation method.	High
Software malfunction / service needed	Irresponsive software system in ventilation control, gas mixer or UI Delay for UI malfunction: 6 s.	Move to safety state, device shuts down.	Contact manufacturer. Start alternative ventilation e.g. Ventrain.	High
* Disconnection respiratory circuit	Disconnected ventilation line or large leak proximal from Tritube. Delay: 2 s.	None	Check connections of the respiratory circuit.	High
Pressure mismatch / Measured pressures via pressure and ventilation lumen differ too much	Ventilation lumen pressure measurement and pressure lumen measurement differ too much. Difference could not be solved by pressure lumen purge or ventilation lumen purge.	Ventilation pause until condition ceases.	Purge both lumens manually using a syringe with water (solution).	High
Gas supply pressures too low / Both O_2 and air supply too low	Both gas supply pressures below 2.7 bar. Delay: 5 s	Alarm is reset when condition ceases.	Check O_2 and air supply. Consider to switch to jet mode at low driving pressure.	High

Alarm Text	Condition	Device Action	User Action	Priority
O_2 pressure low / Set conditions cannot be reached. FiO_2 continues at 21%	Set conditions cannot be reached because of low O_2 supply pressure.	Continue ventilation on air supply. When condition ceases alarm is reset and Evone switches to both gas supplies.	Check supply pressure. Consider to connect to O_2 cylinder.	High
FiO_2 deviation / FiO_2 deviates from set value	Mismatch in set and measured FiO_2 percentage > 5% point Delay: 30 s	Alarm is reset when condition ceases. Delay: 5 s	Check O_2 and air supply. If alarm persists, contact manufacturer.	High
Gas supply pressures > 8 bar might damage equipment. When pressure > 9.5 Bar, flow is stopped	Gas supply pressure > 8 bar Delay: 2 s	None	Check supply pressures, switch to alternative gas sources. Consider to start alternative ventilation.	High
Battery low / Battery level assures maximal 5 minutes of ventilation	Battery level not sufficient for more than 5 minutes of ventilation. Delay: 15 s	Alarm is reset when condition ceases.	Connect to mains power.	High
Air pressure low / Set conditions cannot be reached. FiO_2 continues at 100%	Set conditions cannot be reached because of low air supply pressure.	Switch to 100% O_2. When condition ceases alarm is reset and Evone switches to both gas supplies.	Check supply pressure. Consider to connect to air cylinder.	Medium
Gas supply pressure high / Gas supply pressure >6.6 bar	Gas supply pressure > 6.6 bar	Alarm is reset when condition ceases.	Check O_2 and air supply.	Low

Alarm Text	Condition	Device Action	User Action	Priority
Air supply pressure low / Air supply pressure < 2.7 bar	Insufficient air pressure < 2.7 bar. Delay: 5 s	Alarm is reset when condition ceases.	Check air supply.	Low
O_2 supply pressure low / O_2 supply pressure < 2.7 bar	Insufficient O_2 pressure < 2.7 bar Delay: 5 s	Alarm is reset when condition ceases.	Check O_2 supply.	Low
Self-check failed / Self-check failed on critical function	Failed self-check on critical function.	No ventilation before problem has been solved.	Restart Evone. If problem persists, contact manufacturer.	Low
No proper CO_2 measurement / CO_2 sensor damaged or not properly connected	Disconnected or broken CO_2 sensor	Alarm is reset when condition ceases.	Please check status and connection of CO_2 sensor.	Medium
CO_2 measurement accuracy reduced / Deviation from zero baseline detected	Drift of CO_2 sensor or contaminated Evone airway adapter.	Alarm is reset when condition ceases.	Please check Evone airway adapter and calibrate CO_2 sensor.	Low

* In case of decannulation (extubation) of Tritube or endotracheal tube no 'Leakage respiratory circuit'- alarm is triggered.

Table 9.1 Alarm list of Evone

10 Technical Specifications

10.1 Evone Parameters

Parameter	Value / Limits	Units
Physical Parameters		
Size L x W x H	399 x 320 x 287	mm
Weight	21	Kg
Dead Volume	42 (in configuration with Evone Breathing Tubing) 52 (in configuration with Evone Conventional Tube Adapter) (internal dead volume of Evone, i.e. breathing system)	mL
Electrical Parameters		
Power Voltage	115 – 230	V
Frequency	50 / 60	Hz
Protection Class	Control Unit: Class I	-
Applied Parts	CO_2 Sensor, Evone Breathing Tubing, Evone Cartridge, Evone CTA: Type BF	-
Power	120	VA
Operational time on fully charged battery for all intended tidal volumes	2	Hrs.
Fuse	T2AH 250V	-
Standard	*Emissions class/group or Immunity test level*	
CISPR 11	Class: A / Group: 1	-
EN 61000-3-2	Class: A	-
EN 61000-3-3	PASS	-
IEC 61000-4-2	± 15 kV air ± 2 kV, ± 4 kV, ± 6 kV, ± 8 kV contact and air	-
IEC 61000-4-3	1 Radiated RF EM fields: 3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz RF wireless communications equipment: Frequency: Immunity test level: 385 MHz 27 V/m 450 MHz 28 V/m 710 MHz 9 V/m 745 MHz 9 V/m 780 MHz 9 V/m 810 MHz 28 V/m	-

Parameter	Value / Limits	Units
Standard	*Emissions class/group or Immunity test level*	
IEC 61000-4-3	RF wireless communications equipment: Frequency:Immunity test level: 870 MHz 28 V/m 930 MHz 28 V/m 1720 MHz 28 V/m 1845 MHz 28 V/m 1970 MHz 28 V/m 2450 MHz 28 V/m 5240 MHz 9 V/m 5500 MHz 9 V/m 5785 MHz 9 V/m	-
IEC 61000-4-4	AC power: ± 2 kV, 100 kHz repetition frequency Serial Interface: ± 1 kV, 100 kHz repetition frequency	-
IEC 61000-4-5	AC power (line-to-line): ± 1 kV AC power (line-to-ground): ± 2 kV	-
IEC 61000-4-6	3 V_{rms}, 0,15 MHz – 80 MHz 6 V_{rms} in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	-
EN 61000-4-8	30 A/m	-
IEC 61000-4-11	0% UT; 1 cycle 70% UT; 25 cycles >5% UT; 250 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	-
Gas Supply Parameters		
Gas Supply Pressure	3.0 – 6.0 +/- 10%	bar
Gas Supply Types	Medical grade oxygen and medical grade compressed air	-
Ventilation Parameter Ranges		
Oxygen Measurement (compensated for ambient pressure)	0 – 100 (compensated for ambient pressure)	%
Inspiration Flow	2 – 20	L/min
Inspiration Flow Accuracy	4% of setpoint or 0.1 %FS (FS = 100l/min) whichever is greater	%
Maximum Minute Volume	9	L/min
FiO_2	21 – 100	%
I:E ratio / inspiration percentage	*FCV*® 1:1.0 – 1:2.5 / Jet 20–50%	-
Driving Pressure	0.3 – 1.5	bar

Parameter	Value / Limits	Units
Frequency	60 – 150	BPM
Pressure Set Range	-10 – 100	mbar
Ventilation Parameter Accuracies		
Average Peak pressure	±2 +3% of set value	mBar
Average EEP	±2 +3% of set value	mBar
Maximum deviation in Peak pressure	±2 +3% of set value	mBar
Maximum deviation in EEP	±2 +3% of set value	mBar
Delivered volume accuracy	±4 +10% of actual volume	mL
Maximum deviation in O_2%	±1 +1% of set value	%
Measured Parameters		
Maximum delay time to change O_2 %	3	s
Displayed Values	All pressures and volumes are calculated into ATPD or BTPS	-
A-weighed sound pressure level	67 +/- 2	dB
A-weighed sound power level	75 +/- 2	dB
Environmental Parameters		
Water Resistance	IP21	-
Operation		
Temperature	10 – 35	°C
Barometric Pressure	700 – 1060	HPa
Relative Humidity	30 – 75%, non-condensing	RH
Storage		
Relative Humidity	10 – 95%, non-condensing	RH
Temperature	-15 – 40	°C
Barometric Pressure	500–1060	HPa
Stacking	Do not stack	-
CO_2 Measurement Specifications		
Principle of Operation	Non-dispersive infrared, single beam optics, dual wavelength, no moving parts.	-
Initialization Time	Less than 10 seconds at an ambient temperature of 25 °Celsius, full specifications within 1 minute.	-

Parameter	Value / Limits	Units
CO_2 Measurement Specifications		
CO_2 Measurement Range	0 – 70	mmHg
CO_2 Resolution	0.1	mmHg
CO_2 Accuracy	± 2 or ± 5% whichever is higher	mmHg
CO_2 Stability	< 0.5	mmHg per hour
CO_2 Noise	< 0.25 at 5% CO_2	mmHg
CO_2 sampling rate	100	Hz
Gas standard	CO_2 values are displayed in ATPD or BTPS	
Note 1: $EtCO_2$ values are determined as the end value of the CO_2 curve during expiratory phase. ***Note 2:*** Different frequencies and immunity levels are not expected in the intended environment.		
Regulatory information		
Essential performance	Evone delivers effective ventilation within set alarm limits or generates an alarm.	

Table 10.1 Evone parameters

10.2 Evone Control Unit Pneumatic Scheme

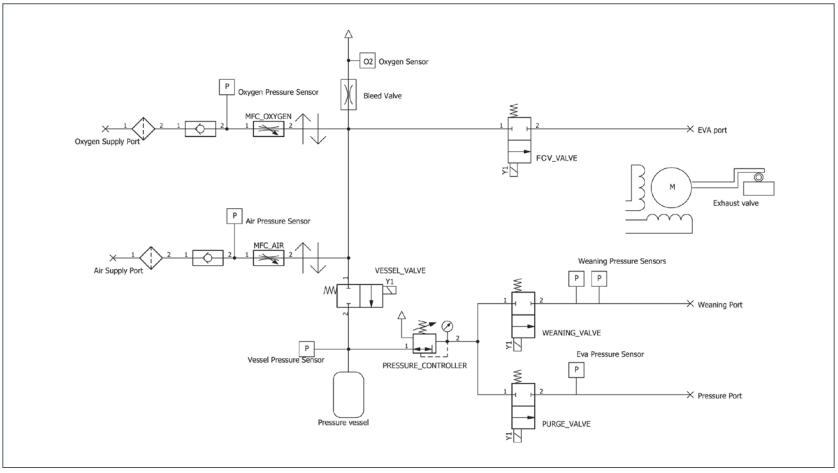

Figure 10.1 Pneumatic diagram of Evone

Figure 10.1 identifies various components of which the details are explained in the table 10.2.

Component	Purpose	Range
Input Pressure Sensor Oxygen Port	Verify gas input pressure.	0–10 bar
Input Pressure Sensor Air Port	Verify gas input pressure.	0–10 bar
MFC Oxygen	Mix the right amount of oxygen.	0–100 l/min
MFC Air	Mix the right amount of air.	0–100 l/min
O_2 Sensor	Check the mixture for correct amount of oxygen.	0 – 100%
Pressure Vessel Pressure Sensor	Check pressure vessel pressure.	0–5 bar
Pressure Controller	Control mixture pressure for Jet mode.	0–6 bar
Jet Port Pressure Sensor	Check pressure on the Jet port, this consists of two sensors of different ranges.	+/- 1 bar
Pressure Port Sensor	Sensor for measuring the intratracheal pressure.	+/- 200 mbar

Table 10.2 Components pneumatic scheme Evone

10.3 Safety Philosophy

1 Correct measurement of intratracheal pressure is essential for both prevention of barotrauma / volutrauma and efficient oxygenation / ventilation. The Evone breathing system has two separate lumens: a pressure lumen and a ventilation lumen. Each lumen is connected to a dedicated reliable pressure sensor inside the Evone Control Unit enabling measuring intratracheal pressure in two fully independent ways.

A Both pressure sensor readings are compared at regular intervals (i.e. 10 breaths for FCV® Mode). To enable optimal direct comparison, the ventilation is shortly paused at these intervals, creating a no-flow situation through the ventilation part.

B If other measurements (timing, flow) indicate a potentially incorrect continuous pressure measurement via the pressure lumen, the device pauses ventilation (no flow situation) and directly compares the pressure reading via the pressure lumen with the independent reading via the ventilation lumen.

Upon a significant deviation of both measurements in any of the above two situations, the device purges the pressure lumen with air to remove any debris that may obstruct that lumen. In case this situation is triggered during expiration, also the ventilation lumen is purged to ensure this lumen is free of any obstructions. After the purge, the pressure reading of the pressure lumen is again compared with the pressure reading through the ventilation lumen. If still inconsistent, a second purge cycle is applied. When the pressure difference still remains, an alarm ('Pressure mismatch') is given.

2 Inspiratory volume is determined by multiplying the measured inspiratory flow with the duration of inspiration. Expiratory volume is calculated by multiplying the calculated expiratory flow with the duration of the expiration. If the inspiratory volume and the expiratory volume differ too much from the set volume limits, the device pauses ventilation and compares the pressure reading of the pressure lumen with a measurement via the ventilation lumen, as explained above.

3 The device is constructed in such a way that the device can stop the gas flow from and to the patient in all conditions including (technical) fault conditions. This is called the Safety State.

4 The initial cycle of the FCV® Mode uses a pre-set, low, inspiratory volume. This initial cycle is used to check system integrity and reliability of pressure measurements.

Appendix I - Guide to Symbols

Symbol	Description
	Consult Instructions for Use
CE	CE marking
Rx Only	Caution: Federal law (USA) restricts to sale by or on the order of a licensed practitioner
UDI	Unique device identifier
	Indicates separate collection for electrical and electronic equipment (WEEE)
REF	Model / article number
SN	Serial number
IP21	Enclosure protects against fingers or similar objects and protected against dripping water
MD	Medical Device
	Manufacturer
	Do not use if packaging is damaged
	Fuse that is used within the product
	Stand-by button
	Release of Evone cartridge
	Sign indicating warning/caution which needs to be taken into account
	Type BF applied part
	Audio Paused / Mute
	Evone operates on mains power, battery charging

Symbol	Description
	Evone operates on battery power. Battery almost empty, less then 30 minutes ventilation time left.
	Evone operates on battery power. Battery almost full, more than 30 minutes ventilation time left.
	Evone operates on mains power, battery full

Table appendix I.1 List of used symbols

Appendix II - Glossary

Abbreviation	Description
ATPD	Ambient Temperature, Pressure, and Dry conditions
BTPS	Body Temperature, Pressure and Saturated conditions
BPM	Breaths Per Minute
ET	Endotracheal
$EtCO_2$	End tidal CO_2 value
EEP	End Expiration Pressure
FCV®	Name of ventilation method based on controlling both inspiratory and expiratory flow.
FiO_2	Percentage of O_2 within the gas mixture
HMEF	Heat Moisture Exchanger with Filter
HME	Heat Moisture Exchanger
I:E Ratio	Inspiration to Expiration Ratio
Peak	Peak Pressure (FCV® Mode)
PIP	Peak Inspirational Pressure (Jet Mode)
PP	Pause Pressure (Jet Mode)
$PaCO_2$	Systemic CO_2 partial pressure
$tcpCO_2$	transcutaneous CO_2 partial pressure
UI	User Interface
ΔP_{alv}	Effective aggregate alveolar pressure swing
ΔP_{trach}	Intratracheal pressure driving pressure

VENTINOVA
MEDICAL

CE 0344

IES MEDICAL®
Bizkaia Science and Technology Park
Ibaizabal Street, Building 500
48160 Derio (Bizkaia), Spain

T +34 94 400 88 47
info@ventinovamedical.com