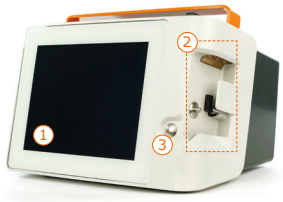
EVONE® – FCV ® DURING ONE LUNG VENTILATION (OLV) – APPLICATION NOTE

! This information does not replace the Instructions for Use !

- FCV® allows safe and efficient ventilation of totally intravenous anesthetized (TIVA) patients
- Compatible with conventional adult (double lumen) endotracheal tubes
- Unique in controlling both inspiration and expiration
- Ventilation with constant and continuous flow between chosen Peak and End Expiratory Pressure (EEP)
- Linear increase and decrease of intratracheal pressure
- For applying FCV® effectively the airway needs to be sealed with a cuff

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

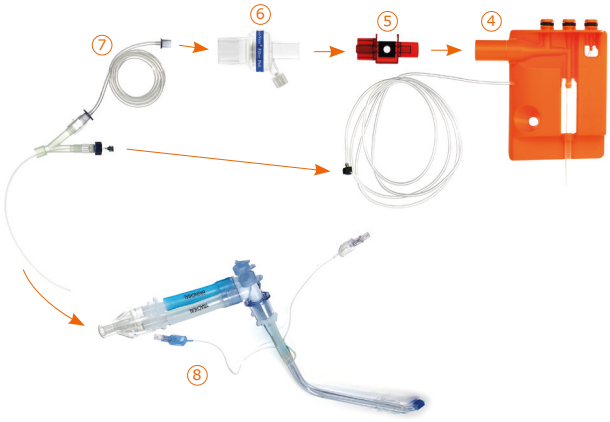
Evone Control Unit



① Touch screen
② Area to place the Evone Cartridge
③ Release-button to release Evone Cartridge from control unit

Additional materials

④ Evone Cartridge – to be inserted into the control unit as depicted
⑤ Evone Airway Adapter
⑥ Humid-Vent Filter Pedi straight (HME Filter)
⑦ Evone Conventional Tube Adapter (CTA)
⑧ Conventional adult (double lumen) endotracheal tube



Assembly of the breathing circuit

Installation and set up

1 Switch on Evone.
2 Perform Startup checks successfully.
3 Patient set up menu: select patient gender and fill out characteristics. Accept default settings or start with last used.
4 Check and if required adapt alarm limits.

Start FCV® ventilation

In case patient is not yet mechanically ventilated:

1 Induce anesthesia (TIVA).
2 Intubate patient as usual with tube of choice (DLT ≥ 35Fr).
3 Oxygenate patient as preferred to allow deepening of anesthesia.
4 Connect tube to CTA of Evone when anesthesia is deepened.
Connection CTA and position pressure line:
- Connect the CTA to the y-piece adapter of a DLT and position the pressure line as displayed in Figure 1.
- Connect the CTA directly to the tracheal or bronchial lumen of a DLT and position the pressure line as displayed in Figure 2.

Figure 1

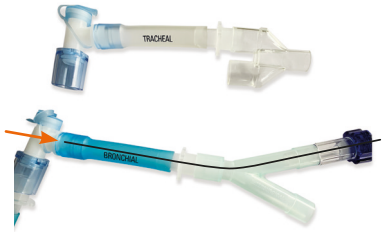


Figure 2

5 Start FCV using default settings.
Note that default settings are:
- FiO_2 50%
- Inspiratory Flow 12 L/min
- I:E ratio 1:1.0
- Peak 15 mbar
- EEP 5 mbar

Notes:
- Switching from two lung ventilation to one lung ventilation: Keep similar settings, tidal volume and the compliance shall automatically decrease. Frequency shall increase.
- Switching from one lung ventilation to two lung ventilation: Keep similar settings, tidal volume and the compliance shall automatically increase. Frequency shall decrease.

Adjust according to blood gas values.
A triangular pressure curve appears on the screen.

Measured values

Adjustable parameters

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

Note: The achievable minute volume of Evone is limited to maximally 9 L/min.

Optional: Individual optimization of FCV® ventilation based on patient compliance

Note: These optimization steps have shown beneficial effects in individual patients and a porcine study[1,2], but have not yet been validated in randomized controlled trials.

1 Find 'Best EEP'
- Change both EEP and Peak stepwise by 1-2 mbar; keeping driving pressure (Peak – EEP) constant.
- Monitor tidal volume (V_T): Increased VT indicates increased respiratory system compliance (C_{RS}) and improved ventilation.
- Choose EEP setting resulting in highest V_T; for similar V_T choose lowest EEP for circulatory reasons.

Note: Do not change settings too rapidly. Adequate application of the following steps requires equilibration periods of at least 30-60 seconds.

2 Find 'Best driving pressure'
- Change Peak pressure stepwise by 1-2 mbar.
- Monitor V_T
  - Per mbar increase of driving pressure, V_T is expected to increase with value of C_{RS};
  - If V_T increases over-proportionally, C_{RS} will increase -> improved ventilation;
  - If V_T increases under-proportionally, C_{RS} will decrease -> ventilation not further improved.
- Chose Peak setting resulting in highest C_{RS}.

Note: This step might lead to the application of higher tidal volumes than generally advised by common guidelines.

3 Find 'Best flow'
- Adjust flow depending on measured $etCO_2$.
- To reduce $etCO_2$: increase inspiratory flow
  - Results in higher frequency with same V_T and higher minute volume.
- To increase $etCO_2$: decrease inspiratory flow
  - Results in lower frequency with same V_T and lower minute volume.

Sedation, relaxation and wake up phase

Because of the small lumen (high resistance) of the breathing circuit, coughing may result in tube dislocation.

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

In case of light anesthesia (indicated by e.g. irregular pressure curves, increased/decreased compliance, coughing, BIS>60, TOF>90%):
- Disconnect CTA.
- Use alternative means of oxygenation if preferred.
- Optimize anesthesia.
- Reconnect CTA when anesthesia is optimized and continue FCV® ventilation.

Wake up phase patient:
- Set FiO_2 as preferred.
- Disconnect CTA from tube to allow waking up using preferred method of oxygenation.

References:

1 Bergold M et al. *Flow-controlled ventilation: A novel approach to treating severe acute respiratory distress syndrome.* Poster WAMM 2019

2 Spraider P et al. *Individualized flow-controlled ventilation compared to best clinical practice pressure-controlled ventilation: a prospective randomized porcine study.* Crit Care. 2020 Nov 25;24(1):662

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