

» EVONE® – FLOW-CONTROLLED VENTILATION (FCV®) IN THE ICU – APPLICATION NOTE

! This information does not replace the Instructions for Use !

- FCV® allows safe and efficient ventilation of fully anesthetized patient
- Compatible with conventional adult 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

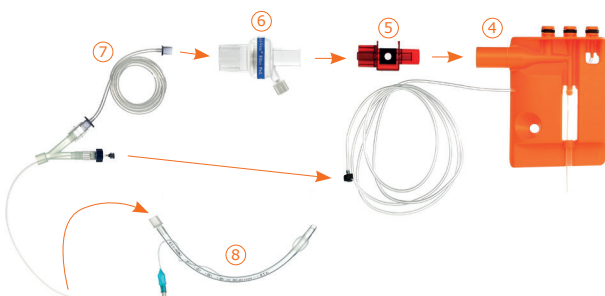


- 1 Touch screen
- 2 Area to place the Evone Cartridge
- 3 Release-button to release Evone Cartridge from control unit

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 endotracheal tube (≥5 mm ID)



Assembly of the breathing circuit

For more details on ventilation of ARDS- / COVID-19 patient and optimization of FCV® based on compliance, see backside.

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.

Note that default ventilation settings are:

- FiO₂ 50%
- Inspiratory Flow 12 L/min
- I:E ratio 1:1.0
- Peak 15 mbar
- EEP 5 mbar

Ventilation with conventional tubes

- 1 Induce 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 CTA of Evone when anesthesia is optimized.
- 5 Start ventilation in FCV® mode. A triangular pressure curve appears on the screen (Fig. 3).



Fig. 3 FCV® mode active

- 6 If needed adapt ventilation settings:
 - FiO₂ as preferred
 - EEP as preferred
 - Peak to adjust Tidal Volume
 - Inspiratory Flow to adjust Minute Volume.

Sedation, relaxation, and weaning

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.

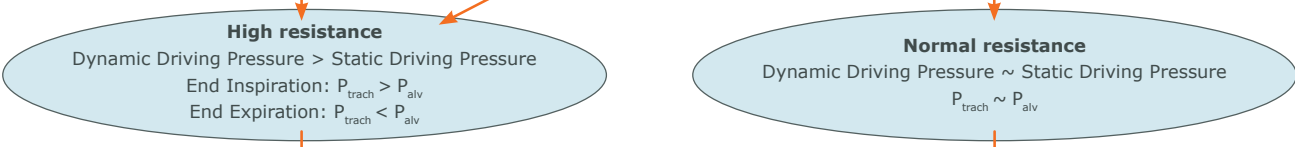
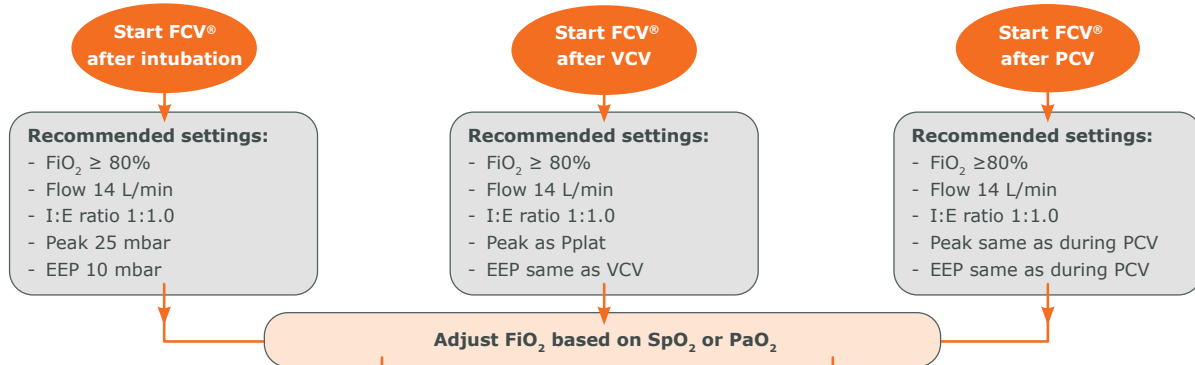
For weaning the patient:

- Set FiO₂ as preferred.
- Disconnect CTA from tube to allow weaning using preferred other mechanical ventilator.

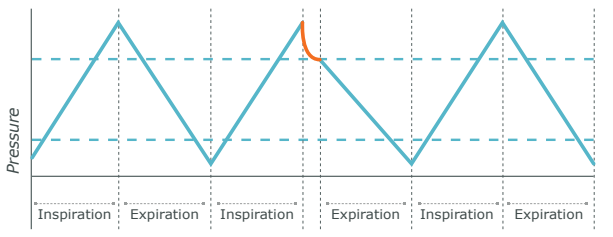




IN CASE OF ARDS- / COVID-19 PATIENTS



Confirm pressure settings by judging the plateau pressure displayed every 10 cycles in the pressure curve (orange part in curve in figure below)



Note: The absolute discrepancy in pressure between the dynamic intratracheal pressures and static (mean alveolar) pressure increases with higher airway resistance and/or higher inspiratory and expiratory flow.

Note: When the similar pressure settings of PCV or VCV in FCV[®] result in too small tidal volumes, it is suggested to first increase driving pressure (increase Peak and /or decrease EEP) before starting optimization.

Reassess the FCV[®] settings intermittently (e.g. 3 and 6 hours after initiating FCV[®] and longer intervals of e.g. 12 hours if situation is stable; new arterial blood gas analyses may be considered).

References:

- 1 Bergold M et al. *Flow-controlled ventilation: A novel approach to treating severe acute respiratory distress syndrome.* Poster WAMM 2019
- 2 Spraidler P et al. *Individualized flow-controlled ventilation compared to best clinical practice pressure controlled ventilation: a prospective randomized porcine study.* Int J Crit Care 2020 Nov 25;24(1):662

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.
- 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}.
- 3 Find 'Best flow'
 - Adjust flow depending on measured etCO₂ and/or PaCO₂.
 - To reduce etCO₂ and/or PaCO₂: increase inspiratory flow
 - Results in higher frequency with same V_T and higher minute volume.
 - To increase etCO₂ and/or PaCO₂: decrease inspiratory flow
 - Results in lower frequency with same V_T and lower minute volume.

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