EVONE® – FLOW-CONTROLLED VENTILATION (FCV®) IN THE ICU – QUICK REFERENCE CARD

! 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 PEEP pressures
- Linear increase and decrease of intratracheal pressure
- For applying FCV® effectively the airway needs to be sealed with a cuff

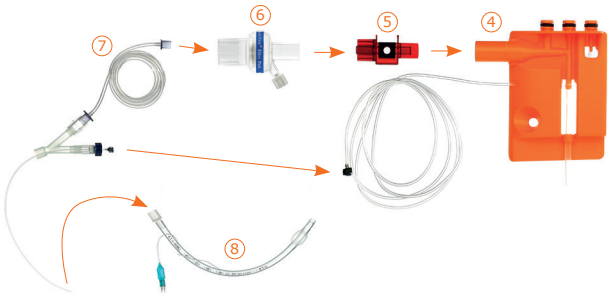
Evone is intended to be used by or under **direct and undivided supervision of an anesthesiologist or intensivist** in all settings.

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

Installation and set up

1 Switch on Evone and perform Startup checks successfully.
2 Patient set up menu: select patient gender and fill out characteristics. Accept default settings.

The settings have to be adjusted according to the following situations:

A Start FCV® (patient was not on other mechanical ventilator) EEP: min. 10 mbar, Peak 25 mbar (driving pressure 15 mbar), FiO_2 min. 80%, Flow start at 14 L/min.
B Switch from VCV to FCV®: Use same PEEP value of VCV for FCV®, use Plateau pressure for Peak FCV® (not mean pressure!).
C Switch from PCV to FCV®: use same P(EEP) and Peak pressures.

3 Check and if required adapt alarm limits.
Note: Setting alarm limits towards extreme values may render the alarm system useless.

Start FCV® ventilation

A In case patient is not yet mechanically ventilated:
1 Induce anesthesia (TIVA).
2 Intubate patient as usual with tube of choice (ID ≥ 5mm).
3 Oxygenate patient as preferred to allow deepening of anesthesia.
4 Connect tube to CTA of Evone when anesthesia is deepened.
5 Recommended settings: FiO_2 min. 80%, Flow start at 14 L/min, Peak 25 mbar, PEEP 10 mbar.

B In case patient has been ventilated in VCV mode:
1 Connect CTA to endotracheal tube.
2 Recommended settings: FiO_2 min. 80%, Flow start at 14 L/min, Peak as Pplat during VCV (not Pmean!), PEEP same as during VCV.

C In case patient has been ventilated in PCV mode:
1 Connect CTA to endotracheal tube.
2 Recommended settings: FiO_2 min. 80%, Flow start at 14 L/min, Peak and PEEP same as during PCV.

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

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 PEEP'
- Increase both PEEP and Peak stepwise by 1-2 mbar; keeping driving pressure (Peak – PEEP) constant.
- Monitor tidal volume (V_T): Increased VT indicates increased respiratory system compliance (C_{RS}) and improved ventilation.
- Choose PEEP setting resulting in highest V_T; for similar V_T choose lowest PEEP 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'
- Increase 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 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.
- Deepen anesthesia.
- Reconnect CTA when anesthesia is deepened and continue FCV® ventilation.

For weaning the 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. *Improved ventilation and lung recruitment in flow-controlled ventilation (FCV) compared to pressure-controlled ventilation (PCV) – A prospective, randomized porcine study.* Abstract presented ESICM 2019 and AIC 2019

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