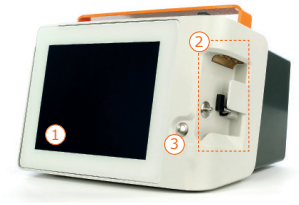
EVONE® – FCV® IN THE ICU – APPLICATION NOTE

! This information does not replace the Instructions for Use !

- FCV® allows safe and efficient ventilation of fully sedated 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.

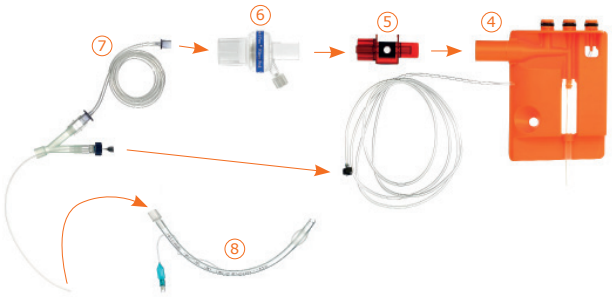
Evone Control Unit



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:

- FiO_2 50%
- Inspiratory Flow 12 L/min
- I:E ratio 1:1.0
- Peak 15 mbar
- EEP 5 mbar

Ventilation with conventional tubes

1 Sedate the patient (TIVA).
2 Intubate patient as usual with tube of choice.
3 Oxygenate patient as preferred to allow deepening of sedation.
4 Connect tube to CTA of Evone when sedation 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:
- FiO_2 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 sedation (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 sedation.
- Reconnect CTA when sedation is optimized and continue FCV® ventilation.

For weaning the patient:
- Set FiO_2 as preferred.
- Disconnect CTA from tube to allow weaning using preferred other mechnical ventilator.

IN CASE OF ARDS- / COVID-19 PATIENTS

Start FCV® after intubation

Recommended settings:
- FiO_2 ≥ 80%
- Flow 14 L/min
- I:E ratio 1:1.0
- Peak 25 mbar
- EEP 10 mbar

Start FCV® after VCV

Recommended settings:
- FiO_2 ≥ 80%
- Flow 14 L/min
- I:E ratio 1:1.0
- Peak as Pplat
- EEP same as VCV

Start FCV® after PCV

Recommended settings:
- FiO_2 ≥80%
- Flow 14 L/min
- I:E ratio 1:1.0
- Peak same as during PCV
- EEP same as during PCV

Adjust FiO_2 based on SpO_2 or PaO_2

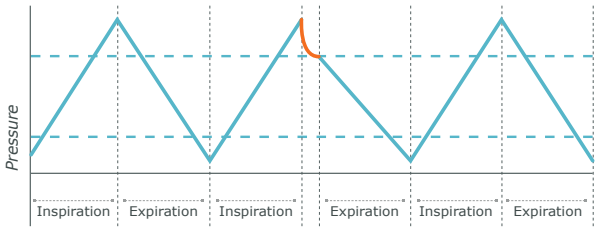
Obstructive problems
(e.g. COPD / asthma)
High resistance

Restrictive problems
(e.g. pneumonia, ARDS)
Low compliance

High resistance
Dynamic Driving Pressure > Static Driving Pressure
End Inspiration: $P_{trach} > P_{alv}$
End Expiration: $P_{trach} < P_{alv}$

Normal resistance
Dynamic Driving Pressure ~ Static Driving Pressure
$P_{trach} \sim P_{alv}$

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



- Intratracheal Pressure (dynamic)
- Intratracheal Pressure (static)
- Schematic range mean alveolar pressure

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).

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 2 minutes.

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 $etCO_2$ and/or $PaCO_2$.
- To reduce $etCO_2$ and/or $PaCO_2$: increase inspiratory flow
  - Results in higher frequency with same V_T and higher minute volume.
- To increase $etCO_2$ and/or $PaCO_2$: 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.

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.* Int J Crit Care 2020 Nov 25;24(1):662

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