REDEFINING VENTILATION

Flow-Controlled Ventilation

Evone®

We can ventilate so much better ...

VENTINOVA MEDICAL

REDEFINING VENTILATION

Flow-Controlled Ventilation

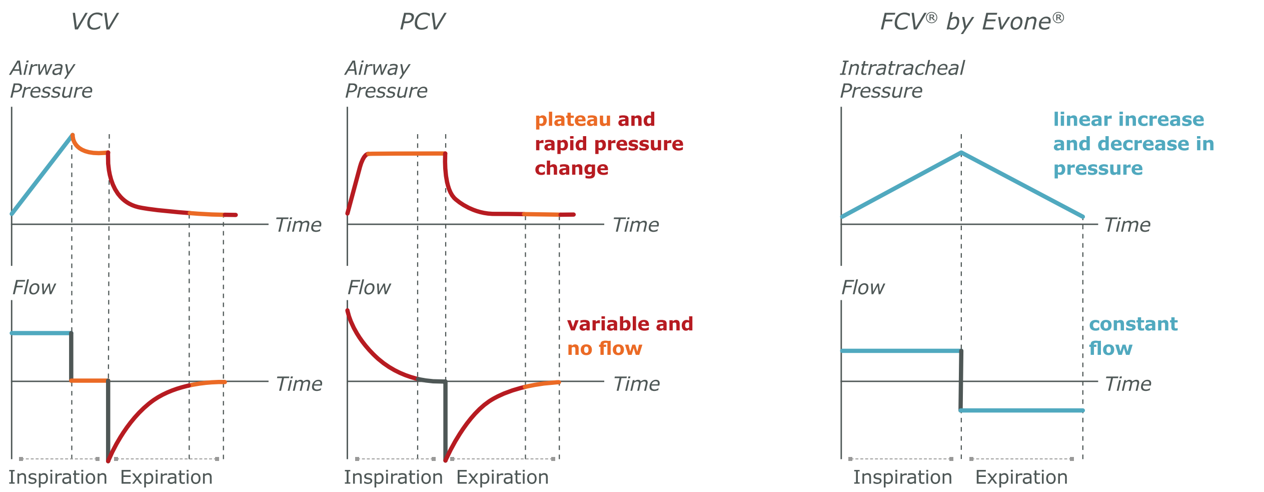
Ventinova Medical introduces **Evone®**, the first and unique mechanical ventilator that provides Full-Controlled Ventilation of the entire ventilatory cycle.

Evone® is an innovative mechanical medical ventilator, based on Flow-Controlled Ventilation of both inspiratory and expiratory flow.

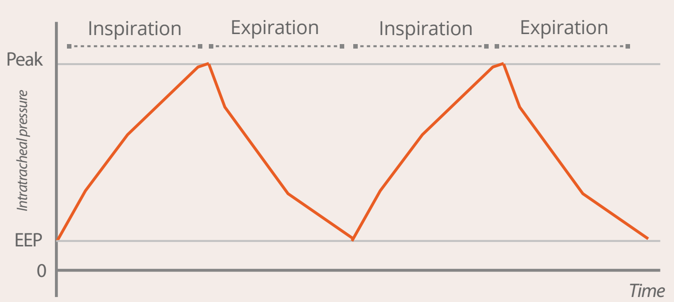
FCV® creates a stable gas flow into or out of the patient's lungs to generate an inspiration or expiration, respectively.

FCV® has an entirely dynamic Flow Profile, without pauses, aiming for linear changes in both volume and pressure. There are no abrupt intrathoracic pressure drops because of the controlled espiration.

- continuous,
- linear
- identical inspiration: expiration (I:E) flow



FCV Mode intratracheal pressure profile



Inspiration is performed with the set (constant) Inspiration Flow until the intratracheal pressure reaches the set Peak pressure.

Evone® then starts an actively supported **expiration** phase resulting in controlled decline in intratracheal pressure until EEP and the set I:E is reached.

Evone® provides a meticulous DYNAMIC MEASUREMENT performed during both inspiratory and expiratory flow

Such reliable lung-mechanical data even permits a unique way of INDIVIDUALISED VENTILATION

The FCV® ventilation cycle is governed by four operator settings only:

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

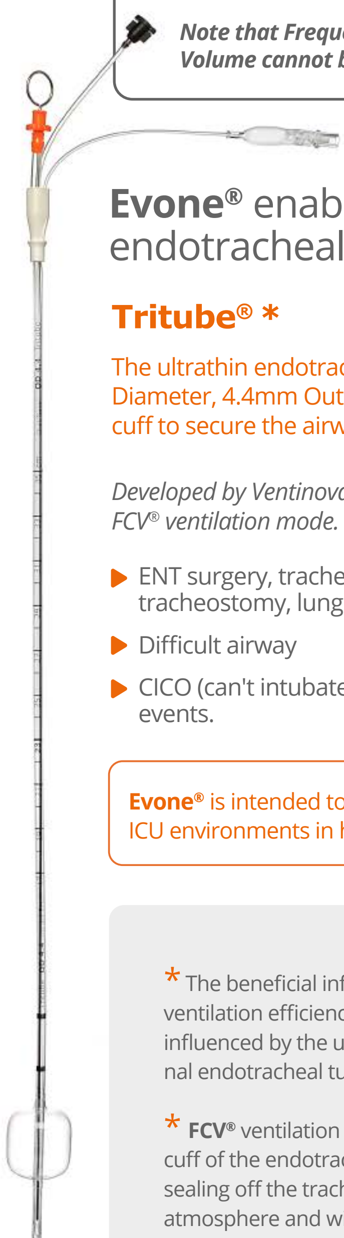
- **Therefore only the set flow and I:E ratio determine a patients minute volume.**
- **Set Peak and EEP determine the inspiratory volume.**
- **Ventilation frequency is a result of parameter settings and does not affect minute volume.**

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

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
- ✔ Better aeration of the lungs
- ✔ Higher ventilation efficiency (oxygenation and CO2 removal)
- ✔ Lower energy dissipation in the lungs
- ✔ **Evone®** provides safe and efficient ventilation through small bore and large bore



Evone® enables Full-Controlled Ventilation of a patient using various endotracheal tubes (~2 mm ID to ~10 mm ID).

Tritube® *

The ultrathin endotracheal tube, (2.5mm Internal Diameter, 4.4mm Outer Diameter) with an inflatable cuff to secure the airway.

Developed by Ventinova for small lumen FCV® ventilation mode.

- ENT surgery, trachea resection, tracheostomy, lung surgery.
- Difficult airway
- CICO (can't intubate, can't oxygenate) events.

Evone® is intended to be used in operating rooms and ICU environments in hospitals. All patients >40 Kg. IBW

* The beneficial influence of **FCV®** on the ventilation efficiency or low energy is not influenced by the use of the CTA with a conventional endotracheal tube or Tritube.

* **FCV®** ventilation can only be applied when the cuff of the endotracheal tube is fully inflated, sealing off the trachea from the ambient atmosphere and with total intravenous anesthetized (TIVA) patients.

Conventional Tube Adapter (CTA)*

The conventional adapter developed by Ventinova provides **FCV®** ventilation mode throught any conventional endotracheal tube.

Conventional endotracheal tubes (size 5-10 mm ID).

During surgery in patients prone to desaturate or to develop atelectasis (e.g. obese patients, laparoscopic surgery); **FCV®** improves gas exchange and aeration.

Double lumen tubes to allow one and two lung ventilation.

During (cardio-) thoracic surgery, when connected to a double lumen tube; **FCV®** may result in an improved ventilation efficiency during one-lung ventilation.

(laser resistant) MLT-5 and MLT-6.

During laryngeal surgery, when CTA is connected to (laser resistant) MLT-5 or MLT-6; **FCV®** provides highly efficient ventilation.

Higher **Efficiency**

"FCV keeps the lung open in a very smooth way"

Prof. Dr. med. Dietmar Enk
Inventor / Anesthesiologist / Intensivist, University Münster, Germany

- **FCV®** uses relatively low flow rates that range typically between 8 and 16 L/min to adequately ventilate a patient.
- At these lower flows, gas is better able to reach the lung units that have higher resistance and the dependent lung parts, that have a better perfusion.
- By controlling the expiration flow, **FCV®** maintains airway pressure and keeps the gas longer in the alveoli.
- Thus, **FCV®** can avoid or delay airway and alveolar collapse, and thereby avoid atelectasis while improving gas exchange.
- Together, **FCV®** results in a higher efficient ventilation as compared to conventional ventilation techniques.

Improved regional ventilation in obese patients by FCV®

The first clinical study comparing ventilation of obese patients with **FCV®** vs VCV was published in BMC Anesthesiology by Weber et al. With comparable tidal volumes and lower peak pressures, **FCV®** better maintained end-expiratory lung volume as compared to VCV (P<0.001) during only seven minutes of ventilation, respectively. This strongly indicates that the constant expiratory flow during **FCV®**, in combination with an elevated mean intratracheal pressure, ***has a recruiting effect and may help to prevent atelectasis often occurring during ventilation of obese patients.***

FCV® beneficial during one lung ventilation of COPD patient

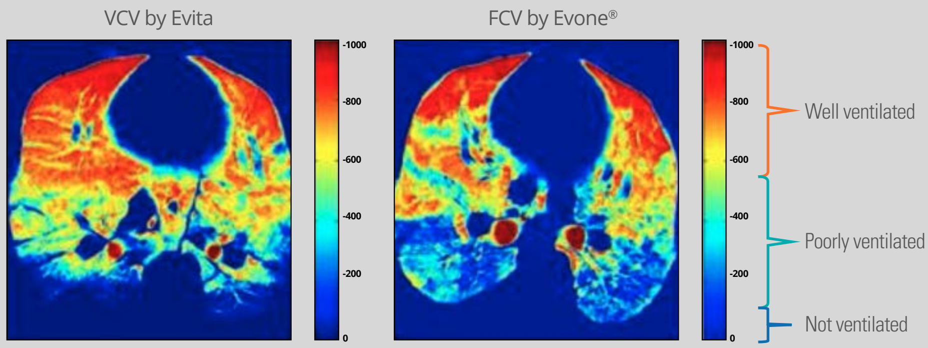
A COPD patient undergoing open thoracic surgery for esophageal resection was successfully ventilated with Evone. Ventilation with **FCV®** led to very stable respiratory parameters: with an FiO2 (fraction of inspired oxygen) of only 30%, an oxygen saturation of 99-100% was maintained throughout large phases of the intervention. The anesthetists appreciated the benefits of **FCV®** ***"With conventional ventilation, usually an FiO2 of 80% would be required to reach comparable saturation." Meanwhile, the surgeons were satisfied with the calm operation field: "It seems as if nothing is moving!"***

FCV® adequately ventilated one lung in challenging patient case

Prof. Dr. med. Arnd Timmermann, Chefarzt Anesthesiology, DRK Kliniken Berlin | Westend und Mitte, Germany, used **Evone** ®in a special case of one lung ventilation. Surgical removal of a large thoracic wall tumor required ventilation of only the right lung, which was significantly reduced in size due to a previous medical condition. Using Tritube inside a double lumen tube, the right lung was adequately ventilated with **FCV®**, while the patient remained stable throughout the procedure. The surgeon: ***"Absolutely smooth movements of the ventilated lung and the heart, which does not disturb my operation field."***

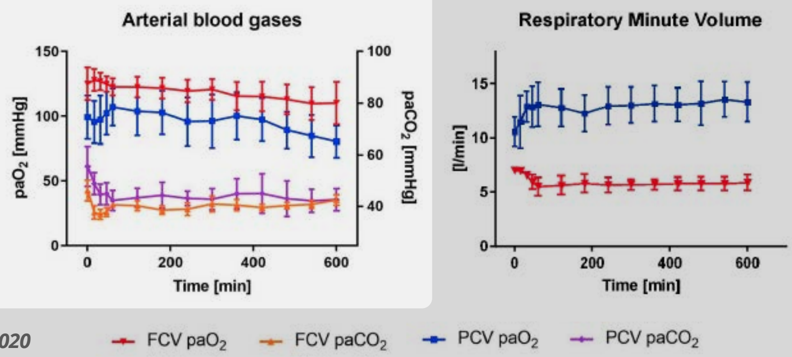
Dynamic CT scans after 180 min for FCV and VCV

FCV® allowed significantly higher efficient ventilation lung-sick pigs



Adapted from Schmidt et al., Crit Care Med 2020

- FCV allowed higher efficient ventilation with significantly improved gas exchange
- FCV improved lung recruitment and maintained better lung aeration
- Evone allows individual optimization of ventilation settings based on compliance



Adapted from Spraider et al, Crit Care 2020

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:

- Keeps the lung open by controlling the full ventilation cycle
- Results in better lung recruitment as compared to VCV and PCV
- Results in better aeration of the lungs as compared to VCV and VCV
- Provides higher efficient ventilation as compared to VCV, and PCV, evidenced by improved oxygenation and CO2 removal
- Reduces atelectasis in dependent lung parts as compared to VCV in porcine ARDS and morbidly obese patients
- **Evone®** allows individual optimization of ventilation settings based on compliance

Lower **Energy**

> *"Dissipated energy is minimized when FCV is used"*

Prof. emer. Tom Barnes
Fellow of the Institute of Physics, London, UK

Conventional mechanical ventilation generates more power than is needed to induce inspiration and expiration. The net overspill of energy is dissipated in the lungs, which has been shown even when applied for only a few hours to be a source of lung injury, so-called 'ventilator-induced lung injury' (VILI).

As energy dissipation can be calculated based on factors such as pressures, flow and respiratory rate, independent top leaders in the field postulated that the ideal ventilator should monitor and display energy dissipation in order to really apply 'safe' ventilation.

Over the last decades, innovative 'lung-protective ventilation' approaches have been developed to reduce VILI in the context of the two current golden standard ventilation techniques Pressure Controlled Ventilation (PCV) and Volume Controlled Ventilation (VCV).

Up to now, these strategies are limited to suggested values for tidal volume settings (6 mL/kg of predicted body weight), positive end expiratory pressure (PEEP) and plateau pressure in a "one size fits all" fashion.

Conventional mechanical ventilation: A cause of lung damage Ventilator-Induced Lung Injury (VILI)

- ✖ Mechanical ventilation applies energy to the respiratory system
- ✖ Excess energy is dissipated into the lungs and is a key factor for VILI
- ✖ Passive expiration is a source of dissipated energy
- ✖ Occurs frequently, even when ventilation is applied only for a few hours
- ✖ Is associated with high mortality rates on intensive care units (ICUs)
- ✖ Ideal ventilator should display energy dissipation, allowing 'safe' ventilation to be applied

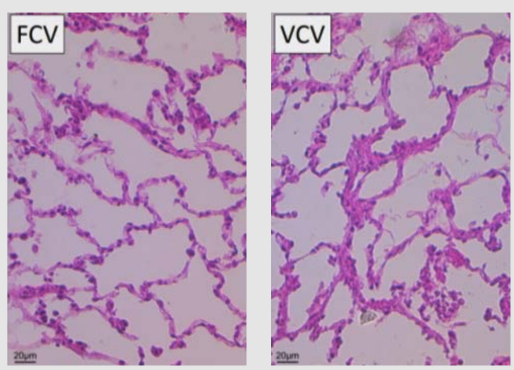
While current 'protective' ventilation strategies mainly focus on optimizing inspiratory ventilation, the passive and abrupt expiration that occurs with conventional methods is considerably relevant and potentially a key factor in inducing lung damage.

FCV® results in lower energy dissipation

FCV® is based on the generation of a constant flow into and out of the lungs, resulting in linear increases and decreases of intratracheal pressures that are just high or low enough to facilitate mechanical breathing with efficient gas exchange.

The sudden alveolar pressure drop during passive expiration with conventional ventilation is prevented. In other words, the amount of energy generated by the ventilator is just enough to facilitate respiration.

Thereby, the impact on the lung tissue by dissipated energy is kept to a minimum, enabling ventilation with a markedly reduced risk of lung damage.



Stained lung tissue samples retrieved after VCV or **FCV®** ventilation of ARDS pigs, revealing less thickening of alveolar walls in **FCV®** group, cell infiltration was lower, and surfactant protein A concentration was higher in the FCV® group, indicating the potential for **FCV®** to attenuate lung injury and to provide lung-protective effects.

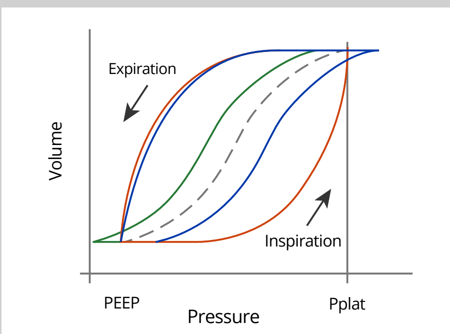
Adapted from Schmidt et al. 2018

Recently, clear theoretical evidence was provided for lower energy dissipation in the lungs by **FCV®** as compared to VCV or PCV. A relatively simple analysis and numerical calculations indicated that energy dissipation is minimized by controlling the ventilation flow to be constant and continuous during both inspiration and expiration, and by ventilating at an I:E ratio close to 1:1. In other words, by using **FCV®**

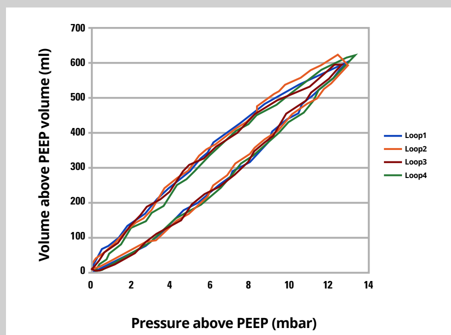
Energy dissipation can be calculated from the hysteresis area of pressure-volume loops obtained during ventilation. PV loops calculated based on routine ventilation protocols showed a 53% reduction in energy dissipation by **FCV®** as compared to PCV and a 32% reduction as compared to VCV .

Additionally, it was emphasized that accurate measurement of intratracheal pressures is crucial for calculating energy dissipation. Where other VCV and PCV ventilators rely on calculated airway pressures, Evone is the only device that actually measures intratracheal pressures and is thus capable of measuring energy dissipation accurately.

This theory was further validated on a patient. Pressure-volume (PV) loops were recorded in real time, and the energy dissipated in the patient's lungs was calculated from the hysteresis area of the PV loops. Strikingly, the energy dissipation was just 0.17 J/L, which is even lower than values reported for spontaneous breathing (0.2–0.7 J/L)



Left: Idealized PV loops (the enclosed area of each loop is the dissipated energy) during PCV (red line), VCV (blue line) and **FCV®** (blue line during inspiration, green line during expiration). The dashed line is the static compliance curve of the lung/chest system in this example.



Right: Real-time measured PV loops of a patient ventilated with **FCV®**, demonstrating minimized hysteresis area of the PV loops (=energy dissipation).

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:

- **FCV®** results is smooth tidal movements of the diaphragm and thoracic wall throughout the ventilation cycle.
- **FCV®** controls expiration and prevents abrupt airway pressure drop.
- Relies on accurately measured intratracheal pressures and inspiratory flows, allowing precise calculation of energy dissipation
- Hysteresis area of pressure-volume loops reflects the energy dissipated
- Constant gas flow in combination with an I:E ratio of 1:1 minimizes energy dissipation down to values reported for spontaneous breathing
- Provides ventilation with reduced mechanical power compared to VCV and PCV.
- Has lung-protective potential

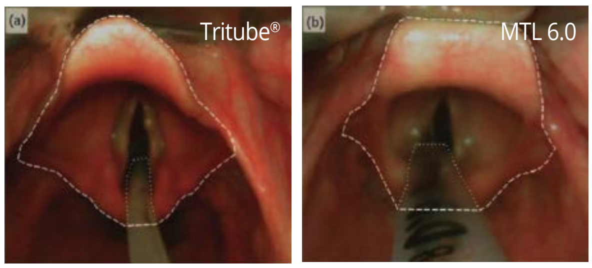
Small **Lumen**

> *"Tritube makes my life so much easier, as it provides a great view and an effective ventilation in the compromised airway"*
>
> **Prof. Dr. Hans Mahieu**
> Laryngologist, Meander Hospital Amersfoort, The Netherlands

Surgical and lung mechanical benefits of Tritube and FCV during laryngeal surgery

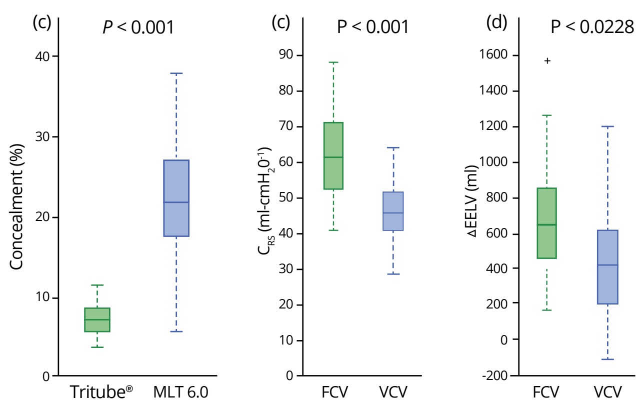
In the first randomized controlled trial Dr. Schmidt and colleagues showed clear clinical benefit of using Tritube and **FCV®** over using a microlaryngeal tube (MLT-6) and Volume-Controlled Ventilation (VCV) in patients undergoing laryngeal surgery.

Tritube significantly reduced the concealment of laryngeal structures and thereby improved surgical conditions for surgeons with a lower level of expertise. Furthermore, the authors demonstrated that **FCV®** enhanced lung aeration and improved the respiratory system compliance, while using similar PEEP and a lower inspiratory plateau pressure.



Glottic visibility for laryngeal surgery: Tritube vs. microlaryngeal tube

- ✔ **Tritube®** improves surgical conditions for surgeons.
- ✔ **FCV®** enhances alveolar recruitment and improves lung aeration compared to VCV.



Ultrathin Tritube allowed safe intubation and ventilation in extremely narrow airway

In a patient with extreme airway obstruction due to a huge thyroid enlargement, Evone and Tritube prevented the use of ECMO to allow required surgery, as reported by Dr. Nabil Shallik (Hamad Medical Corporation, Qatar). Preoperative examination of the patient revealed a severe tracheal stenosis with a residual airway opening of only 4 mm, excluding the use of conventional endotracheal tubes to apply controlled ventilation. Instead, Tritube could be passed through the stenosis and allowed adequate ventilation using Evone during the six hour surgery

Shallik et al. Qatar Med J. January 2021 | Volume 2020 | Article 48

Potential Benefits

The following benefits as compared to Volume Controlled Ventilation (VCV) and Pressure Controlled Ventilation (PCV) with conventional endotracheal tubes may be expected while ventilating patients in **FCV®** mode with ultrathin **Tritube®**:

- Provides an easier intubation especially in difficult airways
- Provides unprecedented view of the intubated airway during oral, pharyngeal, laryngeal or tracheal procedures in adults
- Provides improved surgical exposure as compared to an MLT-6
- Clear sight and non-vibrating vocal cord
- Offers several new surgical options for treatment during ENT/laryngeal/tracheal surgery
- Allows awake tracheal placement
- Allows adequate ventilation of adults in combination with Ventrain or Evone
- Is well tolerated in awake patients (>1 hour after surgery!) at least as well tolerated as an airway exchange catheter
- Allows talking of intubated patients
- Allows mask ventilation of intubated patients
- Reduces the risk on aerosol generation as compared to ventilation in an open airway

Jet Mode

Additionally, Evone has a (High Frequency) **Jet Ventilation mode**, which requires an open airway.

The Jet Mode, can be postoperatively used to liberate the patient from mechanical ventilation and to stimulate spontaneous breathing.

The maximum driving pressure is limited to 1.5 Bar.
Jet mode shall only be used with Tritube, not with conventional endotracheal tubes, with the cuff of Tritube fully deflated to enable expiratory gases to freely egress.

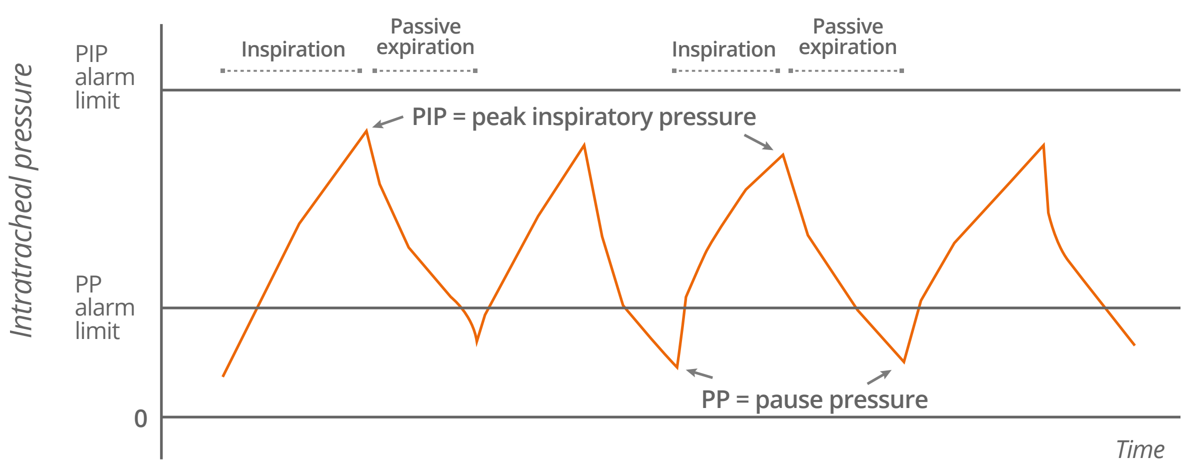
The Jet cycle is governed by three operator settings being:

- Frequency
- Inspiration Percentage
- Driving Pressure

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.

Jet Mode intratracheal pressure **: typical sequence of Jet breathing cycles is shown.**



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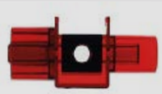

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