CoroVent device schema and description

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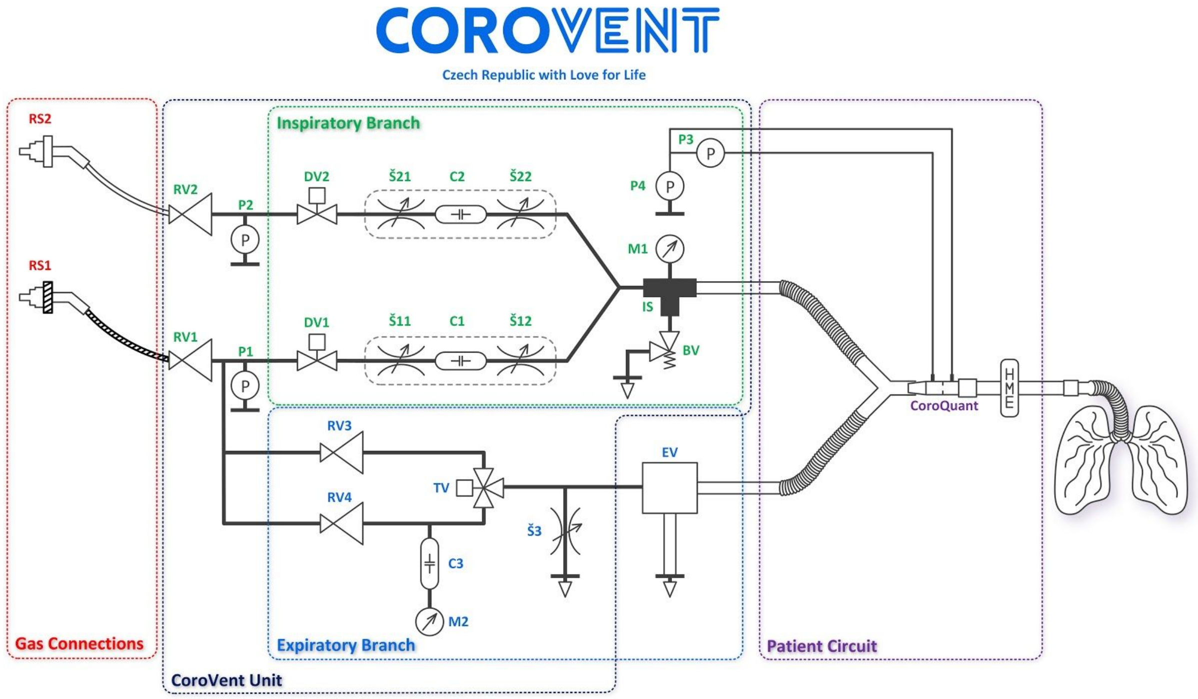
Pneumatic schematics of the device follows. The color coding used in the chart for various blocks/subsystems matches the color of corresponding titles in the following text.



List of the components:

Gas Connections

- RS1 medicinal air connector, male
- RS2 medicinal oxygen connector, male
- RV1 reduction valve for air
- RV2 reduction valve for oxygen

Inspiratory Branch

- DV1 electrically controlled 2/2 valve for air
- DV2 electrically controlled 2/2 valves for oxygen
- Š11 primary throttle valve for air
- Š12 secondary throttle valve for air
- Š21 primary throttle valve for oxygen
- Š12 secondary throttle valve for oxygen
- C1 compliance in the air circuit
- C2 compliance in the oxygen circuit

- M1 pressure gauge indication pressure (Ppo) in the patient circuit
- BV safety pressure relief valve
- IS inspiratory node equipped with a port for connection with the patient circuit

Expiratory Branch

- EV expiratory valve
- RV3 reduction valve for pressure control of PEEP
- RV4 reduction valve for pressure control of Plim
- M2 pressure gauge indicating the preset Plim
- C3 compliance stabilizing pressure gauge M2 reading
- TV electrically controlled pneumatically driven 3/2 valve
- Š3 throttle valve

Gas connections

Hose adapters connect the ventilator to the hospital air and oxygen supply systems. The pressure range for input is approximately 0.4 MPa (0.35-0.6 MPa).

Air Connection

The air branch starts with a medicinal air connector, male (according to the EN ISO 7396-1). This connects to the hospital system).

An alternative is considered, providing an additional outlet at the connection point, to allow for connecting of an additional device. In that case, the air branch starts with a T fitting, with:

- medicinal air connector, male (according to the EN ISO 7396-1). This connects to the hospital system
- medicinal air connector, female. This provides additional connection for further device(s) if required.
- barbed fitting that connects the air hose (black/white according to the EN ISO 7396-1), leading to the ventilator itself.

Oxygen Connection

The oxygent branch is identical in design, just the connectors are suitable for oxygen and the hose itself is white (EN ISO 7396-1).

Pressure Reducing Valves

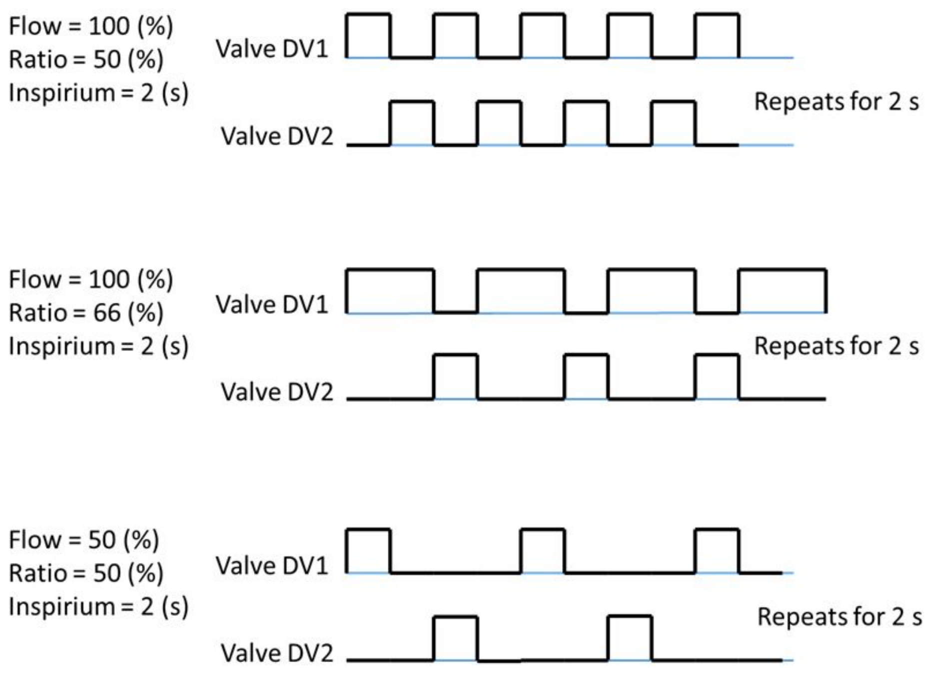
The intake hoses are connected to the pressure reducing valves RV1 and RV2 inside the ventilator. They reduce the pressure from the hospital manifold to the working pressure of the ventilator, when the recommended value of this working pressure is 0.2 MPa for both air and oxygen. Pressure reduction valves must allow sufficient gas outlet flow (min 55 L/min, preferably 60 L/min, SLPM). Reduction valves must also have approximately the same pressure drop when the 2/2 valves in the oxygen and air branches are opened so that the flows generated have the same impedance characteristics.

It is important that the pressure reduction valves are mounted inside the ventilator enclosure in a way that their output pressure can be adjusted only during service calls by qualified personnel.

Inspiratory Branch

Tubing inside the ventilator unit is, unless otherwise stated, made with tubing and fittings for 6 mm tubing outer diameter.

Two quick, electrically controlled 2/2 valves are used to control inspiration. Both valves utilize pulse width modulation (better known from electronics) to generate inspiratory flow and control the fraction of oxygen in the ventilation mixture. At the same time they are able to control the inspiration time and the number of breaths per minute by interrupting this flow. The principle is that the valves alternate as much as possible their respective open and closed states so that the resulting flow is as smooth as possible. An example is shown in the following figure:



It is also critical to understand the minimum time required to open and close the valves (not just reading the datasheet, lab measurement is needed). It is then necessary to adjust the working frequency of the valve accordingly so that it is still possible to control the oxygen fraction with sufficient accuracy even when minimum tidal volumes are generated (that is, to allow the valve to open perfectly even at extreme fraction and volume settings).

Oxygen Branch

Working gas pressure sensor

The sensor is used to monitor the oxygen pressure in the Inspiration branche. It should have at least 0.3 MPa range. Based on the sensor data, alarms are provided:

- low oxygen pressure
- a large difference in gas working pressures
- 2/2 valve malfunction - for this alarm, pulse drops of working pressures are observed when the gas flows through the valve, which serves as an evidence of the valve opening.

2/2 Valve

Used to control the oxygen fraction in the ventilator mixture, tidal volume, respiratory rate and inspiratory / expiratory time ratio. It is important to use valves with the longest possible service life (ideally billions of cycles). The valve shall not restrict the flow of oxygen through the line at a pressure below 60 L/min.

Pulse Filter

Serves to smooth the inspiratory flow. It consists of two throttle valves and a compliance between them. The compliance is in the form of a rigid tube with an inner diameter of 35 mm and the length of 160 mm. For throttle valve settings, see the Ventilator Settings section. The tubing connecting the throttle valves should be as short as possible. Shortening the tubing connecting the 2/2 valve and the first pulse filter throttle to the shortest length is essential for proper breathing volume control.

Air Branch

Designed similarly to the oxygen branch. In front of the 2/2 valve, a pressure supply hose is supplied from the valve to control the expiratory valve.

Air and Oxygen Branch Connection

Both branches are connected to the T-junction with medical dimensions (22mm male conus at the outlet of the ventilator, 22mm internal conus for pressure relief valve connection).

Coupling IS

Coupling IS is a part made ideally out of metal (at least the part that protrudes from the ventilator and to which the ventilation circuit connects must be a standard 22M medical cone, according to ČSN EN ISO 80601-2-12 it must be made out of metal for durability). It is not necessary for the part to be exactly T-shaped. It connects the pneumatic circuits of the inspiratory branch with the patient circuit and the pressure relief valve.

Pressure Relief Valve (safety valve)

The pressure relief valve serves to protect the patient from airway pressures higher than 6 kPa (approx. 60 cmH2O) according to the ČSN EN ISO 80601-2-12 standard. For its proper functioning it is essential that it is connected to the ventilation circuit by a low impedance line (the internal diameter of the piping connecting the pressure relief valve and the ventilation circuit must be comparable to the internal diameter of the patient circuit). The pressure relief valve is connected to the IS coupling.

“Ppo” Pressure Gauge

Pressure gauge at the inlet to the patient circuit. This pressure (Ppo) is approximately the same as the measured pressure in the Y-piece of the patient circuit (Paw) and can, therefore, be referred to as Paw (airway pressure, Pressure in the AirWays) with a certain imprecision. This pressure gauge must be placed as close as possible to the connection port to the patient circuit, ideally at the IS coupling.

Patient Circuit

The standard patient circuit is a consumable to the ventilator. CoroVent is designed to be compatible with conventional patient circuits with a Y-piece and two separate hoses for the inspiratory and expiratory limbs. CoroVent is not suitable for use with a coaxial patient circuit.

Standard Patient Circuit

This is a consumable that changes with each new patient at the latest. In case of insufficient number of patient circuits, a medical Y-piece with a 22 mm male outer and 15 mm female cone at all three ends can be used. Typically 160 cm corrugated hoses (forming the inspiratory and expiratory limbs) are attached to the two ends of the Y-piece and a measuring sensor CoroQuant attached to the third end.

Measuring sensor CoroQuant

It is a measuring element of the patient's airway pressure (Paw) and the patient's flow rate (Qaw). The whole element acts as an obstruction orifice, on which the flow of gas through the obstacle creates a pressure drop, which can be measured by a differential sensor. The relationship of pressure drop across the flow is more or less parabolic. On CoroQuant, there are two fittings (one in front of the obstacle and one behind the obstacle) for a 2.5 mm hose. Using tubing mounted on the measuring outlets, the pressure from the outlets is transferred to the ventilator, where it is connected to a differential pressure sensor (for Qaw) and a sensor for measuring atmospheric overpressure (for Paw). Orifice to ventilator tubing must be rigid enough and must not be significantly longer than the patient circuit to avoid affecting the measured pressures.

Expiratory valve control + expiratory circuit

Expiratory Valve

An expiratory valve is the element that closes the expiratory limb of the patient circuit at inspiration and opens the limb at expiration. In inspiration, it acts as a pneumatically controlled pressure relief valve to limit the maximum inspiratory pressure Plim in the patient circuit (patient). During expiration, it acts as a pneumatically controlled flow resistance, which can be used to regulate the positive end-expiratory pressure (PEEP) along with the expiration time. This valve design makes it possible to compensate for the added flow resistance of the exhalation filter included between the patient circuit and the expiratory valve during expiration. The control pressure setting the maximum inspiratory pressure in the patient circuit and the expiratory flow resistance is supplied to the valve from the expiratory valve control pneumatic circuits via a hose fitting with a 6 mm outside diameter hose.

The expiratory valve is designed for a control pressure to be ten times higher than the controlled pressure in the patient circuit. This is achieved by design of the piston with a tenfold pressure transformation. As a result, small pressures in the patient circuit (kPa units) can be controlled by higher pressures (tens of kPa), which are more readily available with commercially available reducing elements.

The expiratory valve must be manufactured either as a consumable, or it should be verified its stability, durability and sterilizability and use it as a sterilizable accessory.

Pressure Reducing Valve controlling Plimit (Plim)

It is a pressure reducing valve that controls the maximum possible pressure achievable in the patient circuit (Plim) by its outlet pressure. Useful outlet pressures are in the range of up to 50 kPa (which, after transforming the expiratory valve pressures, means pressures in the patient circuit up to 5 kPa).

It is important that this pressure relief valve allows a precise adjustment of the outlet pressure without ripple when opening and closing the 3/2 valve connected to the pressure relief valve outlet. Furthermore, it must respond quickly enough to the pressure drop in the outlet tubing so that the pressure drop is not noticeable on the expiratory valve. Otherwise, due to the drop and subsequent back pressure build-up, the piston in the expiratory valve causing a pressure surge propagates into the patient's respiratory system. Partial compensation of this surge can be achieved by a compliance connected to the pneumatic line between this pressure reducer and the 3/2 valve.

Compliance

The compliance compensates pressure drop in the outlet pneumatic line from the Plim control valve. This compliance also serves as a low-pass filter to filter the pressure oscillations measured by a pressure gauge on which the ventilator operator sees the Plim control pressure.

In our case, the compliance was designed as a rigid tube with an inner diameter of 25 mm and length of 100 mm.

Pressure Gauge for Plim

Pressure gauge with a range of 0-60 kPa (or up to 1 bar). Ideally, it indicates kilopascals, because then (due to the pressure transformation at the expiratory valve piston 10:1) it is sufficient to rewrite the unit on the scale from “kPa” to “cm H2O” and the indicated value then directly corresponds to the set limit pressure in the patient circuit.

Pressure Reducing Valve controlling PEEP (Positive End-Expiratory Pressure)

This reducing valve controls the expiratory valve resistance during expiration. With this valve, it is important to quickly supply gas to the control line when the 3/2 valve is opened. Since PEEP is measured by the Paw pressure sensor and the Paw pressure gauge, there is no need to measure the pressure at the outlet of the PEEP control valve. Thus, in this pressure reducing valve, the gas supply rate is the most important and there are no such demands on the stability of the outlet pressure when opening and closing the 3/2 valve. Actually, we are currently using a slight increase in outlet pressure from the pressure reducing valve when closing 3/2 to accelerate the gas supply to the expiratory valve when opening the 3/2 valve.

3/2 Valve

It is an electrically controlled pneumatically driven valve. This valve switches the expiratory valve control pressure branch between the pressures at the PEEP and Plim pressure reducers outlets. The valve uses compressed air from the hospital manifold (more than 2.5 bar) for its actuation; therefore, extracting this compressed air before the air inlet valve. If the 3/2 valve's electrical control is de-energized, its output should be connected to the PEEP control pressure and not to the Plim control pressure. The same is true in case of failure / absence of valve actuating pressure. This is important for releasing gas pressure from the patient circuit during various unexpected events.

Throttle valve to relieve pressure in the expiratory valve control line

Is a throttle valve whose function is to release pressure from the expiratory valve control line at low flow rates (L/min). This function is important to ensure that the expiratory valve is released when switching to a lower control pressure (i.e. in order to generate PEEP) when the control pneumatic line and expiratory valve are tight. If the expiratory valve drops the desired pressure from the control branch around the inner piston (due to a parasitic leakage or an intended leakage assuring air lubrication) or the drop is facilitated via a calibrated orifice in the control branch, the described additional throttle valve will not be required.

Control Unit

The control unit provides ventilator control, measurement of ventilatory parameters, visualization of measured and set parameters and operator control of the ventilator. The layout of the screen and the way the ventilator is controlled is designed similarly to conventional ventilators. That way the operators do not need to get used to an unusual interface.

Ventilator Unit Control

This design represents a volume-controlled, pressure-limited ventilator. This determines the user-adjustable ventilation parameters (displayed in green text on the screen).

Adjustable parameters are:

- FiO2: oxygen fraction in the range of 0.21 - 1
- RR: respiratory rate in the range of 5 - 30 breaths per minute
- I:E: inspiratory / expiratory time ratio (1:1 - 1:3)
- Vt: tidal volume. Tidal volume is the product of the flow and the inspiration time (more precisely, a time integral of flow rate during inspirium for inspiratory tidal volume calculation and during expirium for expiratory tidal volume calculation). The inspiration time is defined by a combination of RR and I:E parameters. The flow rate can be changed by the Vt+ and Vt- buttons providing twenty steps between minimum and maximum flow (up to 50 L/min). This also ensures adjustment of the tidal volume. The set tidal volume must then be read from the measured parameters.

The system measures the following parameters (shown in white text on the screen):

- Vti: inspiratory tidal volume (mL)
- Vte: expiratory tidal volume (mL)
- PEEP: positive end-expiratory pressure (cm H_2O)
- Pmax: maximum pressure reached during inspiration (cm H_2O)
- Ti/T: ratio of inspiratory time to the breath cycle duration
- RR: respiratory rate (b/min, or simply bpm)

General Remarks

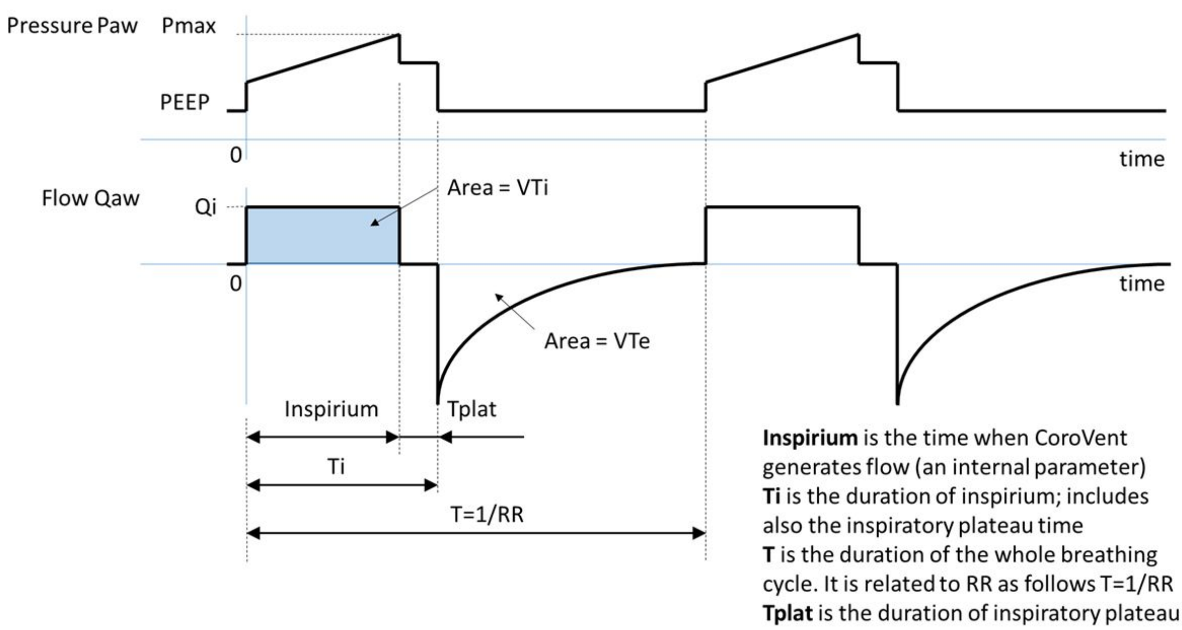
Compliances

The compliance of rigid containers depends almost entirely on the volume of the containers. However, the shape of such a container is also important in our case. The compliances are used as filter elements. Inertia of the gas in the compliances play an important role in filtering the pulsing signal as well.containers, serving as compliances. Therefore, it is best for the purpose to use cylindrical vessels (a larger diameter tubes), where the inlets and outlets are in the axis of these vessels on the opposing sides. This achieves the fact that the vessel ensures compliance and the pressure pulses are simultaneously attenuated over a sufficiently long path by the inertia of the gas in the vessel.

Medical properties of the ventilator and the generation of controlled breath

The ventilator includes one ventilation mode, suitable for patients with Covid-19 respiratory failure. It is a volume-controlled pressure-limited ventilation. This is fully autonomous ventilation without the possibility of synchronization with the patient's breathing effort. However, significant breathing effort of the patient is not expected due to the indications for which CoroVent is intended.

The idealized breathing pattern in the form of proximal Paw pressure and proximal Qaw flow is shown in the following figure. The picture also shows the proper meaning and explanation of the individual parameters of the controlled breaths.



The following pressures are critical for the patient safety:

- PEEP - is generated by the expiratory valve and can be adjusted by the PEEP driving pressure that can be adjusted by a control knob accessible from the front panel of the ventilator.
- Psafe - is the maximum safety pressure above which the patient circuit pressure is not allowed to rise. It is determined by the safety relief valve, factory set at 6 to 6.5 kPa, and cannot be changed by the operator.
- Plim - The limit pressure that can occur in the circuit. It can be set by a knob from the front panel of the ventilator to any value between PEEP to Psafe.

The ventilator is equipped with its own monitoring software, which operates independently of the ventilator control system. This means that it uses only the sampled Paw and Qaw flow rates to calculate the ventilation values achieved and subsequently displayed.