

Prevention of Barotrauma with CoroVent

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Patient safety was our top priority during CoroVent design and construction. As barotrauma represents one of the most dangerous adverse effects of mechanical ventilation, several independent means of protection were implemented.

The ventilator is designed so that a single fault or undesirable condition caused by the ventilator's operation (e.g., complete occlusion of the expiratory limb of the patient circuit, HW malfunction, etc.), will not endanger the patient's respiratory system by excessively high pressure.

In terms of protection against high pressures in the airways, four main principles apply in the following order according to detection and severity of unwanted increase in pressure in the patient's circuit:

1. Software Pmax (maximum pressure, peak inspiratory pressure, PIP) alarm (E13). The Pmax threshold value (Pmax max) may be changed by a user to a desired value up to 45 cm H₂O.
2. Alarm (E23) when Pmax exceeds 55 cm H₂O for 150 ms or longer (150 ms average prevents this alarm from being triggered by short pressure pulses that are not clinically important). Except for visual and audible alarms, this feature causes immediate initiation of expiratory phase when pressure in the patient's circuit exceeds 55 cm H₂O for 150 ms or longer. The threshold is set to 55 cm H₂O by the manufacturer and for safety reasons it cannot be increased by the user.
3. Setting the maximum pressure (Plim) achievable during ventilation. Setting is conducted using a knob on the front panel and indicated by a manometer on the front panel. Plim represents the pressure limitation of the ventilation mode "pressure limited volume controlled continuous mandatory ventilation". This is a pressure value, which may appear as the maximum in the patient circuit during a regular operation and ventilation. The minimum adjustable value is 15 cmH₂O and the maximum adjustable value is 45 cmH₂O.

This safety measure is purely assured by hardware and would work even if the software or the control system of the ventilator fails. During ventilation, it is not possible to exceed the set Plim pressure limit; when the pressure would rise above Plim, the expiratory valve will not allow the pressure increase. Even during inspiration, the expiratory valve would be partly open so that the maximum pressure in the patient's circuit is always below or equal to the preset Plim value.

The functioning of pressure limitation is documented in Fig. 1. The pressure and flow signals are depicted in the figure. During ventilation, Plim value was decreased by a user and as a consequence the maximum pressure in the patient's circuit was reduced by the ventilator accordingly. The Fig. 1 also documents the pressure limitation of the ventilation mode "pressure limited volume controlled ventilation".

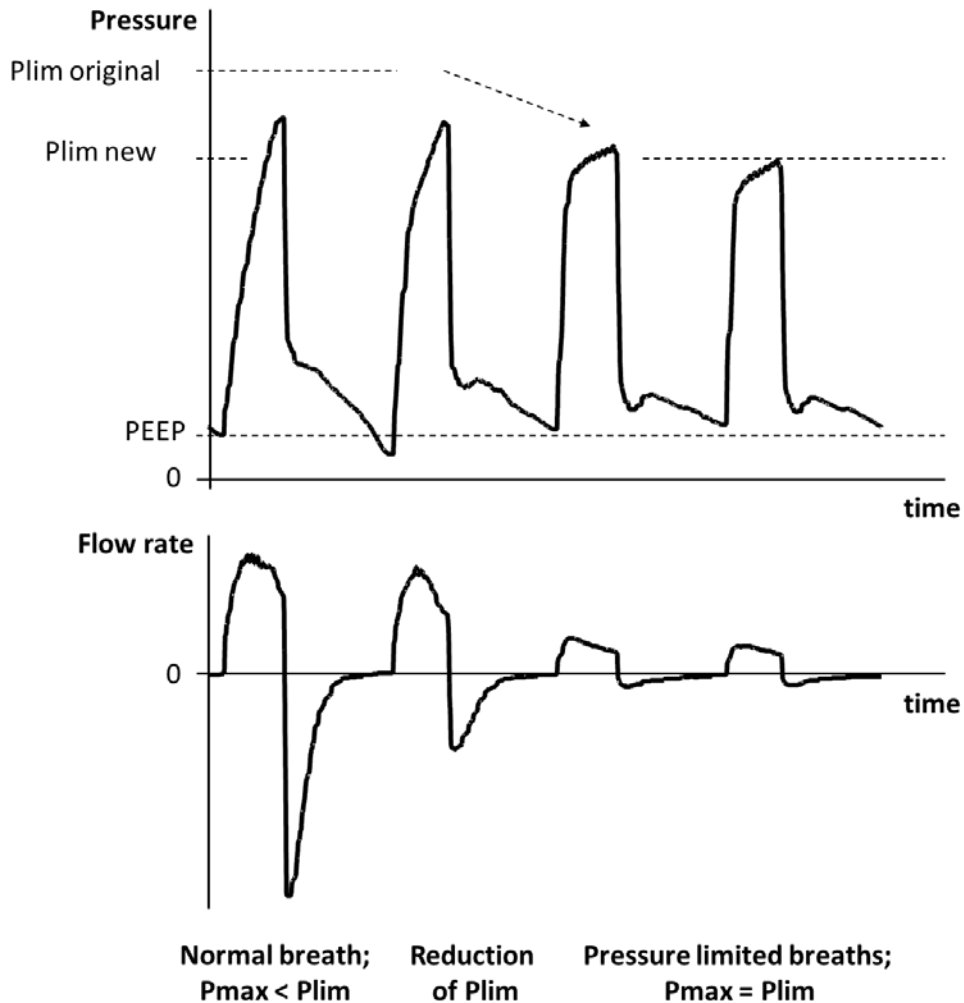


Fig. 1: Pressure and flow measured by the CoroVent ventilator with targeted Plim value reduction, which consequently leads to limiting the maximum pressure Pmax in the patient's circuit ventilator.

4. Impossibility of exceeding Psafe pressure – the maximum safety pressure above which the patient's circuit pressure is not allowed to rise under any situation. It is ensured by a safety pressure relief valve located inside the ventilator body and cannot be changed by the user. It is preset by the manufacturer to 60 – 65 cm of H₂O.

The function of this protective element, i.e. the impossibility of exceeding the Psafe pressure of 60 – 65 cm H₂O at the factory, is documented by signals recorded by the CoroVent ventilator during a complete occlusion of the patient's circuit expiratory limb. This condition was simulated by complete blockage of the corrugated hose of the expiratory limb of the patient circuit with a plug.

Fig. 2 shows that after the occlusion (induced after the first, regular breathing cycle), the pressure in the patient's circuit rises as expected, but when the factory preset P_{safe} threshold is reached, a low-impedance safety relief valve opens to reliably remove excessive gas from the patient circuit, avoiding the possibility of pressure rising in the patient's circuit above P_{safe} value even at very high inspiratory flow rates.

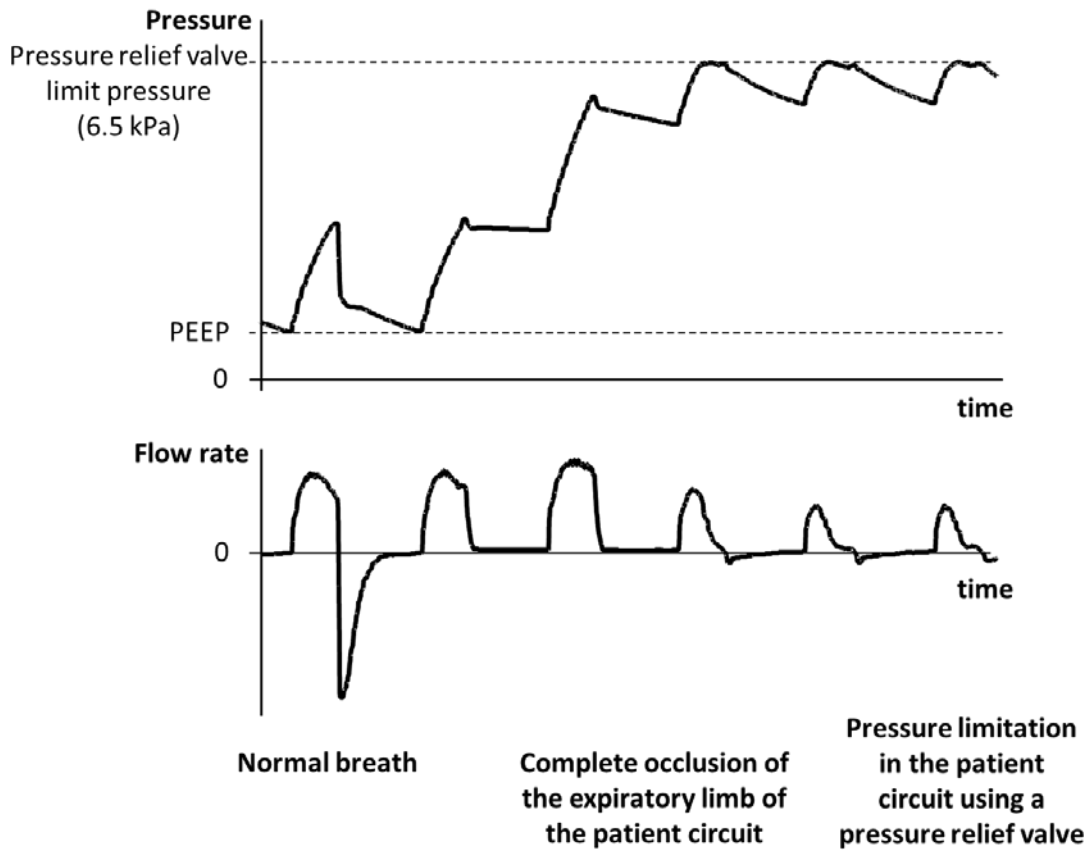


Fig. 2: Documentation of safety relief valve function avoiding pressure increase in the patient's circuit above the P_{safe} value preset by the manufacturer. Pressure and flow signals were recorded after the complete occlusion of the expiratory limb of the patient's circuit.