Basic pressure-controlled ventilation (PCV) functionality for a CPAP system.

Last update: 20.04.2020

!!! Note: The described module is not a certified medical product !!!

Principle: Ventilation in PCV mode requires the controlled alteration between two well-defined airway pressure levels, i.e. PEEP and P_{insp}. To fulfil this requirement, a module (hereby referred to as CARL for **C**PAP **A**pparatus **R**espiratory **L**ife Support) is placed in the ventilation pathway between the CPAP machine and the mask/catheter (see Figure 1). CARL consists of a valve that can be opened and closed to control the airflow and thus the patient's air supply. When the air supply valve is closed, a minimum PEEP value of 6 mbar is maintained and excess air during the exhalation phase is released through an exhalation valve. When the air supply valve is open, the airway pressure increases by P_{insp}. The peak inspiratory pressure, P_{IP} = PEEP + P_{insp}, is set at the CPAP-machine and depends on the machine type (a typical value is 20 mbar).

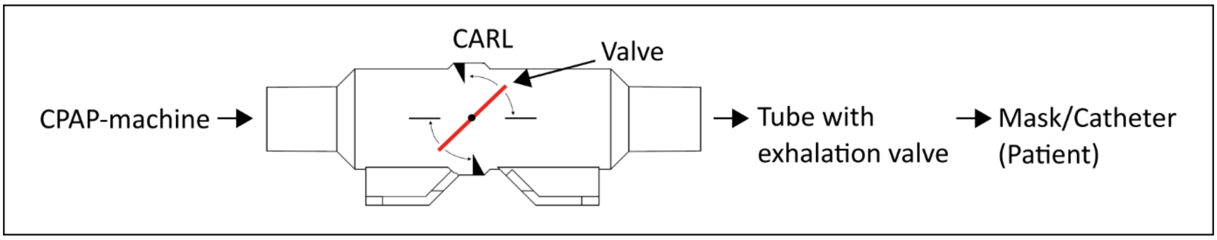

Figure 1: Schematic of CPAP system with PCV functionality.

Properties:

- Ventilation mode:	PCV	
- PEEP:	5 - 7 mbar	variable, P_{insp} dependent
- P_{Insp}:	13 - 15 mbar	
- I:E ratio:	1:1 and 1:2	
- Respiratory rate:	8 - 30 min^{-1}	freely adjustable

Pressure Curve:

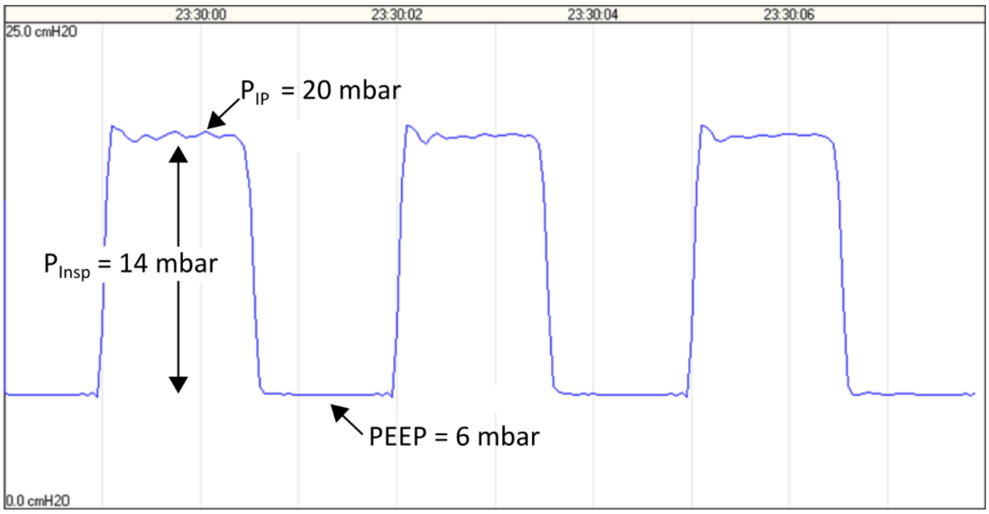

Figure 2: Plot of the airway pressure as a function of time for a CPAP-machine with CARL. The data represents the airway pressure over a time interval of 10 s. Respiratory rate = 20 min^{-1}. I:E ratio = 1:1.

System Properties:

PCV-Mode	With a common CPAP-Machine (max. 20 mbar), it is possible to perform time-triggered and pressure-controlled ventilation. The values for PEEP and P_{Insp} are in the range of 5 - 7 mbar and 13 - 15 mbar, respectively. Larger values for the inspiratory pressure (max. 25 mbar or 30 mbar) can be achieved with BiPAP-Machines that are operating in CPAP-mode. In geographical regions with limited health infrastructures, it may be possible to replace CPAP-machines with other positive airway pressure ventilators, if they can generate similar airway pressure and flow values.
I:E ratio	CARL supports two I:E ratios: 1:1 and 1:2. The selected I:E ratio is highlighted via a green LED on the front panel.
Respiratory rate	Can be set to any value in the range of 8 - 30 min^{-1}.
Oxygen supply	There is an adapter to supply the patient with oxygen, that is placed in the ventilation pathway between CARL and the mask/catheter. It turns out that an oxygen supply close to the patient is an efficient way to reach high oxygen levels.
Centralised monitoring	A medical monitor, that is typically used for hemodynamic monitoring, can be connected to the tube facing the patient. This makes it possible to monitor the airway pressure and alarms during ventilation.
Tidal volume	Is calculated in real-time by measuring the pressure difference at the patient’s mask. The tidal volume value (and therefore the volume during the inhalation and exhalation phase) is displayed on the front panel of CARL.
Pulse oximetry	Is typically applied through an additional external system that is common in hospitals. Therefore, no interface is currently planned.
ASV	An ASV functionality to support spontaneous breathing is part of the CARL.

Safety functionalities:

PEEP	During ventilation, a minimum PEEP value in the range of 5 - 7 mbar is maintained. It is generated by connecting the two chambers before and after the valve with a tube. The PEEP value depends on the pressure that has been set on the CPAP machine: for a value of 20 mbar and 14 mbar the PEEP is 7 mbar and 5 mbar, respectively. Additionally, the PEEP value depends on the oxygen level (see Table 2).
Pressure-limiting valve	Spring keeps the valve closed unless airway pressure exceeds 30 - 40 mbar. A prototype for the pressure-limiting valve has been developed as a detachable attachment to CARL.
Vacuum valve	A membrane-based valve that allows the patient to inhale should the air supply valve be closed at the time of inhalation.
Bacteria filter	Can be attached in the ventilation pathway between CARL and the patient.
Alarm (air supply valve)	A constant sound is played should the valve remain closed during ventilation.

Alarm (Motor)	CARL monitors the operation time of the motor. It is possible to set up the maximum operation time to signal the user that the motor should be checked. For this purpose, a short sound is played and a red LED on the front panel is turned on.

1. Tidal Volume and Respiratory Minute Volume

Measurements of the airway pressure and flow with the extended CPAP system are conducted on an artificial lung (Test Lung 190, Maquet). To release the excess gas during ventilation, an exhalation valve (Whisper Swivel II, Philips Respironics) is attached to the end of the tube facing the patient. The data is acquired with a pneumotachometer heater control (Model 3850, Hans Rudolph Inc.) and a DC bridge amplifier (MIO-0501, FMI GmbH). The ventilation volume is calculated from the flow measurements. Figure 3 shows a plot of the measured data. The tidal volume can be extracted from the ventilation volume data. The respiratory minute volume can be calculated by multiplying the tidal volume with the respiratory rate.

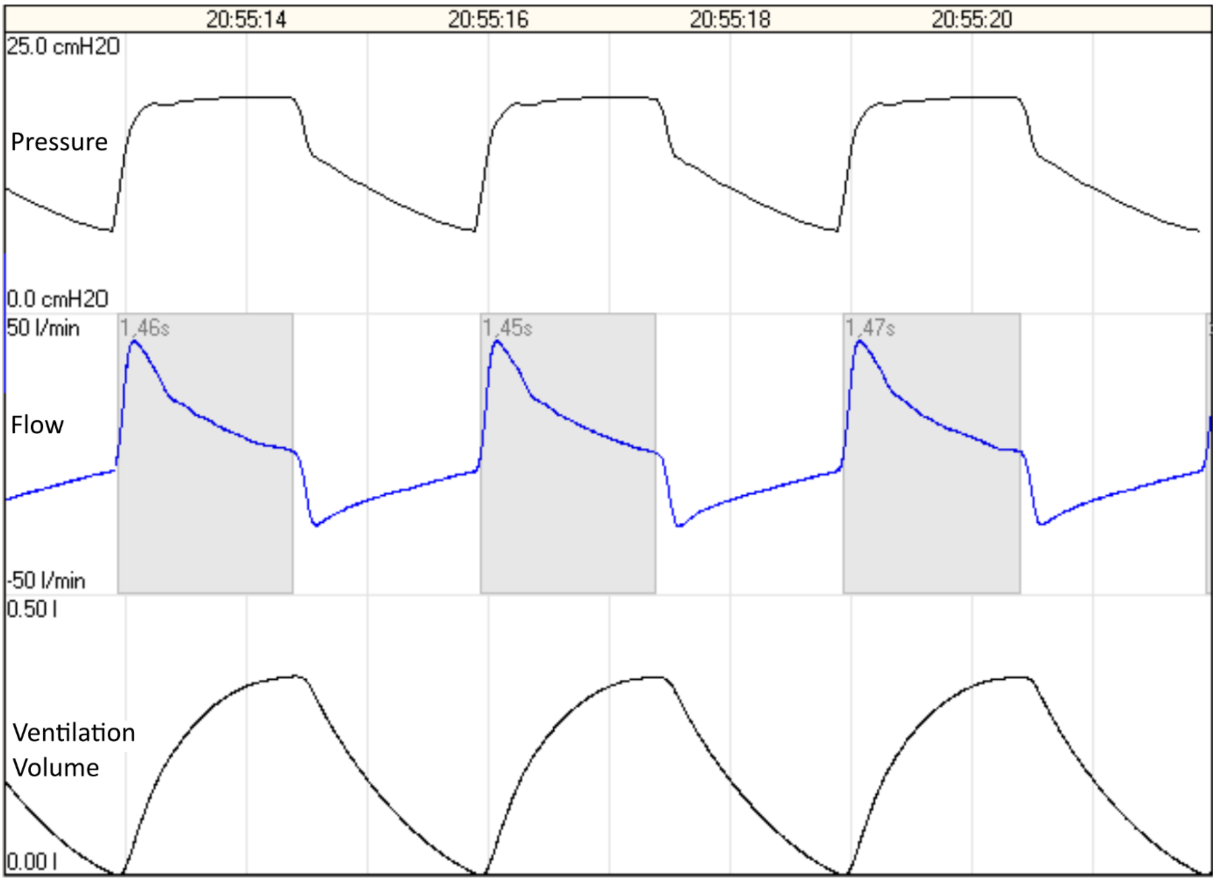

Figure 3: Measured pressure and flow as a function of time. The tidal volume is calculated from the flow.

Table 1 shows the measured values of the tidal volume and the respiratory minute volume for different parameter combinations, i.e. I:E ratio, P_{IP} and respiratory rate.

		I:E = 1:1		I:E = 1:2	
P_{IP} /mbar	**Resp. Rate / min^{-1}**	**Tidal volume / l**	**Respiratory minute volume / l**	**Tidal volume / l**	**Respiratory minute volume / l**
20	10	0,39	3,93	0,41	4,11
20	15	0,40	6,04	0,40	6,02
20	20	0,36	7,13	0,36	7,15
20	25	0,31	7,69	0,31	7,77
20	30	0,28	8,27	0,27	8,21
18	10	0,35	3,52	0,35	3,50
18	15	0,35	5,26	0,35	5,28
18	20	0,31	6,23	0,32	6,37
18	25	0,28	6,88	0,28	7,05
18	30	0,25	7,51	0,25	7,55
16	10	0,30	3,01	0,30	3,01
16	15	0,30	4,50	0,30	4,48
16	20	0,27	5,43	0,28	5,52
16	25	0,24	6,12	0,25	6,22
16	30	0,23	6,77	0,23	6,79
14	10	0,24	2,38	0,24	2,37
14	15	0,24	3,59	0,24	3,56
14	20	0,22	4,41	0,22	4,44
14	25	0,20	5,03	0,21	5,16
14	30	0,19	5,82	0,19	5,84

Table 1: Measurements of the tidal volume and the respiratory minute volume for different values of I:E ratio, P_{IP} and respiratory rate.

1.1 Tidal volume during inhalation and exhalation phase

The tidal volume during the inhalation and exhalation phase is measured with a flow sensor (Hamilton Medical) that is connected to a pressure sensor (AMS 5915, AMSYS GmbH & Co. KG). To evaluate the accuracy of the acquired respiration volume, a calibration syringe (Series 5540, Hans Rudolph Inc.) is used. A comparison between the volume measured with the sensors and the volume added to the setup with the syringe reveals a discrepancy of 5 %. The measured volumes are independent of the air flow and the air volume added to the system. A plot of the acquired data is presented in Figure 4. The plot “Trigger (Inhalation)” shows the time at which CARL detects the start of the inhalation phase. The latter is calculated from the ventilation volume and can be later used to develop a spontaneous breathing support mode.

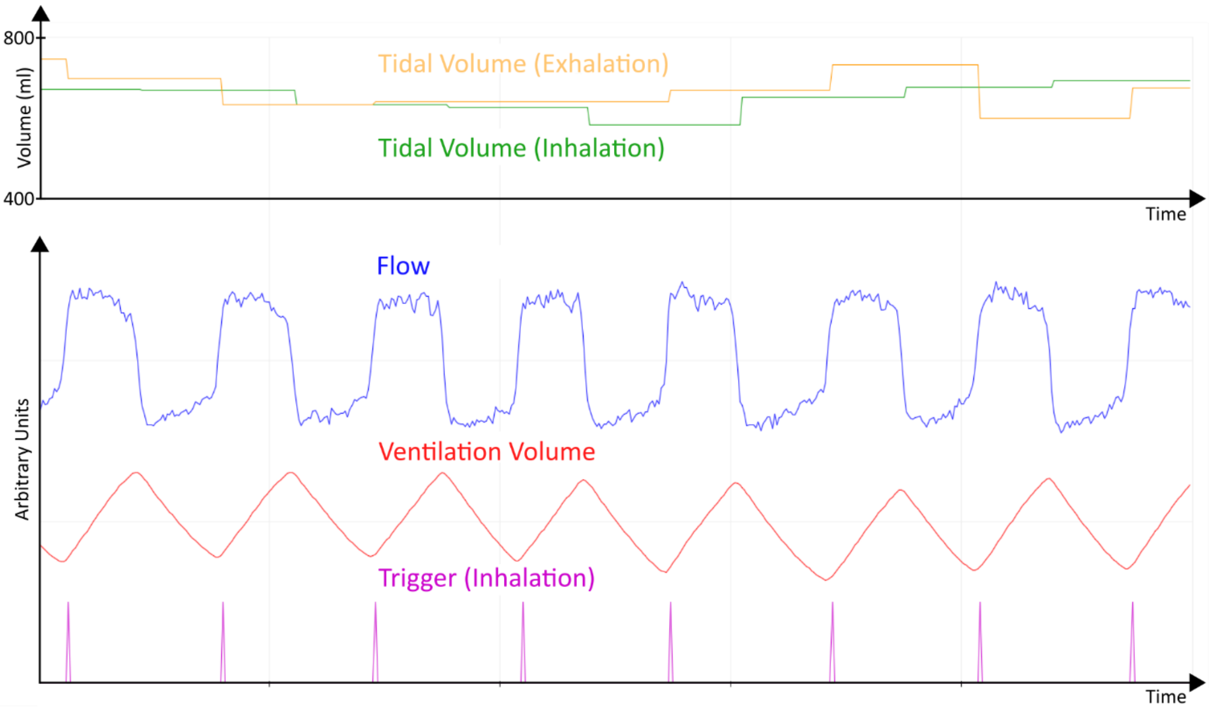

Figure 4: Air volume measurements as function of time. Top: measured volume in the inhalation and exhalation phase. Bottom: Measured airflow and calculated ventilation volume that corresponds to the plot above (scaled up for presentation). The signal on the bottom, marked as “Trigger (Inhalation)” illustrates the start of the inhalation phase which is detected by CARL from the ventilation volume data.

2. Calculation of the FiO_2 value for different oxygen flow rates

The setup for this measurement consists of an artificial lung (see section 1) and a patient monitor (Carescape B450, GE Healthcare) with a *e-sCAiO* module. To acquire the data, the patient monitor is connected to the ventilation tube before the artificial lung.

The FiO_2 is measured for different values of the oxygen flow rate, the I:E ratio (1:1 and 1:2), P_{IP} (16, 18 and 20 mbar) and respiratory rate. An analysis of the acquired data including the uncertainties reveals that the FiO_2 values are independent of P_{IP} and the I:E ratio. On the other hand, the FiO_2 value does vary for different values of the respiratory rate but these variations are negligible.

Oxygen flow rate / $l \cdot min^{-1}$	FiO2 / %	PEEP / mbar
0	21	5,7
½	25	5,7
1	28	5,8
2	35	6,2
3	38	6,5
4	44	6,6
6	58	6,5
8	68	7,2
10	78	7,8
12	90	8,5

Table 2: Measured values for FiO_2 and PEEP for different oxygen flow rates. Fixed parameters: P_{IP} = 20 mbar, I:E ratio = 1:1, respiratory rate = 20 min^{-1}.

3. Comparison of the tidal volume achieved with CARL and with a commercial ventilator

In the following, we measure the tidal volume achieved with the extended CPAP system, i.e. the CPAP system with CARL, and the volume achieved with a commercial ventilator (Primus, Dräger). The measurements are conducted on a human patient simulator (CAE Healthcare).

The parameters for both systems are as follows:

I:E ratio = 1:2   PEEP = 6 mbar P_{Insp} = 14 mbar

The measured values for the tidal volume are presented in the following table:

Respiratory rate / min^{-1}	Tidal Volume	
	extended CPAP	*Dräger Primus*
20	ca. 700 ml	ca. 700 ml
25	ca. 500 ml	ca. 450 ml

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