Can CPAP machines be repurposed to solve the ventilator shortage?

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Method Article

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Abstract

The worldwide shortage of medical-grade ventilators is a well-known issue, that has become one of the central topics during the COVID-19 pandemic. Given that these machines are expensive and have long lead times, one approach is to vacate them for patients in critical conditions while patients with mild to moderate symptoms are treated with stripped-down ventilators. We propose a mass-producible solution that can create such ventilators with minimum effort. The central part is a module that can be attached to CPAP machines and repurpose them as low-pressure ventilators. Here, we describe the concept and first measurements which underline the potential of our solution. Our approach may serve as a starting point for open-access ventilator technologies.

Introduction

The COVID-19 pandemic plunged many countries, such as Italy, Spain and the United States, into a health crisis due to the sudden demand for medical facilities, staff and equipment[1,2]. Since the search for a vaccine is still ongoing, treatments revolve around symptom control and life-sustaining measurements. Patients with COVID-19-related respiratory failures often require prolonged mechanical ventilation[3–5]. Such a treatment, however, cannot be provided due to a long-term worldwide issue: the shortage of medical-grade ventilators[6]. These costly devices have long lead times because of their complexity. Consequently, this shortage may continue to be the one of few central issues during a potential second wave of the disease.

In response to the urgent need for ventilators, many designs were proposed to serve as life-sustaining measurements or to vacate medical-grade ventilators for patients in critical conditions[7]. The lead time for each proposed design depends on the range of functionalities, cost and, more importantly, the available production facilities. One prominent approach focuses on machines that automatically compress and decompress bag valve masks [8–12]. Other groups pursue ventilator solutions that can be built from scratch with the expertise and the facilities from different industrial branches [13,14].

In the presence of these developments, we propose a mass-producible solution that is built around continuous positive airway pressure (CPAP) machines. These home-level ventilators are commonly used to treat sleep apnea worldwide. Nowadays, many machines sit unused in households[15–17] and thus, there are potentially millions of CPAP machines around the globe that can be repurposed as stripped-down ventilators.

CPAP machines generate and maintain a constant positive airway pressure in the patient. To cover the fundamental functions for mechanical ventilation, however, we need to:

- provide two well-defined airway pressure levels, i.e. the peak inspiratory pressure (P_{IP}) and the positive end-expiratory pressure (PEEP), to assist or replace the patient's breathing during the inhalation and exhalation phase,

- set the respiratory rate,
- set the I:E ratio, which is the ratio of the inhalation and the exhalation time, and
- allow patients to trigger and to cycle inhalation.

Therefore, ventilation by means of CPAP machines requires a modification that regulates the constant airflow with time. We developed a module, referred to as CARL (for **C**PAP **A**pparatus **R**espiratory **L**ife support), that can be attached to any CPAP machine and instantaneously repurpose it as a basic ventilator with minimum effort. We believe that our proposed solution can be used to treat patients with mild symptoms that do not require high-level pressures provided by medical-grade ventilators or to wean off recovering patients from the ventilator.

We would like to clarify that the ventilator presented in this report:

- has only been tested with electric and mechanic equipment,
- is subject to pre-/clinical trials and approval, and
- has yet to be examined and approved by a regulatory health institution.

Therefore, at this stage of development, we strongly discourage the use of our device on humans. Our module should only be reproduced for the purpose of further development and investigation.

Results

CARL is an electronic device that is placed in the ventilation pathway between the CPAP machine and the patient. It uses a microcontroller-activated valve to generate two airway pressure levels from the constant airflow provided by the CPAP machine. The computer assures that the periodic alteration between both pressure levels corresponds to a set respiratory rate and I:E ratio. CARL uses sensors to monitor the airway pressure, the flow and the ventilation volume. That way, users can easily adjust the ventilator settings to the needs of the patient which is comparable to adjustments with medical-grade ventilators.

In the following, we present measurements of the airway pressure, flow and ventilation volume for different ventilation parameters. As a representative patient model, we use an artificial lung (details in ‘Methods’).

3.1 Pressure-related ventilation settings

Ventilation strategies for COVID-19-patients include a minimum airway pressure of at least 5 cmH_2O that must be maintained during the exhalation phase to stabilise the alveoli[5,18–21]. Therefore, for our first set of measurements we vary the P_{IP} value while keeping the respiratory rate and the I:E ratio fixed. P_{IP} value is set and adjusted on the CPAP machine. Our measurements of the airway pressure, flow and volume as a function of time for two different P_{IP} values can be observed in Figure 1a (P_{IP} = 15 cmH_2O) and 1b (P_{IP}

= 20 cmH_2O). From the pressure curves, we can see a decrease of the PEEP value with the P_{IP} value: when the latter is set to 20 cmH_2O or 15 cmH_2O, we get a PEEP value of 7.5 cmH_2O or 5 cmH_2O, respectively.

To investigate the impact of the CPAP machine model on the ventilation performance, we repeated the same measurement as above with another model. These measurements are also presented in Figure 1a and 1b. The comparison reveals minor differences between the ventilation curves, which are due to the machine's capability to maintain the set pressure. The values for the P_{IP} and the PEEP, on the other hand, are unaffected by the CPAP machine model.

3.2 Time-related ventilation settings

In contrast to the pressure-settings, all time-related ventilation settings, i.e. the respiratory rate and the I:E ratio, are adjusted on CARL. For the first measurement, we vary the I:E ratio while the P_{IP} value and the respiratory rate are fixed. The acquired curves of the airway pressure, flow and volume as a function of time are shown in Figure 2a. An evaluation of the inhalation and exhalation durations confirms the correct implementation of the I:E ratios with CARL.

Our measurements for ventilations with different respiratory rates while the P_{IP} value and the I:E ratio are fixed are presented in Figure 2b. The ventilation volume data shows a drop of the maximum ventilation volume as the respiratory rate increases. This is expected since the duration of the inhalation phase decreases as the respiratory rate increases. We found that the respiratory rate agrees with the value that is set on CARL over the duration of the measurement.

3.3 Patient-triggered/Patient-cycled ventilation

Patients who receive no sedation may breathe spontaneously during ventilation[22,23]. To support such events, the ventilator must be able to recognise the patient's breathing effort, so that they can trigger and/or cycle the inspiration phase themselves. Our implementation relies on airflow monitoring which is demonstrated in Figure 3. Here, the start of the inhalation and exhalation phase are marked as 'o' and 'x', respectively. When no breathing effort is detected, e.g. when patient's breathing ceases, the ventilation is provided in accordance to the parameters set on CARL. The latter functionality is known as 'backup ventilation function' in medical-grade ventilators.

Discussion

The previous results demonstrate that our module CARL can repurpose CPAP machines to basic ventilators which provide ventilation pressures up to 20 cmH_2O. Such ventilators may serve as a temporary solution for patients with mild respiratory conditions or as solution to wean off recovering

patients from the ventilator. CARL has a clear and easy-to-use interface that allows constant patient monitoring and instant access to the ventilation settings, i.e. the respiratory rate and the two I:E ratios.

Owing to CARL's modular design, we can develop additional components to include more functionalities without interfering with the ventilator design. One potential component is a module to supply oxygen to the patient at a given oxygen level. This will also imply the addition of an oxygenation measurement device.

Further adjustments of CARL's design could be made to improve the infection control of the module. The design should allow the user to easily clean its surface within a reasonable time frame. In our case, this would primarily concern the components that are in the ventilation pathway. However, since these components are affordable and easy to produce, it may be safer to dispose and replace them instead. Owing to the working principle of CARL, our device could repurpose any continuous positive pressure machine to a basic ventilator. As such, CARL may be the starting point for an open-source ventilator solution. Such decisions, however, require testing the device carefully on animals or patients, which is beyond the scope of this report.

Summary And Outlook

The rapid dissemination of COVID-19 has led to a short-term shortage of ventilators worldwide. We believe that CPAP machines repurposed as stripped-down ventilators can help with the crisis in the short-term. Our mass-producible solution could be used to vacate medical-grade ventilators for patients in critical conditions. However, in the worst case and after further development and regulatory approval, our solution may be used as a last resort to save the patient's life.

It is important to note that CARL must be rigorously examined and tested before it can be used on humans. This includes stress tests for both hardware and software, performance measurements under clinical conditions and a biocompatibility evaluation of all materials in the ventilation pathway.

Methods

6.1 Ventilation specifications for a minimally acceptable ventilator

Our set of ventilation specifications is aimed at COVID-19 patients with mild symptoms as they may not require all functionalities provided by a medical-grade ventilator. A summary of the ventilation variables supported by our system is presented in Table 1. For the definition of the ventilation variables and modes we use the terminologies and the guidelines provided by Charburn et al. [24].

Ventilation Variable	Description	Values
Triggering mechanism	A method to initiate the inspiration phase.	time-triggering, flow-triggering
Cycling mechanism	A method to end the inspiration phase.	time-cycling, flow-cycling
Breath control variable	A parameter that describes the mechanism to assist the patient's breathing.	pressure-control (PC)
Breath sequence	A pattern of mandatory and/or spontaneous breaths.	intermittent mandatory ventilation (IMV)
Targeting Scheme	A method used by the ventilator to achieve a specific ventilation pattern.	set-point (s)
Ventilation Mode	A term to describe the set of ventilation operations based on the selected breath control variable, breath sequence and targeting scheme.	PC-IMVs,s
I:E ratio	The ratio of the inspiration (I) and the expiration (E) phase during ventilation.	1:1, 1:2
Respiratory rate	The amount of breaths per minute (bpm). Here, it is the number of mandatory breaths per minute. The number of spontaneous breaths per minute cannot be lower than the number of mandatory breaths per minute.	8 - 30 bpm
Positive end-expiratory pressure (PEEP)	The airway pressure at the end of the exhalation phase.	at least 5 cmH_2O
Peak inspiratory pressure	The airway pressure set at the CPAP machine.	15 - 20 cmH_2O
Maximum airway pressure	The upper pressure limit in the patient's airways.	30 cmH_2O

Table 1: Specifications for a minimally acceptable ventilator to treat COVID-19 patients with mild or moderate symptoms.

In addition to the ventilation specifications, we also implemented functionalities in CARL's design that ensure the patient's safety during therapy and the safe operation of CARL. These functionalities are summarised in Table 2.

Function	Description
Contamination protection	Protection of patient and medical equipment from pathogens.
Constant monitoring (settings)	Visual display of airway pressure, tidal volume and current ventilation settings.
Constant monitoring (hardware and software)	Visual and acoustic signals for hardware and software failures during operation.

Table 2: Design requirements for CARL to ensure the patient's safety during ventilation.

6.2 CARL

For the development of our module CARL, we aim for a mass-producible solution that can be manufactured worldwide. To fulfil this criterion, we developed a design that only uses easy-accessible hardware and electronic components. Our current design for CARL is presented in Figure 4, where the essential components are optimised for mass-production using plastic milling. We also developed and tested a version that can be built with a 3D printer. Subsequent tests show, however, that the results strongly depend on the 3D printer model and, thus, we focus on the plastic-milled version as it yields superior and more consistent results.

CARL serves as an intermediate module that we place in the ventilation pathway between the CPAP machine and the patient (see Figure 5). The airway pressure that is generated by the CPAP machine in the ventilation pathway is regulated with a rotatable valve: when the valve is open, the airway pressure increases to the peak inspiratory pressure; when it is closed, the airflow stops and the airway pressure drops to zero. A flexible tube is used to bypass the valve and to allow for a continuous minimum airflow to the patient. That way, a PEEP of at least 5 cmH_2O can be maintained even when the valve is closed. To meet the set respiratory rate and I:E ratio during ventilation, the valve is attached to a computer-controlled motor. The patient receives air through a mask or a catheter. Any excess air during the patient's exhalation phase can escape through an exhalation valve that is placed between CARL and the patient.

We also designed a pop-off valve and a low-pressure valve to contribute to the patient's safety. The former component makes sure that the airway pressure does not exceed 30 cmH_2O, e.g. in the event of a cough. The low-pressure valve guarantees that patients can inhale spontaneously in the event of a hardware or software failure. Additional ventilation parameters, e.g. the FiO_2 value, can be extracted by connecting a patient monitor to the provided connector.

To measure the airway pressure and the flow, we use a flow sensor (No. 281637, Hamilton Medical) that is connected to two implemented pressure sensors (AMS5915, Analog Microelectronics GmbH). The flow data is evaluated to determine the ventilation volume and to trigger and to cycle inspiration. As such, we can monitor and evaluate the patient's breathing behaviour during mechanical ventilation.

We use an Arduino Uno and an Arduino Nano to control all electric components in CARL. To implement the ventilation modes in Table 1, we use our own code that is written in C++ and only employs standard

libraries. All electronic parts are protected by a professional casing, to comply with safety precautions while in operation.

6.3 Interface/GUI

The use of clear labels is essential for the safe use of CARL by the medical staff. To achieve this, all descriptions use standard terms that are recognised by qualified medical personnel. Figure shows a photo of CARL's user interface. To operate CARL, the user can set the desired I:E ratio and the respiratory rate. The current ventilation parameters and ventilation quantities are displayed on the screen. The red LED next to the description "Alarm" implies an error during operation. These errors can be defined and implemented into our code.

6.4 Measurement of ventilation quantities

All pressure and flow measurements that are acquired with CARL are validated with an external setup which consists of a pneumotachometer heater control (Model 3850, Hans Rudolph Inc.) and a DC bridge amplifier (MIO-0501, FMI GmbH). To acquire and evaluate the data from this setup we use the Embla RemLogic Software.

To release the excess gas during ventilation, we use an exhalation valve (Whisper Swivel II, Philips Respironics) with a microfilter attached to it. The filter reduces the concentration of released air contaminants in the environment and thus, the overall infection risk for the medical staff. As a patient model, we use an artificial lung (Test Lung 190, Maquet). All measurements are taken with two different CPAP machines from Löwenstein Medical: prisma SOFT and prisma25.

Declarations

Acknowledgements

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Author contributions

GK, KK proposed the concept for CARL; ECC proposed the study supported by MK, MK coordinated the workgroup; CB, JH, PL, AP, DG contributed to the development of the software framework; GK, CB, JH, CS, CSo contributed to the implementation of the electronic components; PM, NH, BLT, HB, GK, KK contributed

to the development of the CARL prototype; KK, JN, JH performed and evaluated all measurements; RH, PW, TW, BB provided medical experitise; KK, JH, PL, CB, JN contributed to the documentation; JN, GS, MK provided coordination between the medical, mechanical/software developers and test experts; The manuscript was written by JN, ECC. All authors reviewed the manuscript.

Competing interests

The authors declare no competing interests.

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Figures

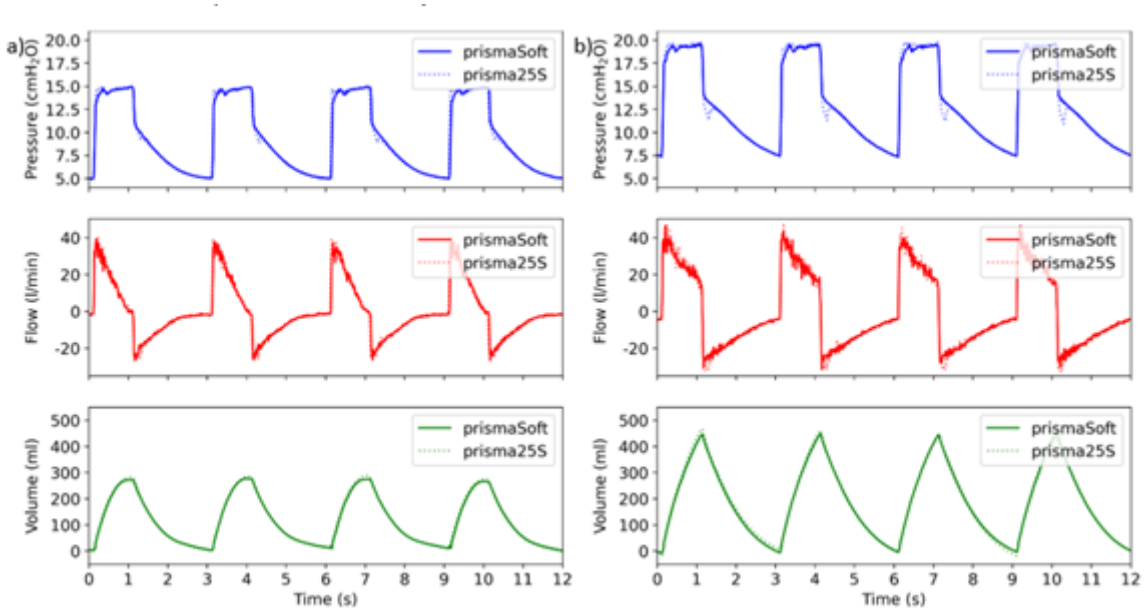

Figure 1

Plots of the airway pressure (blue), flow (red), ventilation volume (green) as a function of time for the PIP values a) 15 cmH2O and b) 20 cmH2O. prismaSoft: Data acquired with the CPAP machine model 'Löwenstein SOFT'. prisma25S: Data acquired with the CPAP machine model 'Löwenstein prisma25S'. All measurements are performed on an artificial lung. Respiratory rate: 20 bpm, I:E ratio: 1:2.

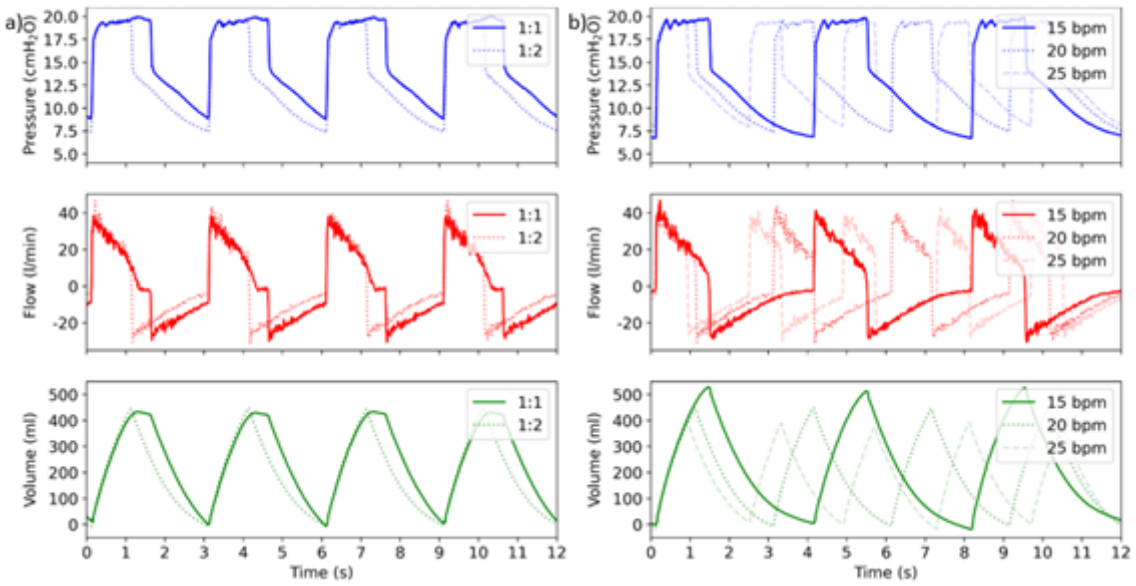

Figure 2

Plots of the airway pressure (blue), flow (red), ventilation volume (green) as a function of time. a) Ventilation data plots acquired for the I:E ratios 1:1 and 1:2 while the respiratory rate and the PIP value are set to 20 bpm and 20 cmH2O, respectively. b) Ventilation data plots acquired for the respiratory rates 15 bpm, 20 bpm and 25 bpm while I:E ratio is 1:2 and the PIP value is 20 cmH2O. All measurements are

conducted on an artificial lung and the pressure is generated with the CPAP machine ‘Lowenstein prisma SOFT’.

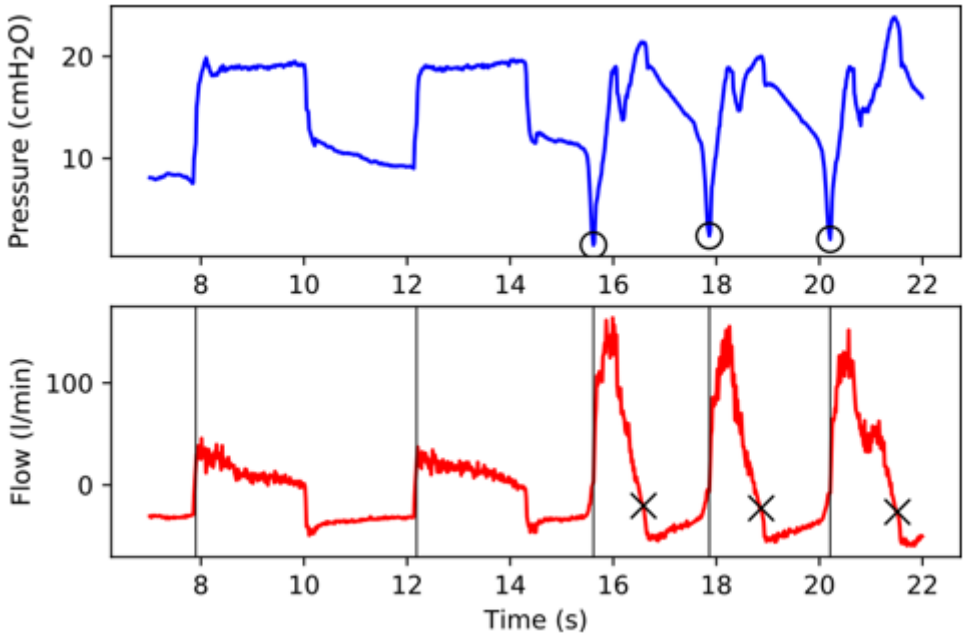

Figure 3

Illustration of patient-triggered and patient-cycled ventilation. The plots show the measured airway pressure (blue) and flow (red) as a function of time for in the event of spontaneous breathing during ventilation (from ~16 s). The patient-initiated start of the inhalation and exhalation phase are marked as ‘o’ and ‘x’, respectively.

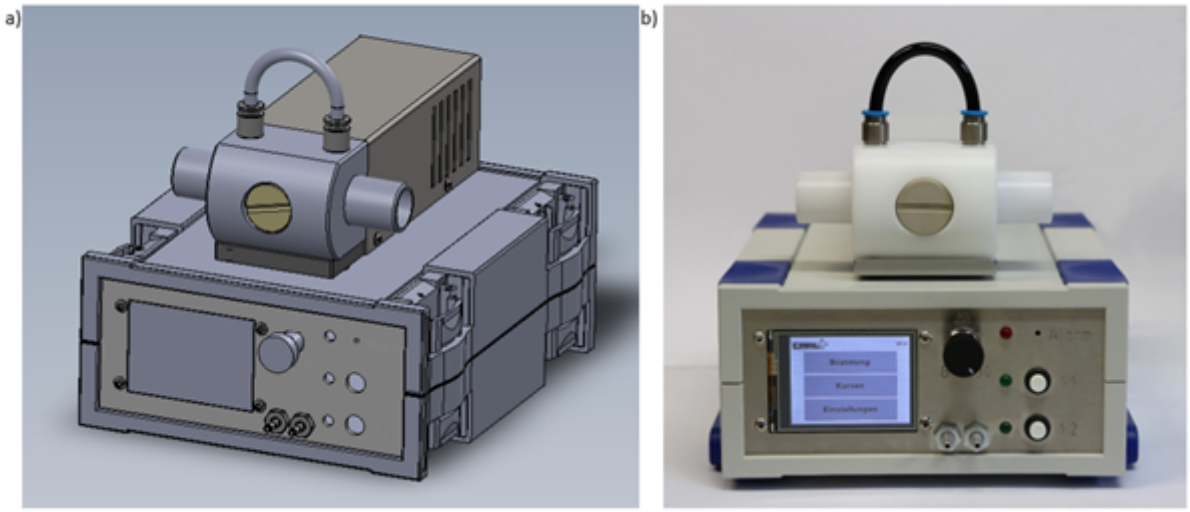

Figure 4

Illustrations of the module CARL. a) 3D model of the module CARL. b) Build model of CARL.

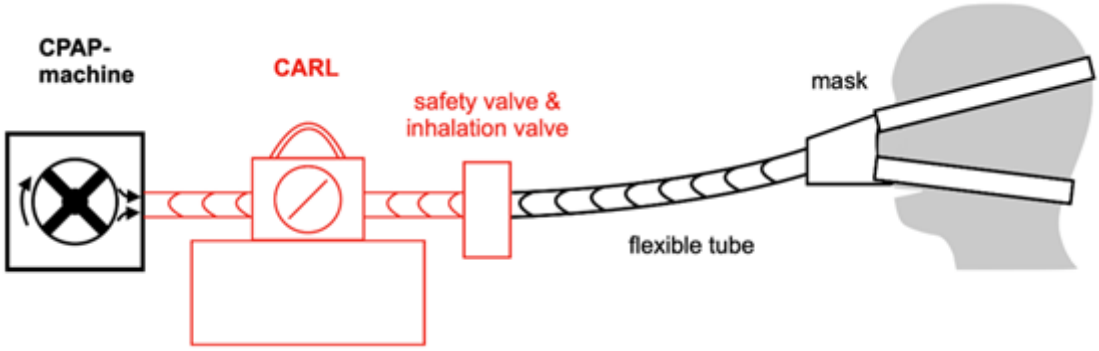

Figure 5

Schematic of a basic ventilator with a CPAP machine and the module CARL.

Figure 6

User interface of CARL.