

Firmware update of CPAP home mechanical ventilators for respiration of COVID19 patients during the worldwide shortage of clinical ventilators

My professional background

I am a professor for the Medical Engineering Bachelor degree programme of the Faculty of Electrical Engineering, Precision Engineering, Information Technology at the Nuremberg Institute of Technology. My main focus is mechanical ventilation and anesthesia. Previously I worked for Dräger, the largest German ventilator manufacturer. My background is in electrical engineering, not medicine. Therefore, all medical aspects in this document must be scientifically assessed and evaluated and medical specialists must decide in all cases of patient treatment.

Introduction

Ten thousand to one hundred thousand people in Germany suffer from obstructive sleep apnea (OSA) – worldwide, there are millions [1]. During sleep, the tongue slips backwards into the pharyngeal area and closes the trachea, which is almost always associated with strong snoring. The obstruction also causes a decrease in oxygen saturation, a stress hormone release, and sleep disruption, which ends the apnea. This process recurs cyclically and can cause serious health consequences in those affected [2].

The treatment usually consists of CPAP (Constant Positive Airway Pressure) therapy, in which the patient is exposed to a constant overpressure through a mask. This pushes the tongue, forcing it forward, and prevents the respiratory obstruction. This is called pneumatic splinting.

The therapy is carried out with small, bedside CPAP home ventilators, such as the AirSense10 by ResMed or the DreamStation by Philips Respironics.



Figure 1: ResMed AirSense10 [15]



Figure 2: Philips Respironics DreamStation [3]

CPAP therapy, which is also available in the clinical settings for other diseases, would be helpful in COVID19-induced pneumonia to prevent atelectasis, but life-sustaining only to a limited extent.

Another non-invasive form of ventilation (NIV), BIPAP (Biphase Positive Airway Pressure) and similar ventilation modes, could significantly support corona patients in breathing and thus mitigate Acute Respiratory Distress Syndrome [4], [5]. In BIPAP, the positive airway pressure is varied at alternating levels, supporting natural breathing.

There are home ventilators based on the same hardware platform as CPAP devices that can also provide BIPAP and other NIV ventilation forms. For example, the Devices AirCurve and Lumis from the company ResMed:



Figure 3 ResMed AirCurve 10 [6]



Figure 4 ResMed Lumis 150 [7]

The three devices shown in the pictures (AirSense 10, AirCurve 10, and Lumis 150) differ in name, the housing color, and in price, but are fitted with the same or nearly identical hardware system, in my opinion. The weight of the respective units is exactly the same, to the gram, and the interior views from FCC authorization applications [8] as well as the repair videos that are available on the internet support my assumption. If this is the case, the difference between the apparatus as related to their capabilities would be in the embedded software (firmware).

Other manufacturers, for example, Philips Respironics, have common hardware platforms for their CPAP and BIPAP devices.



Figure 5 Philips Respironics DreamStation (CPAP) [3]



Figure 6 Philips Respironics DreamStation BiPAP S/T30 AAM [9]

However, BIPAP/BiLevel machines are much less widespread than CPAP machines, because the illnesses that are treated with BIPAP machines have a much lower prevalence than obstructive sleep apnea.

An approach for treating COVID-19 patients and a short-term measure to meet the worldwide demand for ventilators [10] [11]

As CPAP machines, whose hardware platforms are the same as BIPAP ventilation machines, were already produced in high numbers before the COVID-19 pandemic, it is far easier to extend their production in large numbers in order to ventilate COVID-19 patients non-invasively.

If such a potential increase in production is still not adequate, **it stands to reason to make use of the CPAP machines already in the market by updating their firmware to permit their use as BIPAP or other supportive ventilation formats. These updated machines could be used for patients, for whom no clinical ventilators are available.**

Because the proposed solution is solely based on a software update, it could be made available very quickly.

Of course the medical device regulations of respective countries must be adhered to. Relaxation or shortening of such authorization processes for ventilators, in particular, has already been enacted or is in the process of being enacted in many countries, for example in the USA [12], due to the COVID-19 pandemic.

The treatment of sleep apnea is important in the long-term, however, to my knowledge it is in most cases acceptable to interrupt treatment if needed. Therefore, existing CPAP machines from sleep apnea patients could be borrowed in high numbers and made available in hundreds of thousands, or even millions worldwide, for the treatment of COVID-19 patients.

The patient benefit of a non-invasive ventilation can be further increased by additionally administering oxygen into the ventilation hose of the CAPA/BIPAP machines to prevent the main cause of death of COVID-19, respiratory pump failure through exhaustion and the resulting hypoxia.

It was recently shown [13] that the intensive care units overflowing with corona patients in Italy and Spain could be an essential factor in the transmission and infection rates of COVID-19.

The approach described in this article could make the treatment of COVID-19 patients in peripheral hospital wards possible. In some cases, treatment at home could be possible with management or instruction from nursing staff, which could mitigate the infection problem. Certainly in such a scenario, it is of particular importance to consider that incorrect fitting of the mask or patient non-compliance are causes of the high error rate in non-invasive ventilation.

Of course, severe cases would still need to be treated in intensive care units in hospitals with invasive ventilation (intubation, cannulation).

Viral load from exhalations in surrounding air

If the condition of a COVID-19 patient worsens so that breathing becomes difficult and the blood oxygen levels (SPO_2) decrease, oxygen is delivered via a nasal cannula. If this treatment is not adequate, it is an option to transition to high flow oxygen therapy, also via nasal cannula, in which the oxygen flow is increased to 30-50 L/min. However, this results in aerosolling of nasal discharge which carries a high viral load, that contaminates the air in the room and respectively increases the infection risk for hospital personnel. Therefore, this treatment for COVID-19 patients is currently controversial [4].

Clinical ventilators have separate hoses for inhalation and exhalation which are merged in a y-piece near the patient. This permits the collection of exhalations, which are then released into the room through an HME filter. Devices for non-invasive ventilation (NIV) usually have only one hose. Exhalations are released without filtering via a valve that works like a desired leak. Therefore, NIV can lead to a much higher viral contamination in the air than clinical ventilators. Addressing

exhalations is a pressing topic that must be pursued. On this topic in particular, thinking outside-the-box, as seen in the *Easy-Covid19* working group [14] associated with the Italian start-up ISINNOVA, can be extremely effective.



Figure 7 ISINNOVA: re-functioned snorkeling mask as a ventilation mask [14]

In this project, a standard snorkeling mask was re-functioned by using a 3-D printed component; and incidentally solves the exhalations problem described above by using an attachable filter.

Questions such as: “Can available NIV masks be modified in simple ways and using available means, such as an exhalation filter?”, “Is it possible to siphon exhalations, clean them via an HME filter, and then release them into the surroundings?” and “Considering the current shortage of HME filters, can the siphon-filter be replaced by heat-sterilizing the outgoing air?” should urgently be addressed. We must take the liberty to think outside-the-box here to find inspiration: consider a “reverse” hot-air fan or hair

dryer.

Summary

It is possible that the approach described here to **upgrade millions of available CPAP home therapy machines to function as BIPAP/Bilevel machines** together with so-called vented masks or products similar to *Easy-Covid19* may help to mitigate the current global threat of a shortage of ventilators. The concept may help to prevent the scenario that soon potentially thousands of COVID-19 patients will not be able to receive the necessary and sometimes life-saving respiratory support. This solution could be made available in very short time, because it is purely software based.

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