

Adapted Diving Mask Bench Tests as an Autonomous Respiratory Support in Healthy Volunteer

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Research

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Abstract

Purpose

The scenario of global health crisis due to SARS-CoV-2 pandemia combined with the shortage of resources in many countries has justified numerous studies to design easily replicable and economic respiratory support devices. We have developed an adapted diving mask (ADM) to be used as an autonomous and safe respiratory support. The objective was to prove a minimum positive end expiratory pressure (PEEP) with the ADM without any adverse events.

Methods

Bench tests was done in 22 healthy volunteers with our ADM prototype. Expiratory-inspiratory flow and pressure were registered apart from blood and transcutaneous hypercapnia.

Results

There were no statistically significant differences in the baseline analysis results and after therapy, except in pO₂. Mean PEEP measured was 8.2 ± 4.2 cmH₂O with a peak measured pressure of 20 cm H₂O.

Conclusions

The ADM has shown good tolerance and a therapeutic mantaining PEEP with no evidence of any deletereous effect or hypercapnia with its continuous use.

Introduction

In February 2020, the World Health Organization (WHO) designated the disease caused by the new coronavirus, SARS-CoV-2, originating from Wuhan, China, as COVID-19. It was declared a public health emergency in January 2020 and a pandemic in March 2020, currently exceeding the four million confirmed cases globally. This pandemic has spread over almost the entire territory of Spain, being one of the countries with the highest number of confirmed cases. This exponential growth of cases caused the saturation of the Spanish health system, mainly of intensive care units (ICU), causing the shortage of approved ventilatory support devices and stimulating the search for effective and safe alternatives [1]. The expansion of the pandemic in the rest of the world, especially in Latin America, continues. In this way, the WHO has already warned of the "worrying upward trend" in Africa and Latin America area and several studies estimate that if the pandemic is not controlled, up to 190,000 people could die and up to 44 million could be infected, probably reaching the limit of their resources . [2]

The interstitial pneumonia is the main lung affectation due to SARS-CoV-2, causing in 41.8% of patients an acute respiratory distress (ARDS), that will require of orotracheal intubation (OTI) or non-invasive ventilation (NIV) in 19 % of them. The mortality of ARSDS in coronavirus disease (COVID) exceeds 50% independently of ICU admission [3, 4, 5, 6]. The administration of high flow oxygen with positive pressure

at the end of expiration (PEEP), represents the minimum rescue respiratory support for many patients in a situation prior to admission to the ICU (7). Although the clinical applicability of homologated PEEP-generating devices (also called continuous positive airways pressure [CPAP] devices) are not very versatile, in many cases they have managed to reduce mortality and OTI. Administering a sufficient PEEP level will be able to avoid alveolar collapse and greater blood oxygenation is achieved meanwhile we provide time for the recovery of the patient or until there is the possibility of admission to the ICU. [8. 9] These approved devices have been highly demanded in the situation of sanitary crisis by SARS-CoV-2. This scenario of global health crisis combined with the shortage of resources has justified numerous studies to design easily replicable respiratory support devices, trying to alleviate the lethal effects of this pandemic.

AIM OF THE STUDY

The main objective of this work is to demonstrate the safety of an alternative prototype of respiratory support with an adapted diving mask (ADM) in the context of the COVID-19 pandemic. The safety will be considered proven if:

- A therapeutic pressure was reached ($\geq 4\text{cmH}_2\text{O}$)
- The absence of hypercapnia demonstrated in arterial blood and through continuous monitoring of transcutaneous capnography during the use of the prototype.

Materials And Methods

Human Resources

Sample size was calculated for a population of 310.000 inhabitants with a 95% of confidence interval and error of 20%. Twenty-two volunteers were included in the study after clinically ruling out SARS-CoV-2 infection. Volunteers with chronic controlled diseases were not excluded.

All volunteers were Caucasian with a mean age of 42.45 ± 8.03 years with 86.4% males and a mean body mass index (BMI) of $25.67 \text{ kg} / \text{m}^2 \pm 4.82$. Only one of them had diabetes and in no case was there a pulmonary disease.

A nurse and a physician were present during the tests. An informed consent was signed to confirm understanding of the technical protocol performed.

Technical resources

- Monitoring: The Aisys CS2 respirator with monitor (Datex-Ohmeda of General Electrics) was used to collect the flow and pressure signals, connecting to its side stream oxygen (O₂) and carbon dioxide (CO₂) sensor incorporated in the system connected in the upper connection. The record of the pressure and flow waves was carried out thanks to the iCollect software installed on an external computer. Oximetry monitoring and transcutaneous capnography (Digital monitor SENTEC Biolyne supply® with the sensor

V-Sign2™ and V-STATS data processing software) were added, placing the sensor in the supraclavicular space of all patients with signal monitoring for the entire duration of the recording. Their automatic reports were generated through the V-stats software.

A portable gasometer (Epic Blood analysis system, Siemens Healthcare®) was used for the arterial blood analysis. The first sample was extracted with patient breathing ambient air and the second sample, before removing the prototype having been at least 3 hours breathing air with a 100% of oxygen by the mask. The values of pH, pCO₂, PO₂, HCO₃ and stO₂ were recorded.

- Materials: Our prototype respiratory support device starts from a diving mask from Decathlon. The Easybreath™ diving mask from 2015 (Figure 1.A) was the model we modified to connect to a PEEP valve and a high flow oxygen output. A total of four 3D printed pieces were developed for this purpose by a multidisciplinary team that includes pulmonologists, emergency physicians, orthopedic surgery at the Hospital Universitario Infanta Leonor and engineers from Airbus and CT. Two of these pieces have a connector function. The remaining two are a PEEP valve with the help of a spring adjusted to the maximum pressure given and an anti-suffocation valve with the sum of a membrane already present in the original mask. The mean PEEP settled reached with the maximum closure of the valve was 8 cmH₂O. These printed pieces comply with the geometric characteristics described in UNE-EN ISO 5356-1: 2015 apt. 3 and 4. The necessary software for printing is freely accessible and distributed in standard STL format. To direct the oxygen inside the mask were assembled four Intersurgical® approved connector pieces as described below: (Figure 1.B)• T-piece 22F-22M-22M: references I1982, I1986 or I1985. • 22M-15M I1943 connector. • Estomeric connector for I1702 flowmeter. • Loose high flow branches I5018. A non-return valve was placed in the front inhalation port of the ADM, reversing the direction of the membrane that by default is in the original mask and serves as an expiratory seal in operation as a diving mask. The Figure 1.C indicates the direction of the inspiratory and expiratory flow of the patient, indicating the entrance of the oxygen flow with the arrangement of all the elements of the previously proposed system.

Healthy volunteers were placed in a sitting position with the monitoring previously mentioned and the mask system connected to a high flow oxygen source (50 liter oxygen bottle) through a flowmeter adjusted to more than 15 lpm.

The four pieces printed have been by stereolithography (SLA) with the Form 2 machine (Formlabs) using a biocompatible Class IIA (I) resin (Dental LT5 Clear) with high resistance to fracture and wear, following the protocols indicated by the manufacturer including cleaning after printing in isopropanol to remove excess unpolymerized resin and a post-cure step at temperature to ensure complete conversion of the resin. With this protocol it is achieved that there are no residual monomers / oligomers that can leave the material. The resins used comply with the ISO 10993-5: 2009 Not Cytotoxic, ISO 10993-10: 2010 / (R) 2014 Non Irritation, ISO 10993-10: 2010 / (R) 2014 Not a sensitizer, ISO 13485: 2016 Medical Devices (Quality Management Systems - Requirements for Regulatory Purposes) and ISO 14971: 2012 Medical Devices - Application of Risk Management to Medical Devices).

Statistics

All the data have been collected in the test bench and have been processed with SPSS version 22. The quantitative variables are expressed as means \pm standard deviation. Categorical variables are expressed as percentages. A value of $p < 0.05$ was considered statistically significant.

Results

There were no statistically significant differences in the baseline analysis results and after therapy, except in pO_2 . (Table1)The transcutaneous capnography records showed a CO_2 minimum, maximum and mean of 31.33 ± 4.10 mmHg, 37.01 ± 3.87 mmHg and 34.71 ± 3.55 mmHg respectively. The minimum oxygen saturation was $74.22 \pm 12.33\%$, the maximum of $100 \pm 0\%$ and the mean of $96.72 \pm 3.41\%$. The printed PEEP valve was kept adjusted to a maximum closure, reaching throughout the recording a mean PEEP of 8.2 ± 4.2 cmH₂O with a peak measured pressure of 20 cm H₂O. Figure 2 shows the evolution of the flow and pressure measured in a volunteer with ADM at baseline respiratory rate and tachypnea in ranges of 30 seconds.

Discussion

In this manuscript we report the bench test results in healthy volunteers of a new respiratory device created as a result of shortness of conventional CPAP devices in the context of COVID pandemia. Our prototype has met the standard of ventilatory support as it was designed to, presenting the most relevant characteristics of previously approved CPAP devices (easy to use and low resource requirements). No deleterious effect were observed.

One of the main strengths of this prototype is its biosecurity. For most of the homologated devices, the exhaled air through the expiratory leak is not filter or it is necessary to modify the circuit to avoid aerosolization of little particles into the environment. With the use of the ADM, all the expired air will come out entirely filtered through the expiratory port where a high-efficiency electrostatic filter is adapted, solving this problem. [10]

All the respiratory support present pressure fluctuation in situations of tachypnea (> 25 breaths per minute) or respiratory drive increment, due to the high demand for support by the patient. If this happen, the device could not be able to provide the adequate respiratory support, even worsening the respiratory mechanic of the subject. This problem must be keep in mind in the designs of PEEP devices, although in not autonomous devices a better compensation will be expected.

In our bench test in healthy volunteers no drop of pressure was observed during the monitoring even in abrupt inhalation with no significant decrease of FiO_2 . This is due because the pressure in our system depends in a gran part of the high flow oxygen supplied, that must not be less than 15 lpm. The lack of interconnection leaks of the printed parts and their assembly is another cause to explain the stable pressure found in ADM.

In any non-invasive respiratory therapy, the adaptation of the interface to the patient's physiognomy is the main leaks generator, being a higher pressure the main risk factor in their appearance. In our prototype, pressures greater than 10 mmHg H₂O were associated with around-mask leaks appeared that caused a bad tolerability and a suboptimal therapy. Due to this, the tolerable therapeutic pressure with the minimum amount of leaks was the range of 4-10 cm H₂O. Fluctuation in PEEP and maximum peak pressure in the range to consider dangerous to produce lung damage was not achieved (Peak Pressure-PEEP > 15 cmH₂O) [11, 12, 13, 14]. The respirator used in our bench study is not able to quantify the around-mask leaks, as it was mainly for invasive use.

There were no statistically significant differences in the variation of the gasometric parameters at baseline and after therapy, except in pO₂, as a consequence of hyperoxygenation caused by the exposure to a continuous oxygen flow at 100%. This situation is called hyperoxia and surveillance is mandatory due to the possibility of causing secondary hypercapnia and promoting alveolar collapse. [15]. Hyperoxia due to external supply of oxygen can decrease the hyperventilation reflex, in patients with a tendency to retain carbon dioxide, promoting the appearance of respiratory acidosis. This is why the limitation of use for 4-5 hour shifts with intermediate breaks with less oxygen supply and a close monitoring of CO₂ levels is necessary, especially in high risk patients.

The monitoring of pCO₂ in our sample did not show elevation above the maximum pathological threshold (pCO₂ > 45), ruling out hypercapnia during the registration. A tendency to mild hypocapnia (<35mmHg) without having detected any side effect. The choice of a minimum of 3 hours- monitoring was made based on the non-standardized indication of non-invasive respiratory support therapy in the hospital ward, usually indicated to let the patient have breakfast, lunch and dinner once the first acute phase with 24-72 hours of uninterrupted NIV is overcome. Alveolar collapse is another adverse event of hyperoxygenation but neither was detected in our patient.

Mental status of candidates to receive NIV may varies from wide awake to the unconsciousness. In the last group re-breathing and bronchoaspiration can appear. Parenteral treatment and nutrition is recommended to avoid bronchoaspiration. In patients with conscious preserved, maintaining intravenous treatment is not mandatory, but advisable, complemented with liquid diet and might keep tight surveillance of hypercapnia. Re-breathing occurs if the patient breathes in his own previously exhaled air with a high carbonic concentration. This would take place if the circuit does not have a release valve where the expired air can escape or if the arrangement of the system eases its recirculation. In the ADM prototype, the release valve is placed at the top of the mask, where the air flow will exit through the high-efficiency electrostatic filter and the PEEP valve. The location of an anti-return membrane in the outside-in direction is directed to avoid the recirculation of the exhaled air inside the ADM, permitting the high flow oxygen to penetrate into the mask. This way, we will prevent the patient exhaled air from drifting back to the oxygen connection. Thereby, the continuous flow of oxygen will ease the upward direction of the circulating air inside the mask, finally leaving through the upper exhalation port. (Figure 1.C). To allow the patient normal breathing if the flow system fails, our prototype has an anti-suffocation valve to take in air from the ambient if it is necessary.

Ventilator-induced lung injury (VILI) can occur in ARDS ventilated patients. COVID-19 patients with ARSD generates a high inspiratory demand in a normally compliant lung. This high demand can generate peak inspiratory pressures greater than 25 mmHg, which can be damaging to the lung causing barotrauma (pneumomediastinum and pneumothorax), volutrauma (if higher flow is provided) and atelectrauma. Also, the presence of high peak pressures in normally compliant lungs and in a situation in which the patient has a high respiratory drive, can generate alveolar shear forces that end up generating lung injury due to the wide fluctuation of pressures between the granted and the demanded by the patient. Despite in our registry there were no Peak Pressure - PEEP > 15 cmH₂O, it is important to mention that the study population profile is not that expected in the patients usually subsidiary to this respiratory support. (11, 12, 13, 14)

A limiting factor in the use of PEEP autonomous devices is the need of a high flow oxygen supply through a flowmeter that supplies more than 15 lpm). This is due because with a lower flow, a sufficient pressure is not reached for the autonomous PEEP valve to be functional. It is estimated that for the continuous treatment for 4 hours, a 50-liter cylinder of liquid oxygen would be consumed. In a hospital with access to a wall-mounted oxygen output, this is not a problem. However, in circumstances of scarce resources or in developing countries this can limit the use of this devices. Nowadays our prototype has not solved this problem but our team is working on it.

Conclusions

We must remind that the respiratory support of choice in patients with ARDS is invasive mechanical ventilation with OTI. This is not different in COVID patients. However, in a situation of global health crisis, the shortage of resources and hospitals with overflowing ICUs, respiratory support with NIV is mandatory pending the patient's own favorable evolution or the possibility of admission to the ICU later on [16, 17, 18]. In places without access to first level health resources, the possibility of having autonomous respiratory support devices becomes more necessary as could help many of these patients [19] Our aim is not to validate a prototype to use in normal circumstances, but to validate the safety of the clinical use of our ADM as an alternative to other CPAP devices, at exceptional times and in a context of shortages of other homologated devices. This prototype does not require electronic equipment and also due to the characteristics of the materials with which it has been made, it is fully reusable after sterilization. This provides added value for exports to developing countries, in which the existences of autonomous and reusable devices can bring hope to patients who do not even have an option to be admitted to an ICU [20, 21].

Declarations

Ethics approval

The study has been developed after the sign of the informed consent of the healthy volunteers and approval of pertinent authorities

Consent to participate

The study has been developed after approval of pertinent authorities

Consent for publication

Not Applicable

Availability of data and material

All data collected is available under request

Conflicts of interest/Competing interests

The authors declare no conflicts of interests

Funding

The study was financed and carried out thanks to Banco Santander and the assignment of its staff and facilities. Decathlon Spain gave the Easybreath masks to carry out the entire project. The design and study of materials for the parts adapted for the prototype was carried out by AIRBUS and CT engineers. Printed pieces used were thanks to CSIC (ICTP-CSIC)

Authors' contributions

BA analysed and interpreted the patients data. CC collected the data. AC helped to review the bibliography. MJB. Supervised the manuscript. AA facilitated the machines to collect the data; JMM facilitate the installations to carry out the tests and supervise them, RL coordinated the tests.

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The study was financed and carried out thanks to Banco Santander and the assignment of its staff and facilities. Decathlon Spain gave the Easybreath masks to carry out the entire project. The design and study of materials for the parts adapted for the prototype was carried out by AIRBUS (Juan Manuel Canalejo) and CT engineers (Alberto Molina). Printed pieces used were thanks to Juan Rodriguez Hernández of the CSIC (ICTP-CSIC). Thanks to Angel Manuel Sevillano for the review of the paper.

Abbreviations

ADM - adapted diving mask

ARDS - acute respiratory distress

BMI - body mass index

CO2 - carbon dioxide

COVID-19 – Coronavirus infectious disease

CPAP - continous positive airways pressure

ICU - intensive care units

NIV - non-invasive ventilation

O2 - oxygen

OTI -orotracheal intubation

PEEP - positive pressure at the end of expiration

SLA - stereolithography

VILI - Ventilator-induced lung injury

WHO - World Health Organization

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Tables

Table 1. Baseline arterial blood gases (ABG) Values and Previous Withdrawal of ADM

	pH	pCO2 (mmHg)	pO2 (mmHg)	HCO3 (mmHg)	stO2 (%)
Baseline ABG	7,42	38,43	91,68	25,26	96,75
ABG with ADM	7,42	41,22	520,99	26,97	99,94
P	0,63	0,51	0,00	0,51	0,98

Figures

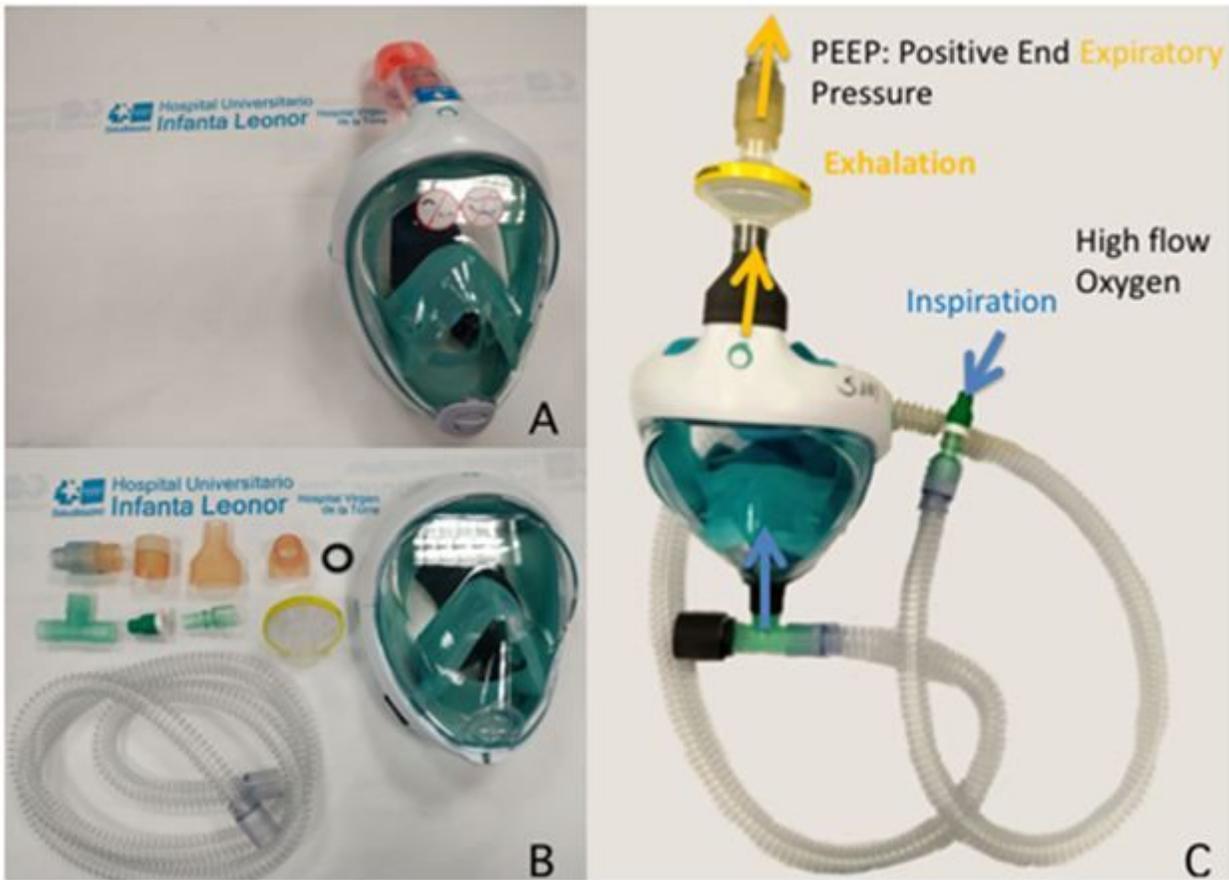


Figure 1

A. Diving mask in its original format. B. 3D printed pieces, O-ring seal, modified mask and standard high efficacy filter and Intersurgical® oxygen connections. C. Air flow circuit from inside to outside the mask.

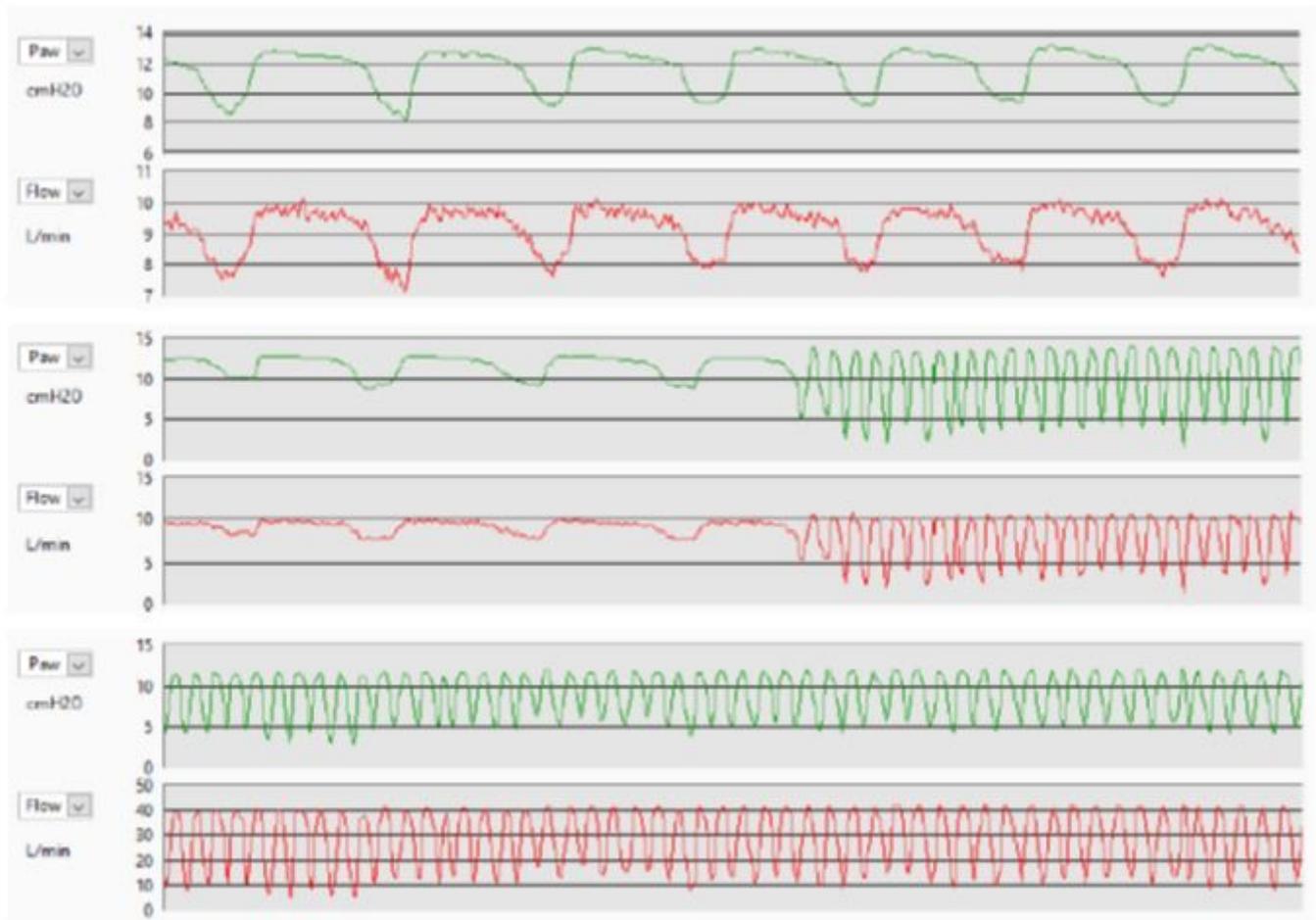


Figure 2

Flow and Pressure curves in 30 seconds ranges. Normal breathing to hyperventilation.

Supplementary Files

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