Boussignac's CPAP valve, for a contamination-free NIV

***Fig.1a**. CPAP system assembly photo- Dr Guillaume Carteaux, Pr Armand Mekontso Dessap - Henri Mondor University Hospital*

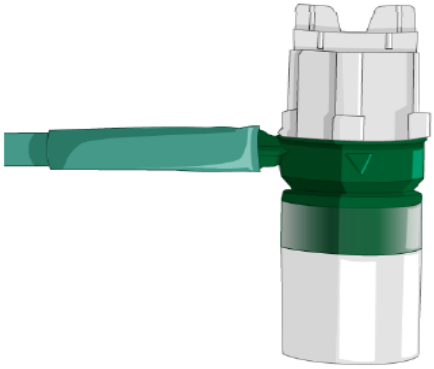

***Fig.1b**. 3D rendering of the Boussignac CPAP valve (Vygon)*

TECHNOLOGY AND RESPIRATORY WORK

Oxygen enters the valve through micro-cannulas that generate a high-speed flow in the center of the tube. Unlike Venturi devices, this high-speed flow creates a turbulent zone that separates the patient's respiratory volume (lungs and dead volume) from the outside air, without creating an airflow for the patient. It is the patient who will call for an air-oxygen mixture at the moment of inspiration. The turbulence zone acts as a valve, a virtual two-way valve that keeps the lungs pressurized on inspiration and creates a brake on expiration (Figure 2).

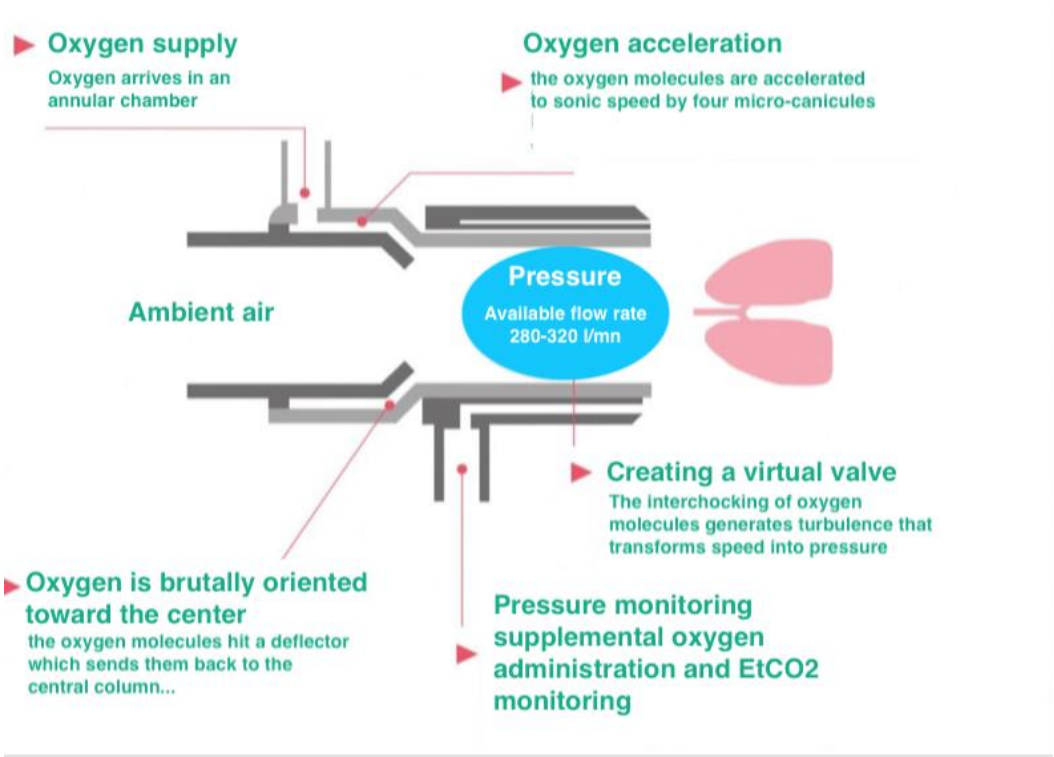

***Figure 2**. Schematic representation of the operation of the Virtual Valve (Vygon source)*

In order to pass through this virtual valve on expiration, the pressure of the gases exhaled by the patient must exceed the set pressure of the valve, which is monitored by a 0-25 cm H_2O manometer.

<u>This pressure is proportional to the oxygen flow.</u>.

Required oxygen flow rate (l min^{-1})	Resulting PEEP (cm H_2O)
16	2.5
22	5
27	7.5
30	10

***Figure 3**. Table of average pressure vs. flow rate, without HME filter*[1]

It is therefore an adjustable valve without changing the circuit (change of PEEP valve for example). It is an open system: the pressure in the patient's lungs can never be higher than that of the virtual valve.

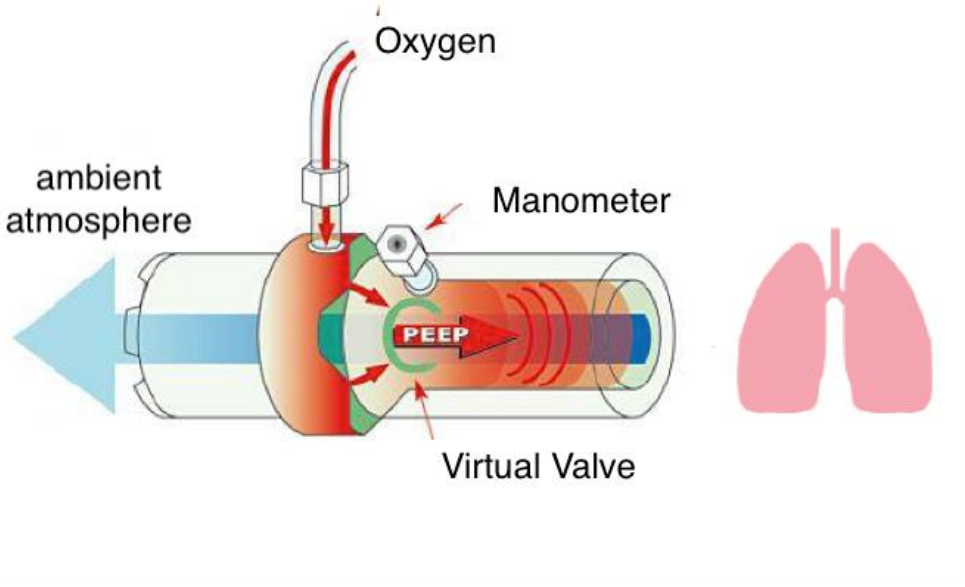

***Figure 4**. Diagram of how to obtain the PEEP in "Open System".*

If the insufflated volume of air were to exceed the alveolar capacity, the pressure would be increased, (> the PEEP), and the air automatically expelled from the patient.

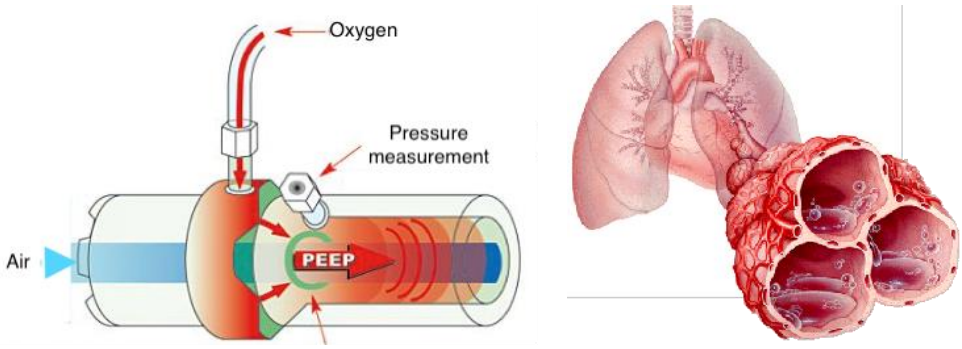

***Figure 5**. Expansion of the alveoli on inspiration*

It is the elastance and compliance of the lung that regulates the speed of gas arrival: the system adapts to the physiopathology of the patient..

<u>Barotrauma or volotrauma are impossible...</u>

[1] Mesure sur banc d'essai des FiO2 délivrées par la CPAP de Boussignac alimentée en oxygène pur; F. Templier et al. / Annales Françaises d'Anesthésie et de Réanimation 22 (2003) 103–107

When the patient breathes in, oxygen and air will pass through the valve. Because of the speed at which the gases spin in turbulence, the "available flow" of the mixture is in the order of hundreds of litres/minute.

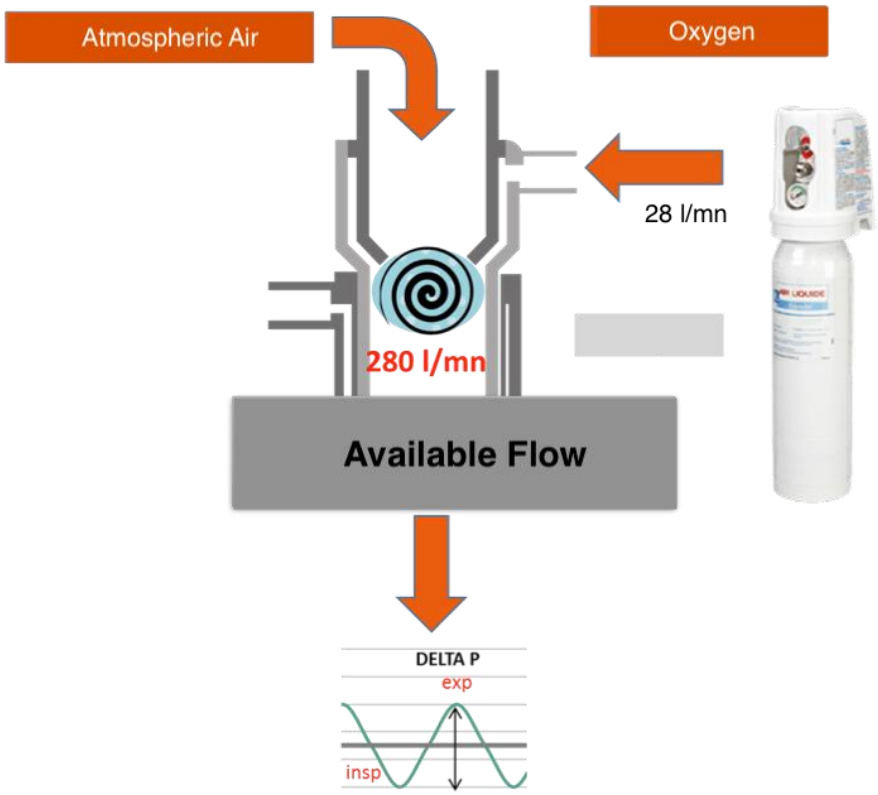

***Figure 6**. Schematic of the turbulence and available flow rate. Delta P = pressure difference*

This "available flow" is always higher than the patient's need, especially the peak inspiratory flow (up to 90l/min for some patients). The available mixing volume is therefore always greater than the patient's inspiratory volume required. This has the effect of limiting the drop in intra-pulmonary pressure, and thus the patient's inspiratory work, which is practically equal to that of breathing in the open air (Figures 6 and 7).

Because oxygen enters the valve at high pressure and flow rate, the percentage of oxygen in the inspired mixture (FiO_2) is almost always greater than 70% during the entire inspiratory cycle

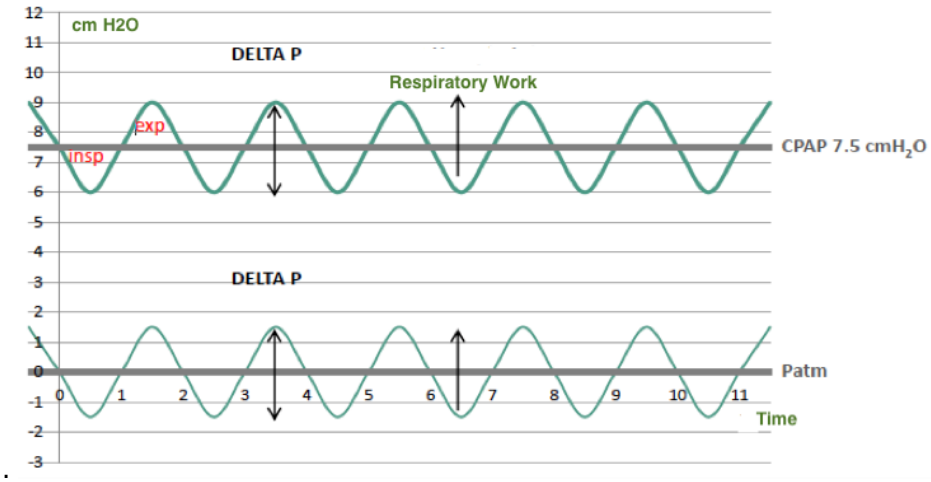

***Figure 7**. Simplified breathing curves for spontaneous breathing and CPAP*

If the available peak flow rate was not sufficient to meet the patient's instantaneous inspiratory need, the intrapulmonary pressure drop would be greater, as shown in the figure below (Figure 7; red curve for less "available flow" than green curve). The patient's work of breathing would be increased in contrast to spontaneous breathing

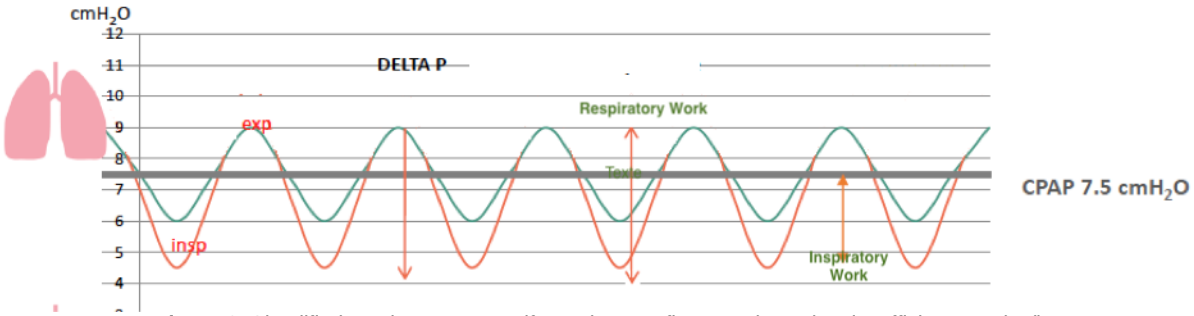

***Figure 8**. Simplified respiratory curves if an adequate flow rate (green) or insufficient one (red)*

The effect of this ventilation is observed by the evolution of the patient's SpO2 (reference value between 90% and 92% depending upon the protocols).

This device does not itself have an audible alarm. This requires regular monitoring of the patient. Only the pressure generated by the valve is monitored by the manometer.

A NIV THAT DOES NOT CONTAMINATE THE ENVIRONMENT

Since the same opening is used for both inspiration and expiration, a high-flow, low-resistance, antibacterial, antiviral HME filter can be installed at the mask outlet. This has the advantage of keeping the gases humid, of reducing the need to insert a humidifier, and of eliminating environmental contamination with pathogens, if the mask is correctly placed on the patient.

Placed directly at the mask outlet, this filter secures the entire circuit upstream against the risk of contamination.

The mask must be leak-proof and must not have any intentional leaks. **Note that the air in the room is gradually enriched with oxygen, its flow rate being high.**

UTILISATION

When caring for patients and handling the system, caregivers must ensure that they wear appropriate protective clothing and accessories, due to the risk of nebulization if the mask position is readjusted.

The valve being adjustable by gas flow regulation, allows to start oxygen therapy with a relatively low pressure, which can be adjusted upwards without changing the device according to the evolution of the patient's SpO2, an essential parameter for patient monitoring. This makes it easier for the patient to get used to the effects of positive pressure!

The pressure can also be adjusted downwards at the end of treatment, when the patient is weaned. Furthermore, if a high FiO2, obtained with a pure oxygen supply, is no longer necessary, it can be reduced by supplying the valve with a more or less important air-oxygen mixture, even up to 100% air, while continuing to provide the patient with the respiratory assistance described above.

Please note that the valve is equipped with a coding system to ensure that it can be fitted to the mask without error.

CONCLUSION

- The Boussignac CPAP valve has the advantage of providing proven respiratory assistance in non-invasive ventilation, with adjustable positive pressure from 3 to 10 cm H2O, proportional to the O2 flow (6 to 30 l/min),

- Generates instantaneous available flow and volume that satisfies the patient's need throughout the inspiratory cycle.

- It generates a high FIO2 generally above 70%.

- The system adapts itself to the patient's pathophysiology.
  Any barotrauma or volotrauma is impossible.

- The system allows the adaptation, to the proximal connection of the mask, of an HME antibacterial and antiviral filter, high flow and low resistance, which considerably reduces the risks of contamination of the environment, (independently of the risks of leaks at the level of the face mask), ideally a HEPA filter for better prevention of contamination risks.
  This filter generates a pressure drop indicated on the instructions or even on the packaging, which may slightly reduce the performance of the system.

- Easy to assemble, it does not require a high level of technical training for its use, the possibility to adjust the PEP without manipulation limits the risks of contamination.,

- The accessories are standard and commonly used in hospitals,

- Be careful, however, with the choice of accessories, particularly for the mask, which should preferably be a NIV mask with a "skirt" (silicone strapping around the perimeter in contact with the patient's face), guaranteeing the best possible seal and comfort.

- The disposable system is inexpensive.

USEFUL LINKS

FAQ BOUSSIGNAC (→ Excellent App on line – To visit absolutely ! In French and in English. Click on the "FAQ ENG" button at the bottom of the screen)

MARS, 3 april 2020, French MoH, in french

Vidéo on the use of the Boussignac CPAP

COVID-19 PROTOCOLES

The Boussignac valve is used by many resuscitation teams for the treatment of Covid-19 patients. It is included in the "Doctrine for the use of ventilation devices and respirators for COVID-19 patients" of the Ministry of Solidarity and Health, dated April 3, 2020.

Some examples of protocols currently used in French hospitals are given in the appendix.

Appendix – Some examples of protocols using the Boussignac CPAP

Boussignac® CPAP System- Short Installation Procedure

Dr Khoubeyb **Abdelhafidh**, Dr Philippe **Goater** & Pr Gilles **Dhonneur**

Paris, Cancer Curie Hospitals Group

Boussignac® CPAP System (B®CPAP) is indicated in Covid19+ (or possible) patients requiring enrichment of inspired oxygen concentration (Sp02 < 92% in ambient air).
B® CPAP can be used continuously or discontinuously depending on the needs.
The use of B®CPAP is associated with close or continuous monitoring (depending on clinical status) of Sp02.

Very short B®CPAP System « set-up »

Make sure the patient's environment is placed in negative pressure or at atmospheric pressure and follow the User Manual (drawing and picture)

A) Assemble the 3 elements of the System: 1 facemask with its attachment ties+ 1 adapted HEPA filter type* + the B®CPAP. *A small connecting piece may be needed to connect the filter to the B® CPA.P. The interSurgical® HEPA filter connects directly to B® CPA.P.

B) Connect the B®CPAP piece to wall-flowmeter

C) Start to increase oxygen flow rate beginning at 6 l/min => measure rest Sa02 , 3 min later
   a. If < 92% increase the flow by 3 cmH20 steps then control Sp02, 3 min later.

   b. If rest SpO2 remains below 92% at 15 l/min flow inform physician from the ICU and propose to use a 30 L/min wall-flowmeter under ICU supervision

Major advantages of the B®CPAP System

Usable in the ward. No energy required. Strictly open system for pressure and ventilation. Protection of care givers against exhaled infected particles. Protection of the environment of the patient. No possibility of overpressure in upper airways. Very low risk of ventilatory leak and aerosolization of infected particles. Adaptive system promoting minor and variable inspiratory assistance (depending upon inspiratory flow rate generated by the patient) and well tolerated low level of positive expiratory pressure in the upper-airways. Allows the use of aerosolizers to deliver treatment directly (bronchodilators) into the lung without contaminating the environment of the patient. Identifies patients who are worsening and evaluate the need for admission to the ICU. Limits hospital oxygen consumption (as compared to others open oxygenation techniques).

CPAP Boussignac for COVID 19

18.03.2020

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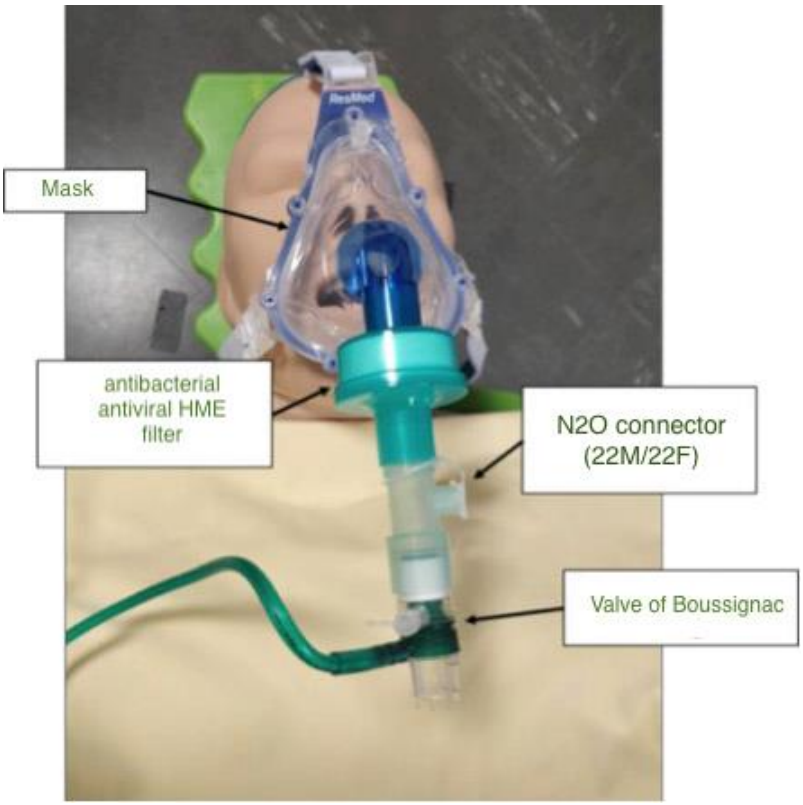
(2) Université Paris Est Créteil, Faculté de Médecine de Créteil, (3) AP-HP.Sorbonne Université, Hôpital Pitié Salpêtrière,

Assembly

An HME filter is inserted between the face mask and the Boussignac CPAP, via a connector.
"nitric oxide."



CPAP Sessions

Installing CPAP (in order)

1. Installing the headgear
2. Attach the headgear to the assembly (mask+filter+connector+CPAP)
3. onnect CPAP to wall-mounted oxygen at a flow rate of 15 to 20 l/min.

Session

- Duration: 6 to 12 hours, then 1 hour break
- Call resuscitating physician if any of the following clinical signs are present for at least 5 minutes on CPAP:
  - SpO_2<90%, Pull, breathing rate > 25/min
  - Systolic blood pressure < 90 mmHg, heart rate > 120 / min, marbling
  - Consciousness disorder

Uninstall CPAP (in order)

1. Turn off the wall oxygen
2. Detach headgear from the assembly (mask+filter+connector+CPAP)