

# Breathe again!

## Innovation in airway clearance

Simeox acts directly on the physical properties of mucus to liquefy secretions and assist their transport.



# Simeox: for a better quality of life

## Innovate to improve the day-to-day life of patients suffering from respiratory diseases

Bronchial clearance of patients with cystic fibrosis is an essential component of the fight to preserve lung function<sup>1</sup>. Chronic coughing and mucus production in COPD patients are very closely associated with the occurrence of exacerbations<sup>2</sup>.

Shortness of breath, fatigue, excessive coughing, an abundant and difficult-to-mobilize mucus significantly affect the day-to-day life of patients with chronic lung diseases. In addition, clearing the airways of those patients is challenging due to their dyspnea, fatigability, level of distension and anxiety.

It is with the intention to address these difficulties that the company PhysioAssist has innovated and developed the Simeox technology, with the objective to provide a solution that can allow those patients to preserve their lung function and relieve their symptoms in order to improve their quality of life.

## Several years of fundamental research in partnership with the CNRS and Inserm

Simeox is the result of several years of research and development in partnership with the CNRS (National Center of Scientific Research), Inserm (National institute of health and medical research) and prestigious university hospitals.

The PhysioAssist research program has been dedicated to studying bronchial mucus and has led to the development of the technology present in Simeox<sup>3,4</sup>.

## Clinical results

- Improvement of lung function characteristics such as FEV1 and FVC<sup>5,6</sup>
- Improved symptoms<sup>5,6</sup> and secretion clearance<sup>7,8</sup>
- Improvement of the quality of life in COPD and Bronchiectasis as assessed by the CAT score<sup>5,6</sup>
- High subjective effectiveness in Simeox performance vs. conventional physiotherapy<sup>7,8</sup>
- Improvement of exercise capacity in Bronchiectasis as assessed by 6MWT<sup>5</sup>

<sup>1</sup> Lester et al. Airway-Clearance Therapy Guidelines and Implementation. *Respir Care* 2009;54(6):733-750. <sup>2</sup> Burgel et al. Cough and Sputum Production Are Associated With Frequent Exacerbations and Hospitalizations in COPD Subjects. *Chest* 2009 ; 135 : 975-982. <sup>3</sup> Lafforgue et al. Thermo-physical properties of synthetic mucus for the study of airway clearance. *J Biomed Mater Res Part A* 2017;105A:3025-3033. <sup>4</sup> Lafforgue et al. Rheological properties of synthetic mucus for airway clearance. *J Biomed Mater Res Part A* 2017;00A:000-000. <sup>5</sup> Benefits of Simeox airway clearance technology in non-CF patients with bronchiectasis, Iwan et al., *ERJ* September 2018, 52 (Supplement 62). <sup>6</sup> Effects of a new Airway Clearance Technology versus manual physiotherapy in COPD, Mihaltan et al., *ERJ* September 2018, 52 (Supplement 62). <sup>7</sup> Rapport de l'étude clinique SIMETOL, Février 2019. <sup>8</sup> *Revue des Maladies Respiratoires*, Volume 36, Supplément, 2019.

# A unique technology

The signal delivered by Simeox exploits the biophysical properties of bronchial mucus, one of them being its thixotropic nature: it acts directly on the consistency of the mucus to liquefy it and transport it from the periphery of the lungs to the central airways of the bronchial tree.

## Principle of operation

Simeox is easy to use. However, the handling of the device requires support from a healthcare professional.

The inspiratory and expiratory phases described below are to be repeated several times during a session.

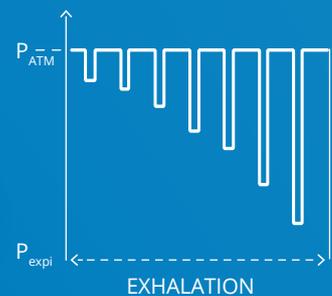
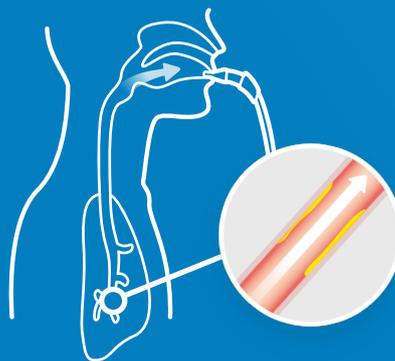
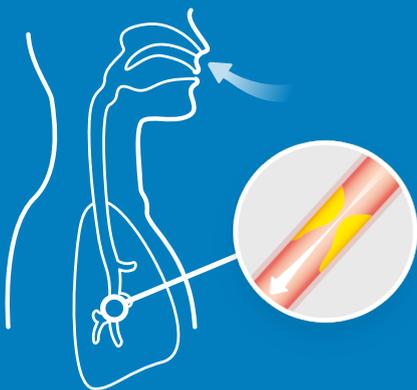
① **The patient inhales slowly through the nose, then does an inspiratory pause to bring the air behind the secretions.**

② **During the relaxed exhalation, the patient activates the Simeox signal by pressing the GO button on the remote control:**

Small volumes of lung air are collected at a frequency of 12 Hz (6 Hz at the end of the cycle).

This very fast air capture generates a negative pressure pulse in the bronchial tree. As the unit continues to withdraw air during exhalation, the generated negative pressure pulse increases, as shown on the graph below.

This succession of very short negative pressure pulses of increasing intensity diffuses a vibratory signal in the bronchial tree that acts on the rheological properties of the mucus to reduce its viscosity. The liquefied mucus is simultaneously transported from the peripheral pulmonary zone to the central airways, and then naturally expectorated by the patient.



## Simeox benefits



### Mobilization and drainage of the deep bronchial mucus

The Simeox signal can spread up to the very distal airways of the bronchial tree to allow the mucus to be collected where it is most difficult to dislodge.



### Fatigue-free drainage

The patient breathes at tidal volume and the patient's exhalation is relaxed, so the patient's fatigue is not increased.



### Reduced risk of bronchial collapse

The Simeox device does not generate continuous flow. The very short negative pressure pulses with in between a reconnection to atmospheric pressure reduce the risk of bronchial collapse.



### A feeling of regained breathing

Simeox helps the patient to exhale allowing him to better «empty» his lungs. The feeling of fresh air that then enters the lungs at the next inhalation gives the patient a real sense of well-being.

# An easy-to-use interface

Carrying handle

## Control Panel

The only adjustments to be made are:

- ▶ the number of exhalations per cycle:  
PROG 1: 6 exh./cycle  
PROG 2: 8 exh./cycle  
PROG 3: 10 exh./cycle
- ▶ signal intensity: 25%, 50%, 75% or 100%.

The visual performance indicator allows the user to know if the signal is being properly transmitted in the bronchial tree.

Remote control to activate the Simeox signal

## Connecting the expiratory kit

The blue light of the ON/OFF button on the control panel stops flashing when a functional kit is detected via the RFID tag on the filter.



# Simeox consumables

PhysioAssist offers a range of single patient use expiratory kits, adapted to the Simeox device, whose design is very specific, in order to allow the Simeox signal to be perfectly transmitted and the system to be efficient.

The expiratory kit consists of a filter, a flexible tube and a mouthpiece.

The filter of the expiratory kit is intended to protect the Simeox device. The air movement generated by the device is always from the patient to the Simeox.

The number of uses of the kit is limited and managed by the tag (TAG RFID) on the filter. This allows to maintain a good hygiene of the expiratory kit, a very important aspect in the management of patients suffering from lung diseases.

## PhysioAssist offers two ranges of kits:

Expiratory kits with reusable mouthpiece	Expiratory kits with single use mouthpiece
25 uses (ref. TUB25)	3 uses (ref. TUB3) or 10 uses (ref. TUB10)
The mouthpiece is washed according to the cleaning and disinfection procedures specified in the user manual. The expiratory kit bag contains 3 mouthpieces (1 mouthpiece + 2 additional replacements in case of loss).	The mouthpiece is for single use only and is discarded at the end of each session. The expiratory kit bag contains as many mouthpieces as the scheduled number of uses.

The choice of the kit depends on the patient's medical condition, which is subject to the assessment of the healthcare professional.



## Product specifications

Dimensions	280 mm x 212 mm x 175 mm (L x l x H)
Weight	5,1 Kg
Frequency	12 Hz / 6 Hz on the last two blue lights of each program
Program	PROG.1: 6 exhalation phases per cycle PROG.2: 8 exhalation phases per cycle PROG.3: 10 exhalation phases per cycle
Signal intensity	25% 50% 75% 100%
Voltage source	230 VAC / 50 Hz
Atmospheric pressure at the place of use	700 hPA to 1060 hPA
Temperature of the place of use	5C° to 40C°

## Product and accessories references

Ref	Description
SIMEOX	Simeox device with accessories (carrying bag, remote control and power cord)
TUB03_EU	Single patient circuit kit (filter + tube) with 3 disposable mouthpieces - <b>3 uses</b> <b>Box of 10 kits</b>
TUB10_EU	Single patient circuit kit (filter + tube) with 10 disposable mouthpieces - <b>10 uses</b> <b>Box of 10 kits</b>
TUB25_EU	Single patient circuit kit (filter + tube) with 3 reusable mouthpieces - <b>25 uses</b> <b>Box of 10 kits</b>
SAC01	Carrying bag
DRAG01	Wrist strap for the remote control
PIEDROULANT01	Roll stand support for Simeox



This Class IIa medical device is a regulated healthcare product that carries, under the regulations, the CE mark.  
Read the instructions in the user manual carefully before using the device.

 To place an order, please contact [simeox@physio-assist.com](mailto:simeox@physio-assist.com)

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