

inogen®



**Leveraging mucus rheology for innovating in airway clearance**

*Simeox acts directly on the physical properties of bronchial mucus to liquefy secretions & assist their transport*

**Inogen® Simeox**

**INNOVATIVE AIRWAY  
CLEARANCE**

**Designed for Comfort  
Engineered to Clear**



**SCHILLER**  
The Art of Diagnostics

# A unique technology

The signal generated by Simeox leverages the biophysical properties of bronchial mucus, one of which is its thixotropic nature: it acts directly on the consistency of the mucus to liquify and transport it from various parts of the lungs to the proximal airways.

## Principle of operation

- 1 At inspiration**, the patient breathes in calmly and slowly through their nose (no more than their tidal volume, no deep inhalation).
- 2 At exhalation**, the patient activates the Simeox signal with the remote control: Simeox intermittently collects air from the lungs, generating specific intrapulmonary vibrations in the bronchial tree.

The unique technology of Simeox works by using high-frequency oscillatory vibrations and intermittent negative pressure applied during exhalations. Within seconds, this signal significantly reduces mucus thickness. To help move and clear mucus, the signal is applied during exhalation, shifting the mucus from deep\* in the lungs to closer airways for easier removal. When the vibrations stop, the mucus recovers its initial status.

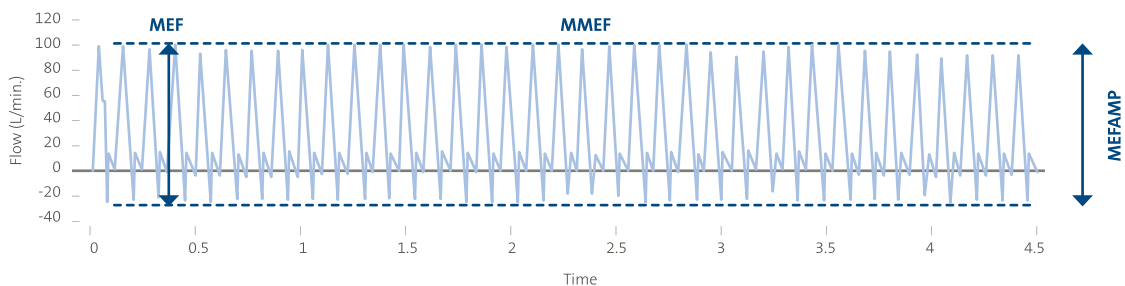
After several assisted exhalations with Simeox (typically 30 to 50 assisted exhalations), bronchial mucus is liquified and rapidly mobilized for productive expectoration.

Simeox has been shown to be easy to use, comfortable and well tolerated. Therapy sessions last 15 to 30 minutes.

This advanced medical technology allows patients to rapidly and sustainably relieve their symptoms associated with excess mucus production and improve their physical well-being. After training by a healthcare provider, Simeox can be used independently, including at home.

*\*tested in a model representing up to generation 20 of the bronchial tree.*

### • Intermittent flow during exhalation with Simeox



MEF: Maximal Expiratory Flow • MMEF: Maximal Mid Expiratory Flow • MEFAMP: Maximal expiratory flow amplitude

## Benefits



**Mucus  
liquefaction**



**Mucus  
mobilization**



**Comfortable**



**Easy  
to use**



**Well  
tolerated**



**Quick  
sessions**

# Efficient Airway Clearing



## QUICK SESSIONS

Simeox works rapidly to mobilize mucus for productive expectoration.

Some patients may benefit from therapy with Simeox in as little as 15 minutes.\*

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

Bronchial clearance of patients with respiratory conditions is essential to preserve lung function. Chronic coughing and mucus production are very closely associated with the occurrence of pulmonary exacerbations<sup>1,2,3</sup>.

Shortness of breath, fatigue, excessive coughing, and abundant mucus can affect the life of patients with chronic lung diseases. Clearing airways can be challenging due to dyspnea, fatigability, level of distension and anxiety.

It is with these challenges in mind that the Simeox technology has been developed and designed.

## Simeox is the result of several years of fundamental research in partnership with research centers.

The PhysioAssist research program has been dedicated to studying bronchial mucus, leading to the development of the technology embedded into the Simeox device.

The Simeox signal leverages mucus rheology to liquefy bronchial mucus, thus facilitating its mobilization from the airways towards the central respiratory tract. Simeox therapy is efficient, safe, well tolerated, and has good patient acceptability.

## CLINICAL OUTCOMES

### • Relieve symptoms associated with excess mucus production:

In a prospective cohort study of 21 adult hospitalized BE patients, health-related quality of life (CAT scores for dyspnea, cough and expectoration) improved significantly in the Simeox group only.<sup>4</sup>

### • Improve physical well-being:

In hospitalized NCFB patients (n=21), walking distance (6MWT) improved significantly in the Simeox group compared to the manual CP group.<sup>4</sup>

### • Facilitate increased mucus clearance from the first drainage session.<sup>5</sup>

• In a study of stable NCFB patients (n=22)\*\*, **81% of patients were adherent<sup>6</sup>**, with Simeox, performing on average  $\geq 3$  sessions/week over 3 months<sup>7</sup>.

1 Lester et al. Airway-Clearance Therapy Guidelines and Implementation. *Respir Care* 2009;54(6):733–750.

2 Polverino E et al. European Respiratory Society guidelines for the management of adult bronchiectasis. *Eur Respir J* 2017; 50: 1700629. doi.org/10.1183/13993003.00629-2017.

3 Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2023 Report) [www.goldcopd.org](http://www.goldcopd.org).

4 Sliwinski, et al, Benefits of Simeox Airway Clearance Technology in Non-Cystic Fibrosis Patients with Bronchiectasis; *Am J Respir Crit Care Med* 2019;199:A5720.

5 Giovannetti P, Morin L, Gaubert MR. Safety and Efficacy of an Innovative Airway Clearance Device Versus Manual Chest Physiotherapy Techniques For Airway Secretion Clearance: a Feasibility Study. *European Journal of Respiratory Medicine*. 2020; 1(2): 132 - 137. doi.org/10.31488/ejrm.107.

6 Self-reported adherence did not differ from use recorded by the Simeox web application.

7 Hamidfar, et al, Feasibility of home initiation of an airway clearance device (SIMEOX) by telecare in people with non- cystic fibrosis bronchiectasis: a pilot study; *BMJ Open Respir Res* 2023;10:e001722. doi:10.1136/bmjresp-2023-001722.

\* Depending on factors such as disease severity, age, and treatment response.

\*\* Hamidfar, et al. is a prospective study including telecare sessions by physiotherapists (3-5 sessions in the first 2 weeks then every ten days).

# 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
- POWER setting (signal intensity):  
25%, 50%, 75% or 100%.

The visual **performance indicator** allows the user to see if the signal is being properly transmitted.

## REMOTE CONTROL

to activate the Simeox signal

## Connecting the EXPIRATORY KIT

The ON/OFF blue light on the control panel stops flashing when a functional circuit is detected (via an integrated RFID tag).



# Simeox consumables

A range of single patient use expiratory kits, specifically adapted to the Simeox device is proposed, allowing transmission of the Simeox signal and ensuring an efficient system.

## EXPIRATORY KIT

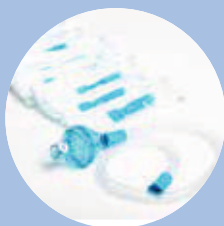
The expiratory kit consists of a filter, a flexible tube and a mouthpiece.

The filter is intended to protect the Simeox device, as the air movement generated by the device is always away from the patient and towards Simeox.

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

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

Two options for the consumables are offered:



### ➤ EXPIRATORY KITS WITH SINGLE USE MOUTHPIECE

#### 10 THERAPY SESSIONS (RÉF: TUB10)

The mouthpieces are for single use only. The mouthpiece is discarded at the end of each session. The expiratory kit bag contains 10 disposable mouthpieces, 1 flexible tube and 1 filter programmed for 10 uses.



### ➤ EXPIRATORY KITS WITH REUSABLE MOUTHPIECE

#### 25 THERAPY SESSIONS (RÉF: TUB25)

The mouthpiece is washed according to the cleaning procedure specified in the user manual. The expiratory kit bag contains 3 reusable mouthpieces (1 mouthpiece + 2 replacement mouthpieces), 1 flexible tube and 1 filter programmed for 25 uses.

# Simeox application

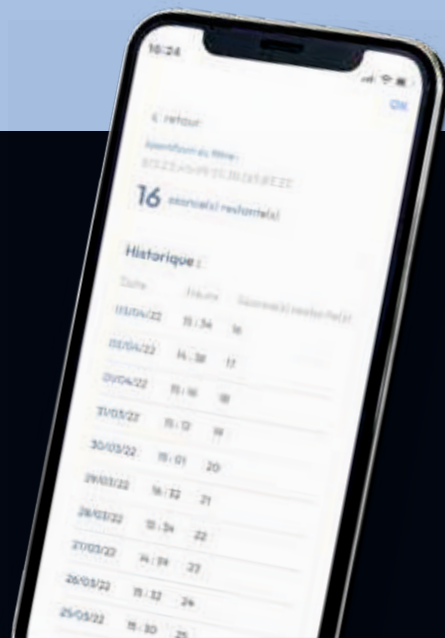
The Simeox app allows to keep track of the number of therapy sessions of the patient kit.



Available on the  
App Store



GET IT ON  
Google Play



## CONTRAINDICATIONS

Absolute contraindications to the use of Simeox are:

- Inability to cough forcefully and independently
- Neuromuscular disease with respiratory muscle weakness
- An active requirement for assistance with inspiration (e.g., ventilatory assistance with endotracheal tube, tracheostomy tube, or ventilated with a mask)

The relative contraindications to its use are as follows:

- Unstable cardiovascular pathologies (recent heart attack, unstable angina, uncontrolled arrhythmias, unstable heart failure)
- Hemodynamic Instability
- Acute pneumothorax or susceptibility to pneumothorax or pneumo-mediastinum
- Active or recent gross hemoptysis
- Recent cardiothoracic surgery, including esophageal surgery
- Severe acute lung injury
- Inspiratory muscle weakness with inability to tolerate increased work of breathing
- Oropharyngeal and/or oral muscle weakness
- Severe restrictive disease (Total Lung Capacity < 60%)
- Airway at risk for aspiration such as recent tube feeding or meal
- Uncontrolled gastroesophageal reflux disease (GERD)



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.

PhysioAssist Quality Management System is ISO 13485:2016 and MDSAP certified.

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The Art of Diagnostics

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