EN

SIMEOX

User manual

PhysioAssist

Contents

1 Introduction to Simeox

1.1 About this user manual

The purpose of this manual is to guide you in the safe use of SIMEOX.

This manual applies to devices with the references:

- Simeox_H_EU to be used in Europe, operating on 230 VAC /50Hz.
- Simeox_H_NA to be used in North America, operating on 120 VAC /60Hz.

Please read the instructions contained in this manual carefully and in full before using the device.
Keep this manual close to the equipment for subsequent use.

1.2 Signalling alerts, warnings and recommendations

This user manual contains alerts, warnings and recommendations for use signalled by pictograms:

This pictogram is used to signal an alert.
An alert indicates a risk of injury for the patient or user.

This pictogram is used to signal a warning.
A warning indicates a risk of damaging SIMEOX, its expiratory kits or its accessories.

This pictogram is used to signal a recommendation.
A recommendation indicates an action that allows improved use of SIMEOX, its expiratory kits and its accessories.

It is your responsibility to read this information and to comply with it, for the safety of the patient and the user.

1.3 Intended use, indications

The SIMEOX from PHYSIO-ASSIST is a medical device intended to be used by adults and children over 8 years of age suffering from a lung disease and who have difficulty in clearing bronchial secretions.

The SIMEOX device is indicated to help to liquefy and transport secretions from the small bronchi of the distal part of the lung to the large bronchi so that they can then be removed by coughing.

The main conditions targeted by SIMEOX are cystic fibrosis, Chronic Obstructive Pulmonary Disease (COPD), bronchiectasis, primary ciliary dyskinesia.

SIMEOX is intended to be used in healthcare facilities, in medical or paramedical practices, or at home.

In the context of home use, the patient is the intended user of the device.

In the context of use in medical or paramedical practices, or in a healthcare facility, the patient can also be the user.

It is therefore recommended:

- That a healthcare professional (doctor, physiotherapist) be consulted beforehand to assure you that the use of SIMEOX is not contraindicated in your case.
- That you be trained in the use of SIMEOX beforehand in order to use it under optimal treatment conditions

1.4 Contraindications

There are no absolute contraindications to using SIMEOX.

The relative contraindications to its use are the following:

- Pneumothorax that has not been treated or drained,
- Unstable cardiovascular pathologies (recent heart attack, unstable angina, uncontrolled rhythm disorders, unstable cardiac failure)
- Massive haemoptysis

If you are in one of these situations, it is recommended that you consult a healthcare professional before using SIMEOX to assess whether the treatment is appropriate for your situation (positive benefit-risk).

SIMEOX should not cause any significant discomfort or pain in the patient: in the event of significant pain or discomfort, stop using SIMEOX immediately and consult a healthcare professional.

In the event that a new unexpected symptom appears or an existing symptom worsens, stop using SIMEOX immediately and consult a healthcare professional.

1.5 Operating principles of SIMEOX

1.5.1 Physical principle

SIMEOX is the result of five years of research at PHYSIO-ASSIST studying the rheology of bronchial mucus under the influence of a vibratory pneumatic signal.

SIMEOX generates a succession of very short negative pressure pulses of a constant air volume at a frequency similar to that of the vibrating cilia of the bronchial epithelium during relaxed expiration by the patient, spreading a vibratory pneumatic signal throughout the whole bronchial tree which acts directly on mucus viscosity and mobilisation.

Laboratory tests and digital simulations demonstrate that our technology exerts a significant liquefying and draining action on bronchial mucus.

1.5.2 Principle of the medical device

The patient uses SIMEOX during successive relaxed expirations.

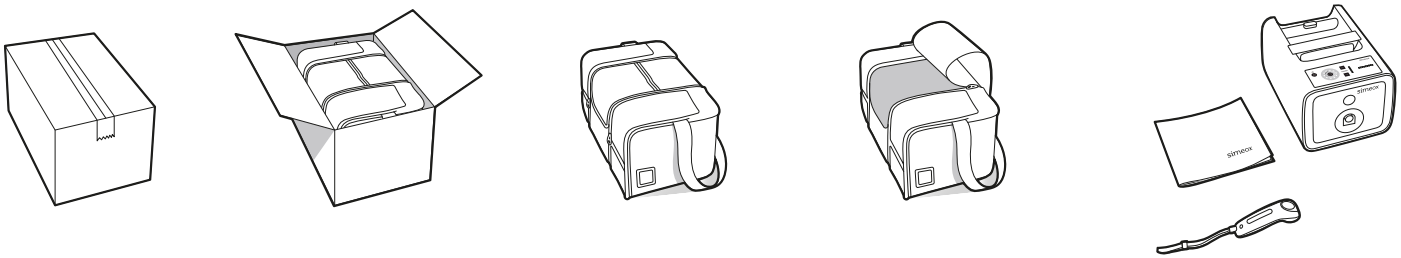
SIMEOX sends a low frequency vibratory pneumatic signal throughout the whole patient's bronchial tree, liquefying the mucus and transporting it from the most distal parts of the peripheral airways to the central trunks to promote its removal by the patient when they expectorate at the end of the session or after the sessions.

Between each very short negative pressure pulse generated by the vibratory pneumatic signal, the patient is reconnected to atmospheric pressure. The patient is thus maintained largely at atmospheric pressure for most of the expiration time (70%) in order to avoid any risk of bronchial collapse, the main obstacle to clearance of the peripheral airways.

1.6 Contents of the packaging

SIMEOX is delivered in a box containing:

- The SIMEOX device
- A power cord adapted to the country of use
- A carrying bag
- A remote control containing a button battery
- A wrist strap to be installed on the remote control (see recommendations for using the wrist strap)
- A user manual



The expiratory kits, essential for using SIMEOX, are supplied separately, in specific packaging.

Each expiratory kit is composed of a filter, a flexible tube and mouthpieces.

The plastic bags and small parts present a suffocation risk: keep them out of the reach of children.

2 General alerts, warnings and recommendations

2.1 Alerts

⚠ Connect the device to a wall socket that supplies the nominal voltage indicated on the machine.

⚠ In order to avoid any risk of arcing, connect the power cord firstly to SIMEOX then to the wall socket.

⚠ Likewise, once the device is switched off, disconnect the cord from the wall socket before disconnecting it from SIMEOX.

⚠ In order to avoid any risk of electrical discharge, never plug in or unplug the device with wet hands, do not use SIMEOX in damp rooms or in bathrooms.

⚠ Monitor the device during use and stop using it in the event of a malfunction.

⚠ Do not let a young patient use SIMEOX without adult supervision.

⚠ The power cable and the tube of the expiratory kits present a strangulation risk: keep them out of the reach of children.

⚠ The mouthpiece and the remote control battery present a suffocation risk: keep them out of the reach of children.

⚠ Only use the accessories and expiratory kits supplied by PHYSIO-ASSIST.

⚠ SIMEOX is designed and manufactured to resist spills of liquids falling vertically on the cover, but as a safety measure, in the event of contact with a liquid, immediately switch the device off and disconnect it from the mains.

⚠ Never use SIMEOX if the plug or the power cord is damaged, if the device presents an operating fault or if it has been dropped, damaged or immersed in water.

⚠ Never dismantle SIMEOX and do not try to intervene if it breaks down: SIMEOX does not contain any parts to be replaced by the user.

You are only responsible for replacing the remote control batteries, as described in this manual.

Only approved personnel are authorised to perform maintenance operations on SIMEOX.

⚠ Do not install SIMEOX against a wall; the main switch must always remain accessible to switch off SIMEOX in an emergency.

⚠ All modifications to SIMEOX are prohibited.

⚠ The male mains plug can be used as a means of separating SIMEOX from the electricity grid.

⚠ The SIMEOX mouthpiece is intended to make contact with the patient's mouth.

Although the materials used are biocompatible, in the event of irritation, tingling or allergies, stop using SIMEOX immediately and consult a specialist.

⚠ Before cleaning, always switch off the device and unplug it from the wall socket.

⚠ When cleaning or disinfecting expiratory kits, make sure to remove all product residues.
Some chemical products used as disinfectants can harm the organism and the expiratory kits of the device.

⚠ After cleaning and drying, store the device and its accessories in its carrying bag, in a dry place, protected from sunlight and dust, at room temperature.Please refer to the section in this manual on storage temperatures for SIMEOX.

⚠ The Lithium button battery in the remote control presents an ingestion risk, to avoid this risk take the following precautions:

- Do not store new batteries within the reach of children
- Do not store used batteries in your home, take them to a collection point
- Do not replace the batteries in the presence of a child
- Do not let children play with the batteries
- Never put the battery in your mouth to test it or to keep your hands free
- Never place the battery beside your medicines, to avoid mistaking it for a tablet

Ingesting a button battery may cause the following injuries:

- necrosis and perforation of the oesophagus through mechanical compression
- electrical burns caused by the heat from the electrical current between the mucosa and the battery.
In the event that you ingest a button battery contact a doctor or the emergency services immediately.

⚠ The base of the SIMEOX housing incorporates openings intended to aerate the device and to evacuate any condensed moisture.

At home in particular, make sure that no objects, especially metal objects such as staples, paperclips, etc. are introduced into the housing through these openings.

Although the live parts cannot be accessed through these openings, a small object could remain stuck in the device and cause a short-circuit.

⚠ The wrist strap supplied is intended to ensure that the remote control is held securely at the wrist during treatment sessions, preventing it from being dropped.

It is not pre-installed.

The user is free to install it if he chooses, depending on the estimated contamination risk.

⚠ Keep the power cord away from all hot surfaces: the heat could degrade the protective sheath and cause a failure, or a risk of electric shock.

⚠ Do not position SIMEOX in such a way that it is difficult to use the disconnection device (the male mains plug).

2.2 Warnings

☞ Never plug the device into a faulty wall socket, which could cause a short-circuit that could damage it

☞ Never connect SIMEOX to other appliances

☞ Never expose SIMEOX to the rain: when transporting SIMEOX use the carrying bag supplied.

☞ Do not use or store the device in a place liable to cause it to fall, in a damp environment or in extreme heat.

Please refer to the technical specifications for the temperatures and atmospheric conditions for storage and use.

☞ Do not use SIMEOX in its carrying bag; the device would be poorly ventilated and could be damaged.

☞ Do not install SIMEOX on a soft surface such as a mattress or a carpet: the holes located on the housing base could be obstructed and cause the internal components to overheat.

☞ Switch SIMEOX off when it is not in use.

☞ Cleaning and disinfection of the device, of its expiratory kits and its accessories, must be carried out in accordance with our recommendations, please refer to the corresponding section of the manual for the relevant recommendations.

☞ Only use the power cord supplied by PHYSIO-ASSIST for SIMEOX, failing which the device may overheat and be damaged.

☞ Please keep the device in its carrying bag when moving it, in order to protect it from liquids and impacts.

☞ After each use, store the device, its expiratory kits and its accessories out of the reach of children, pets, insects, etc.

☞ The following are prohibited as they may damage the power cord of the device:

- twisting the cord

- placing heavy objects on the cord

- pulling violently on the wall plug cord

- placing the cord in a damp area: risk of short-circuit that may cause very serious physical and material damage.

- modifying the cord

☞ Consult the electromagnetic compatibility section of this document: it contains important information on how to install and use SIMEOX to avoid any interference with other electrical devices, including other medical devices.

☞ Never put SIMEOX back in its bag immediately after use.

The moisture present in the machine could condense and cause damage to SIMEOX.

☞ To avoid damaging SIMEOX when turning off the device, please first switch it off before unplugging it from the wall socket.

2.3 Recommendations for use

ⓘ Only use the device on the recommendation of a healthcare professional.

Only use this device if you have been previously trained in its use.

ⓘ Begin the session on a 50% power setting and adjust signal intensity according to patient comfort and tolerance, depending on bronchial stability and sensitivity and the ventilation volume of the patient.

ⓘ Do not place your tongue over the mouthpiece opening, this may prevent the vibrations from reaching the bronchial tree and reduce treatment performance.

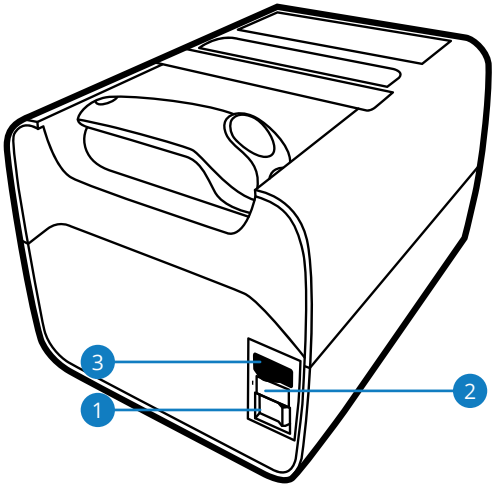
If the mouthpiece is obstructed, the performance indicator lights illuminate in red.

In this case, stop using SIMEOX and adjust the position of the mouthpiece.

ⓘ Do not use SIMEOX if the filter of the consumable is not correctly installed.

3 Description of Simeox

3.1 Components on the back panel



1. **Power switch**
   This I/O switch turns the SIMEOX device on and off, "I" to turn on and "O" to turn off.

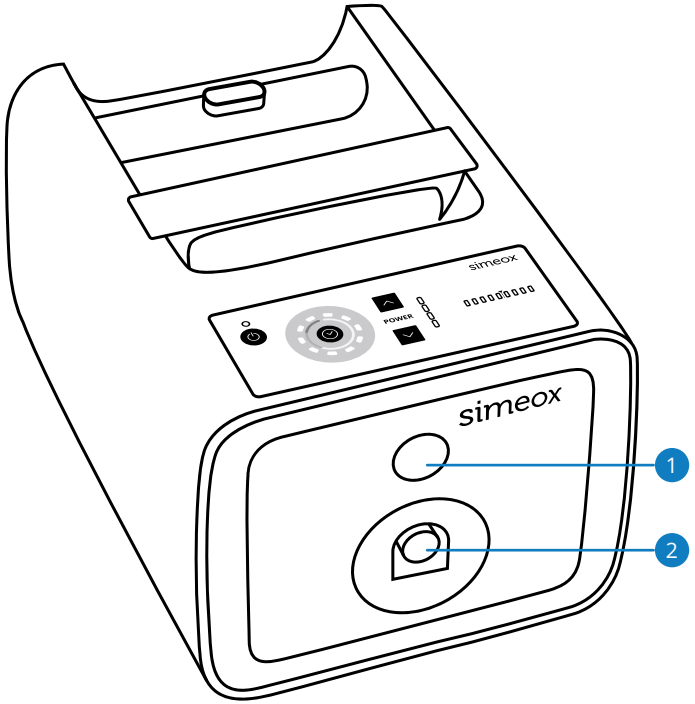
2. **Mains filter fuse**
   This location is intended for the mains filter fuses.

3. **Power socket**
   This connector is for the SIMEOX C17 power cable.

⚠ *Destruction of fuses can only be caused by a critical failure of the SIMEOX electronics, for example in the event of exposure to very high electrostatic discharge, overvoltage, overcurrent, etc.*

Tools are required to replace fuses and this must imperatively be carried out by an approved technician who will first examine the device to determine the cause of destruction.

3.2 Components on the front panel

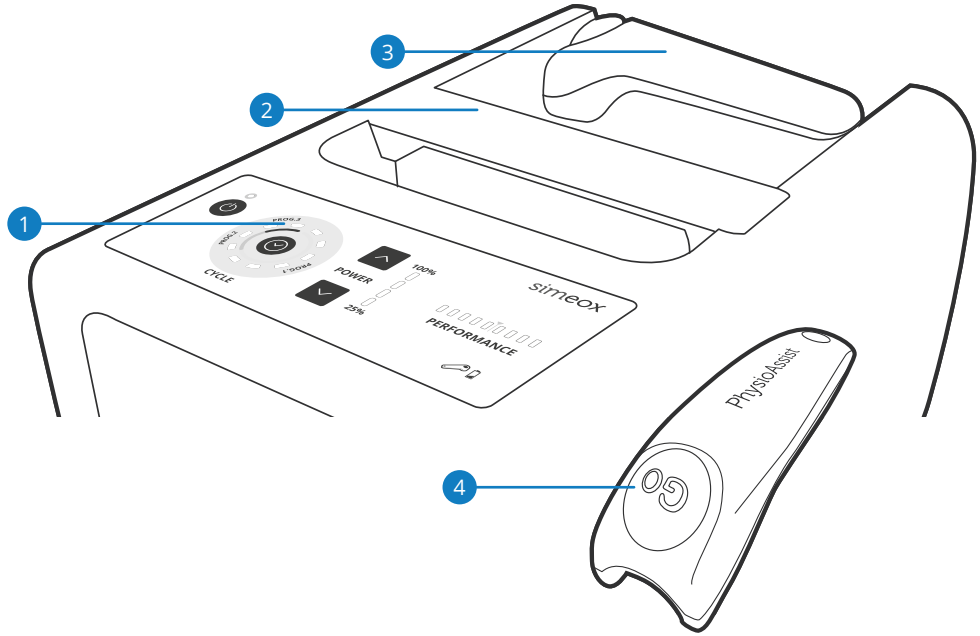


1 **“Go” button**
This button is a backup button in the event that the remote control fails.
On both SIMEOX and the remote control, this button starts the SIMEOX vibratory pneumatic signal.
It must be pressed throughout the expiratory phases.

In the event of significant discomfort or pain, the patient must release the GO button to stop the device.
During a cycle, passing from one expiratory phase to the next requires the “GO” button to be pressed for at least 1.5 seconds.

2 **Connecting the expiratory kits**
Location for connecting the filter of the patient expiratory kit.

3.3 Components on the top panel and the remote control



1 **Control pad**
The SIMEOX control pad (see below)

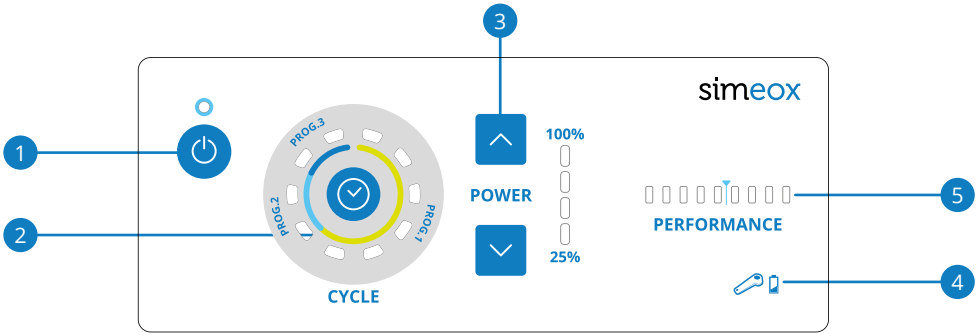
2 **Carry handle**
This handle is used to transport SIMEOX.

> *As SIMEOX is not watertight and does not withstand being dropped, it is preferable to use the bag provided to transport it. In this way your SIMEOX will be best protected from water and impacts.*

3 **Remote control**
The SIMEOX remote control.

4 **Remote control "Go" button**
This button starts up the SIMEOX vibratory pneumatic signal.
It must be pressed throughout the expiratory phases.
In the event of significant discomfort or pain, the patient must release the GO button to stop the device.
During a cycle, passing from one expiratory phase to the next requires the "GO" button to be pressed for at least 1.5 seconds.

3.4 Control pad components



1 **"Standby/On" button**

This button activates operation of SIMEOX and its "standby" mode.

- When the light is yellow-orange, the device is in standby.
- When the light is blinking blue, the device is active but is not yet usable as it has not detected a valid accessory (usable SIMEOX expiratory kit): either the expiratory kit used is not supplied by PHYSIO-ASSIST, or the SIMEOX consumable allowed use counter is depleted.

In this case: you must replace the accessory to be able to use SIMEOX.

- When the light is steady blue (no blinking), the device is active and usable.

In order to avoid unintentionally placing SIMEOX on standby, this operation requires the "Standby/On" button to be pressed continuously for 3 seconds.

Program adjustment button

2 *This button allows the program to be adjusted to the patient according to their tolerance:*

- PROG 1: program 1 is selected for 6 expiratory phases per cycle
- PROG 2: program 2 is selected for 8 expiratory phases per cycle
- PROG 3: program 3 is selected for 10 expiratory phases per cycle

It is possible to change the program at the end of each cycle, or during the 45-second pause.
For each program: The last two phases have a frequency that is lower than that of the preceding phases, in order to increase transport of the mucus.

- This button also triggers a tube dehumidification cycle, see below.

3 **Power adjustment button**

This button adjusts the power of the signal sent to the patient. It can be adjusted at any time in the session based on how the patient feels.
It is possible to change the power setting at any time: during the session, at the end of each program, or during the 45-second pause.

4 **Remote control battery indicator**

This light changes to orange when the remote control batteries need to be replaced.

5 **Performance indicator**

This visual feedback enables the operating quality of the device to be viewed.

- The number of green lights illuminated (between 1 and 5) is an indicator of the quality of transmission of the pneumatic signal in the lower airways
- The five green lights should illuminate when the patient expires.
- If the red lights illuminate, the expiration must be stopped by releasing the remote control button or removing the mouthpiece.

3.5 Additional information on the SIMEOX user interface

The SIMEOX interface displays other visual information.

This information is:

- On start-up, all lights illuminate for 1.5 seconds allowing the user to check that all lights are working properly.

- When pairing the remote control, the “CYCLE” lights illuminate successively clockwise to let the user know that the pairing has been carried out successfully.

- If the remote control pairing is lost, the “CYCLE” lights successively illuminate counterclockwise to allow the user to know that he will have to pair again the remote control, as communication between the SIMEOX and the remote control has been interrupted.

- In the event of obstruction, the four red lights of the performance indicator light up.

  If these lights are illuminated, before resuming the treatment session, the user must stop using SIMEOX immediately and determine what has caused these lights to come on, for example a blocked filter, a use problem such as introducing the tongue into the mouthpiece, etc.

3.6 The expiratory kits

In order to avoid any inter-patient contamination, the expiratory kits are always for single patient use.

According to the medical prescription, the expiratory kit will either contain single use mouthpieces, or reusable mouthpieces, subject to following the cleaning and disinfection instructions recommended by PHYSIO-ASSIST. In all cases, comply with the recommendations of the referent healthcare professional.

In order to secure the number of permitted uses, PHYSIO-ASSIST filters are fitted with an electronic component containing the number of permitted uses for the expiratory kit model (RFID TAG). SIMEOX reads this value before activating: once the number of uses is depleted, SIMEOX will not operate, you must replace the expiratory kit.

PHYSIO-ASSIST offers two types of expiratory kits:

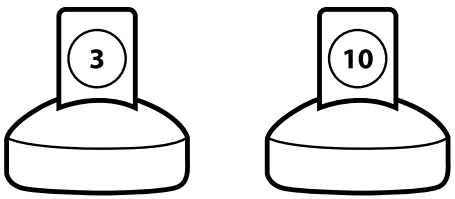
- Expiratory kits containing **single use mouthpieces**, whose packaging bears the symbol

For these kits, the number of mouthpieces supplied is that of the number of possible uses (e.g. 10 mouthpieces for 10 uses): the mouthpiece must be thrown away after each use.

- Expiratory kits containing multiple use mouthpieces

For these kits, 3 mouthpieces are supplied: it is recommended that the mouthpiece and tube be cleaned after use for future reuse.

Examples of filters:
the number of possible uses is clearly indicated, kits with single use mouthpieces are differentiated from kits with reusable mouthpieces by the colour of the filter.



4 Use of Simeox

4.1 Composition and assembly of the expiratory kit

Simeox expiratory kits are single patient.

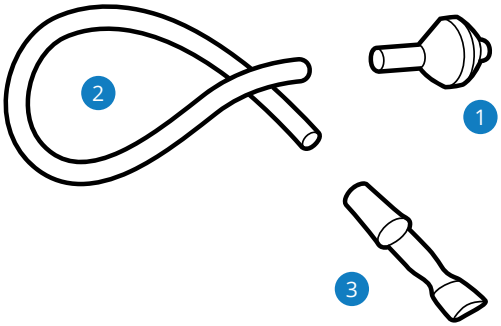
In healthcare facilities and in medical or paramedical practices, each expiratory kit must be allocated to one patient.

The name of the patient and the date of first use of the expiratory kit must be indicated on the label provided for this purpose on the kit bag.

Expiratory kits are available in the form of resealable bags containing all the necessary components (filter, tube, mouthpieces, user manual).
The bag contains basic instructions for use and maintenance, the details of these instructions are included in this user manual.
The kit bag can be resealed hermetically for optimal hygiene.
A label on the bag identifies the patient using the kit.

4.1.1 Composition of the expiratory kit:

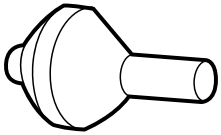
1. A filter fitted with a RFID TAG. This electronic component is intended to:
   - Identify PHYSIO-ASSIST expiratory kits: SIMEOX will not operate with other expiratory kits
   - Count the number of uses of the accessory: once the stipulated number of uses is depleted, the accessory is no longer recognised and cannot be used
2. A tube
3. Mouthpieces



4.1.2 Assembly of the expiratory kit

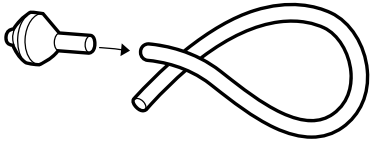
To assemble the expiratory kit:

1. Open the bag taking care not to damage it, as the bag is intended to protect the kit from dust while not in use.

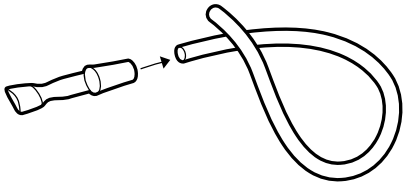


2. Pick up the filter.

The filter may already be installed on the tube when opening the bag. This does not mean that the filter is attached to the tube: it can be removed without difficulty for kit maintenance.

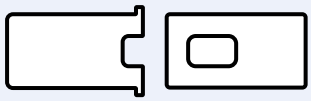


3. Connect it to one end of the tube.

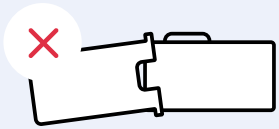


4. Connect the mouthpiece to the other end: the mouthpiece and the tube are keyed to enable the mouthpiece to be installed in an optimal manner and any risk of leakage or disconnection during the session to be avoided.

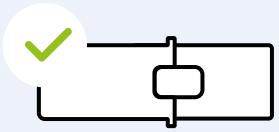
If the mouthpiece packaging is damaged: do not use it and contact PHYSIO-ASSIST or your supplier for information and to replace the kit.



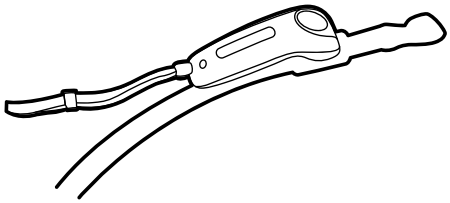
Keyed setup on the tube end sleeve and the mouthpiece



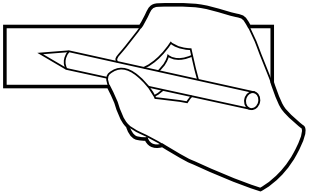
Incorrect assembly: the connection is not optimal



Correct assembly: the two components are connected in an optimal manner



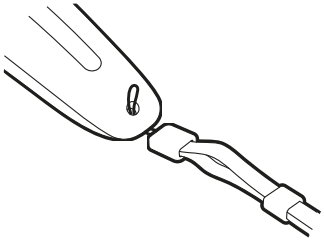
5 The remote control can be fitted on the tube end sleeve to be used as a “trigger” keeping one hand free.



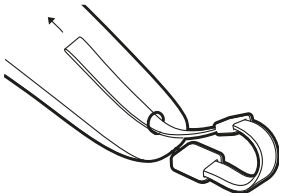
6 Note the date the kit was opened and the patient’s name on the label provided for this purpose.

4.1.3 Wrist strap installation

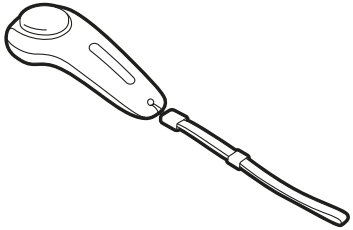
If you wish to install the wrist strap on the remote control, install as follows:



1 Slide the cord into the hole of the remote control



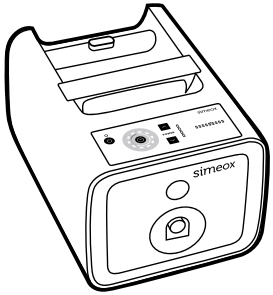
2 Pass the wrist strap through the cord



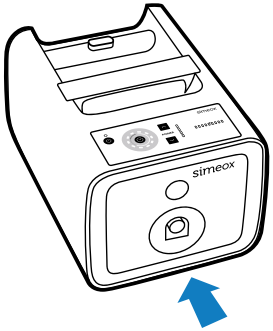
3 Slide the wrist strap into the cord, the installation is finished

- To disassemble the wrist strap, to wash it, carry out the same operations in the reverse order.

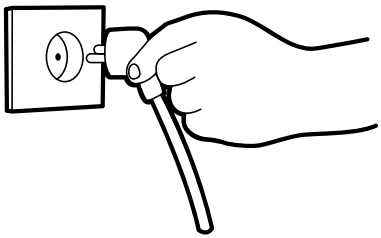
4.2 Installing and setting up SIMEOX



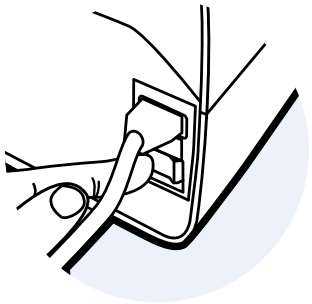
1. Place SIMEOX on a stable, hard, flat surface.



2. Check that the air intake areas on the front and underneath SIMEOX are not blocked. Air must circulate freely all around and under the device;
Connect the power cable to SIMEOX.

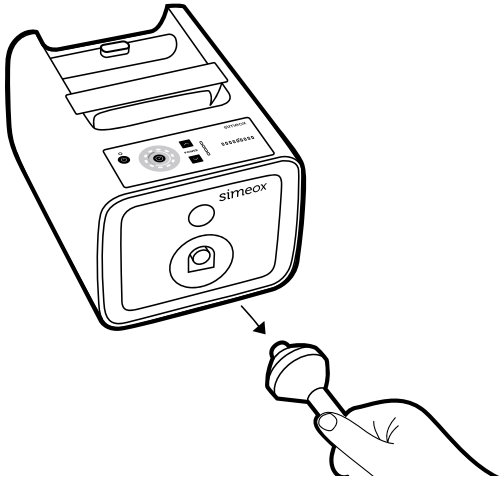


3. Connect the power cable supplied to a power outlet.



4. Turn on the device by setting the power switch on the back of the device to position “1”. The light of the “standby/on” button of the control pad turns yellow-orange. Your SIMEOX is in “standby” mode and ready to be used.

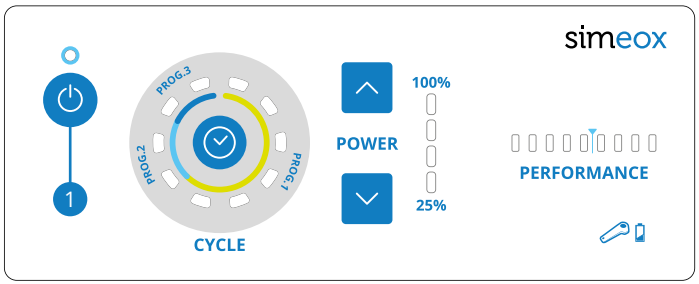
4.2.1 Connecting the expiratory kit to SIMEOX



Connect the expiratory kit to SIMEOX in accordance with the reference marks. The expiratory kit can only be inserted in the correct direction.

Push without forcing to ensure an optimal connection.

4.3 Starting up SIMEOX



Once SIMEOX is powered on and the expiratory kit assembled and connected to SIMEOX:

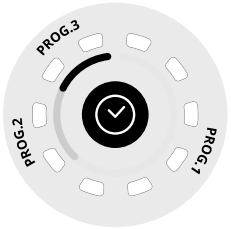
Press the control pad button (1).

When the user presses the "standby/on" button, ALL the SIMEOX lights illuminate and remain steady for 1.5 seconds.

This display lets the user check that all lights are working. If one light does not illuminate, the pad must be replaced, contact PHYSIO-ASSIST or your approved supplier.

Check that the light above the button (1) of the control pad changes to blinking blue, then to steady blue. This indicates that the expiratory kit has been recognised and can be used.

4.4 Pairing the remote control with SIMEOX



The remote control is paired with SIMEOX simply by pressing once the remote control button after SIMEOX is activated and the expiratory kit has been recognised (light 1 steady blue, see above).

When SIMEOX "recognises" the remote control, the "CYCLE" lights illuminate successively clockwise: the user is informed that the pairing has been performed successfully.

After pressing this button, the remote control and SIMEOX are paired, until SIMEOX returns to "standby" mode. This pairing operation therefore has to be repeated:

- Every time SIMEOX is turned on
- Between two treatment sessions

It is therefore normal that at the beginning of a session SIMEOX does not respond when the remote control button is first pressed, as this pressing is used to pair the two devices.

If the wireless connection between the remote control and the SIMEOX is interrupted, the "CYCLE" lights illuminate consecutively in a counter-clockwise direction: the user is informed that the remote control is un-paired.

4.5 Operational check

Before beginning to use SIMEOX it is recommended that a quick operational check be conducted.

A simple test lets you check that SIMEOX is working, and that the negative pressure level generated is compliant to specifications in order to guarantee the performance of SIMEOX.

1. On starting up SIMEOX, when the “standby/on” button is pressed, ALL the SIMEOX lights should be illuminated.

2. Once the expiratory kit is connected as described above:
   - Set power to 100%
   - Block the kit outlet (for example, with a finger)
   - Press the “GO” button briefly
   - Observe the PERFORMANCE lights

PERFORMANCE

All the PERFORMANCE lights should illuminate, including the red lights.

If the test is negative, check that the expiratory kit is correctly connected, and that the kit is indeed blocked, repeat the test.

If the test is still negative, do not use SIMEOX, contact PHYSIO-ASSIST

4.6 SIMEOX settings

The number of cycles and the power level are recommended by the healthcare professional.

Choose the program for the session

The program is selected using the “clock” button.
The number of blue lights illuminated corresponds to the number of expiratory phases per cycle.
The blue lights go out with the progression of successive expirations.

- PROG 1: program 1 is selected for 6 expiratory phases per cycle
- PROG 2: program 2 is selected for 8 expiratory phases per cycle
- PROG 3: program 3 is selected for 10 expiratory phases per cycle

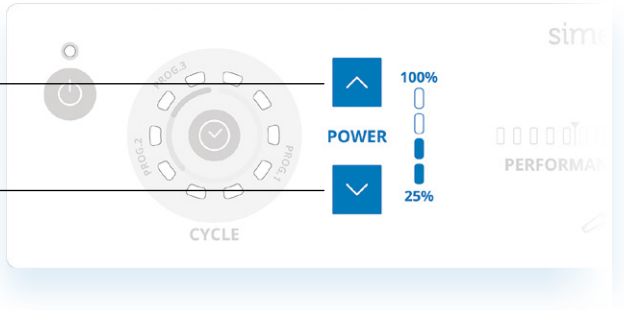
For each program, the maximum number of cycles is 10

Select the power level

- The power of the device is set to 50% by default
- This setting is recommended at the beginning of the session
- It can be adjusted during the course of the session according to patient comfort

Key to increase power

Key to decrease power



4.7 Conducting a session

Reminder: in order to ensure that the device is optimally effective, training in the use of SIMEOX is recommended. Contact PHYSIO-ASSIST, your physiotherapist or your referring doctor for this training.

To conduct a SIMEOX session, the patient must be settled comfortably.

The patient can change positions when using the device (on their stomach, on their back, semi-seated, on their side) in order to maximise drainage from all areas of the lung. SIMEOX does not act during the inspiratory phase, SIMEOX acts only during the expiratory phase

- The patient is relaxed
- The patient begins by slowly inspiring through the nose followed by an inspiratory pause.
- When the patient is ready to release air from his/her lungs, he/she places the mouthpiece in his/her mouth and press the remote control button (or the "GO" button on the front) to start the SIMEOX vibratory signal.
- The mouthpiece is positioned in such a way that it is an extension of the trachea.
- The mouthpiece is placed on the tongue, in such a way that the tongue does not obstruct the mouthpiece during activation of the signal during relaxed expiration by the patient.
- The GO button must be pressed throughout the expiratory phase.
- The patient lets the device take control during his/her relaxed expiration without opposition and feels the vibrations in his/her thorax.
- Repeat the steps above as many times as necessary. A typical SIMEOX session consists of 4 to 5 cycles with a pause of 45 seconds between each cycle – to be adjusted according to the needs and condition of the patient.
- The patient only coughs to expectorate. If the cough is triggered prematurely, it must be controlled.

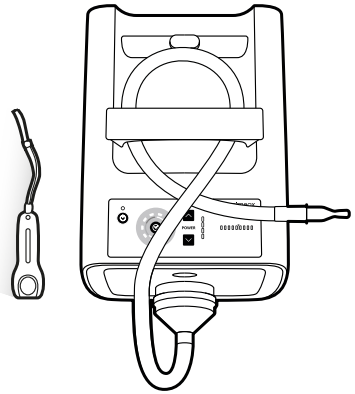
After a 20- to 30-minute session, the patient is drained. He/she coughs naturally at the end of the session and/or at a later stage.

If lights 1 to 5 are illuminated: the transmission quality of the vibratory signal is optimal

If the red lights illuminate, the expiration must be stopped by releasing the remote control button or removing the mouthpiece.

The mouthpiece is badly positioned if the vibrations are felt in the mouth and not in the thorax. An expiration that is too long or forced risks to prematurely trigger a cough, as does an inspiration that is too strong or violent

4.8 Protecting the expiratory kit during the pause



At the end of each cycle/program, in order to allow the patient to rest, the SIMEOX is paused for 45 seconds: the “CYCLE” lights blink, it is not possible to press the “GO” button during this pause time.

In order not to risk contaminating the expiratory kit during this pause time (falling to the ground, contact of the mouthpiece with the table, etc.), we recommend that you store it as shown opposite:

4.9 Drying the tube

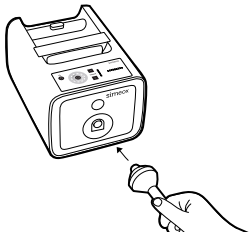
At the end of the session we advise you to use this functionality: as SIMEOX functions during the expiratory phase of the patient, it is possible that the moisture in the expired air will condense in the tube of the expiratory kit.
To remove this moisture, SIMEOX is equipped with a tube-drying functionality.

The patient must first take the mouthpiece out of his/her mouth to avoid being exposed to continuous negative pressure. This functionality can be activated at any time, provided that SIMEOX is in active mode: the expiratory kit is present and recognised by SIMEOX, the “active” blue light is illuminated.

1. Check that the patient has taken the mouthpiece out of his/her mouth
2. Press the button (2), pressure must be maintained until drying is started.
3. After 1 second all PERFORMANCE lights (5) illuminate to indicate that the command has been taken into account.
4. The performance lights switch off one after the other (“countdown”).
5. When all the lights have switched off, SIMEOX enters “dehumidification” mode:
   - SIMEOX generates continuous negative pressure, without vibrations.
   - The “cycle” lights blink simultaneously.
6. At the end of the cycle, SIMEOX returns to its initial state.

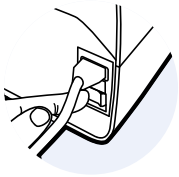
This functionality is intended solely to remove moisture from the tube: the recommendations regarding washing and disinfection of expiratory kits remain valid to ensure optimal device hygiene.

4.10 Shutting down SIMEOX

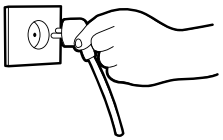


1 Disconnect the expiratory kit, clean and disinfect it (see below) and put in its storage bag

2 Put the device on standby by pressing the “standby/on” button (1) of the control pad



3 Turn off the device by setting the power switch on the back of the device to position “O”.



4 Disconnect the power cable from the power outlet

It is possible that the orange light of the “Standby/On” button will stay illuminated for a few seconds after shutting down SIMEOX. This is normal and is absolutely safe. After 10 cycles, SIMEOX switches back to “standby” mode: the light located above the “Standby/On” button (1) changes back to yellow-orange.

In particular at home, between two uses, store SIMEOX and its power cord in a place out of the reach of children. Between two uses, it is imperative to carry out maintenance of SIMEOX: please refer to the “Upkeep and Maintenance” section of this manual.

SIMEOX should be put into its carrying bag after each use so that it will be protected from dust, liquids and moderate impacts.

It is advised to wait a minimum of 15 min before putting SIMEOX into its carrying bag

5 Cleaning and disinfection

Under normal conditions of use, the expiratory kit circuit transports the patient's exhaled air from the mouthpiece to the filter connected to SIMEOX.

The risk of germs in the system reaching the patient is therefore low. However, in order to avoid any risk of exposure of the patient to pathogens, it is recommended to regularly disinfect the expiratory kits according to the recommendations of a healthcare professional familiar with good hygiene practices, depending on the patient's pathology and the care environment.

The recommendations below are intended to ensure the safety, performance and operating life stipulated for SIMEOX, its expiratory kits and its accessories.

We therefore recommend you, in order to define the processes and frequency of disinfection, in particular for exhalation kits:

- *In institutions, in hospitals: to consult a hygiene professional for the implementation of good practices for disinfecting medical devices.*
- *At home: to contact your doctor who can give you the best hygiene advice according to your pathology.*

In all cases, expiratory kits are single patient devices.

Before cleaning the SIMEOX, always make sure you turn off the device and unplug it from the power outlet.

For cleaning the SIMEOX and the remote control, ensure that disinfectant products or wipes specific to medical devices are used, and not household products or wipes.

When choosing a disinfectant product for the mouthpieces, make sure you select a product compatible with contact with the mucous membranes and check that you are not allergic to one of its components

Follow systematically the instructions provided with the product, particularly in terms of personal protection (gloves, goggles, etc.).

Do not use products containing chlorine, bleach or acetic acid, or household products.

Read the recommendations for use of your disinfectant product carefully, particularly:

- *The exposure time of the disinfectant product to be observed to obtain the desired level of disinfection,*
- *Rinsing and drying precautions.*

After cleaning or disinfecting the expiratory kits, make sure to remove all product residue.

After cleaning, disinfection and drying, keep the SIMEOX, its expiratory kits, and accessories in the supplied protective bags, in a dry place, away from daylight, dust, at room temperature.

Please refer to the section of this manual on storage temperatures for the SIMEOX. In medical and paramedical environments, after cleaning, disinfecting and drying the expiratory kits, make sure they are stored in the patient's bag.

The user will have previously indicated on the label the name of the patient.

5.1 Cleaning and disinfecting SIMEOX

The SIMEOX must be cleaned after each use. The frequency of disinfection is established by the specialist consulted, depending on the patient's pathology and the care environment.

SIMEOX is a medical device containing electronic cards and an electro-pneumatic assembly.
Disinfection by immersion, autoclave or with processes using peracetic acid is therefore totally discouraged: SIMEOX could be irreparably damaged.

After each use:

- Clean the SIMEOX with a cloth dampened with a mild liquid detergent

Disinfection, at the frequency recommended by the specialist:

- Disinfect all surfaces of the SIMEOX with a disinfectant wipe specific to the disinfection of medical devices.
- It is also possible to use a clean cloth soaked in 70% isopropyl alcohol.
- Check that the holes on the front of and underneath the housing are not obstructed.

Important :

- Avoid introducing any liquid into the device.
- Do not use abrasive products or abrasive sponges

5.2 Cleaning and disinfecting the remote control

The remote control must be cleaned after each use. The frequency of disinfection is established by the specialist consulted, depending on the patient's pathology and the care environment.

The remote control is a medical device containing an electronic card.
Disinfection by immersion, autoclave or with processes using peracetic acid is therefore totally discouraged: the remote control could be irreparably damaged.

After each use:

- Clean the remote control with a cloth dampened with a mild liquid detergent.

Disinfection, at the frequency recommended by the specialist:

- Disinfect all surfaces of the remote control with a disinfectant wipe specific to the disinfection of medical devices.
- It is also possible to use a clean cloth soaked in 70% isopropyl alcohol.

Important :

- Do not use abrasive products or abrasive sponges

5.3 Cleaning and disinfecting the accessories

The frequency of disinfection is established by the specialist consulted, based on the pathology of the patient and care environment.

5.3.1 Wrist strap

If you have installed the wrist strap: remove it periodically to wash and disinfect it.
If necessary, if the strap is too dirty, remove it and discard it.
You can contact PHYSIO-ASSIST or your distributor for a replacement.

5.3.2 Carrying bag

Keep the inside and outside clean.
Clean the inside and outside of the bag with a sponge and mild soap, disinfect with disinfecting wipes if necessary.

5.4 Cleaning and disinfecting the expiratory kits

Expiratory kits must be cleaned after each use.

The frequency of disinfection is established by the specialist consulted, depending on the patient's pathology and the care environment.

Although specially formulated for medical devices, some disinfectant solutions can cause allergic reactions in sensitive patients:

- *Always observe the precautions for use (product dosage, exposure time, rinsing and drying operations) of disinfectant products, and stop using them if you notice an abnormal reaction (tingling, itching...) after disinfection.*
- *It is possible to carry out a preliminary test and change the disinfectant solution if necessary.*

PHYSIO-ASSIST offers two ranges of expiratory kits, both being for single patient use:

- Expiratory kits with single use mouthpieces and with a filter limited to 3 or 10 uses. Their references are TUB03_EU and TUB10_EU.
- Expiratory kits with reusable mouthpieces, with a filter limited to 25 uses. The reference is TUB25_EU.

The use and maintenance of those expiratory kits are different, as the context of use imposes adapted hygiene measures.

5.4.1 Maintenance of the filter

The filter of PHYSIO-ASSIST expiratory kits is composed of a 3 mm thick membrane made of polypropylene fibres retaining up to 99.99% of bacteria and viruses.

This filter is also intended to prevent contamination of Simeox and of the treatment environment.

Before each use: check that the filter is not dirty or blocked.

In all cases the filter must be replaced at least once a month.

The filter is NOT washable: exposure to any liquid would damage the filtration membrane.

5.4.2 Maintenance of the tubes and the mouthpieces

PHYSIO-ASSIST tubes and mouthpieces are manufactured from biocompatible polymers, and are latex-free and phthalate-free.

Due to the plastic materials used, disinfection in autoclave (121° or 134°C) is only possible for the mouthpiece. The tube is not autoclavable, and would be damaged if exposed to a temperature above 60°C.

5.4.2.1 Expiratory kits TUB03_EU and TUB10_EU

The mouthpiece packaging carries the "single use" symbol

This indicates that the mouthpiece must imperatively be replaced after each use

The tube must be replaced at the same time as the filter, after 3 or 10 uses

To avoid damaging the filter during washing or disinfection, make sure to disassemble it from the tube and keep it for reinstallation after cleaning.

After each use, wash the tube:

- Wash the tube in soapy water
- Rinse thoroughly
- Dry the tube in the vertical position to remove all traces of water

At the frequency recommended by the specialist, disinfect the tube:

The disinfection process most compatible with the materials used to manufacture expiratory kits is cold immersion.

- Immerse the tube in a container filled with:
  - Either 70% isopropyl alcohol, for 5 min
  - Or 3% hydrogen peroxide for 30 min
- Rinse with sterile water (it is possible to sterilise the water by boiling it)
- Dry the tube thoroughly in the vertical position to remove all traces of moisture and all disinfectant product residues
- Wait until it is completely dry before putting the tube in the plastic bag
- Place the kit in the plastic bag checking that it belongs to the patient concerned

After washing or disinfecting, and before storing the tube in the plastic bag, it is important to rinse it thoroughly and dry it to remove any residual disinfectant.

5.4.2.2 Expiratory kits TUB25_EU

The mouthpiece packaging does NOT carry the “single use” symbol.

To avoid damaging the filter during washing or disinfection, make sure to disassemble it from the tube and keep it for reinstallation after cleaning.

After each use, wash the tube and the mouthpiece:

- Wash the tube and the mouthpiece in soapy water
- Rinse thoroughly
- Dry the tube and the mouthpiece in the vertical position to remove all traces of water

At the frequency recommended by the specialist, disinfect the tube and mouthpiece:

The disinfection process most compatible with the materials used to manufacture expiratory kits is cold immersion.

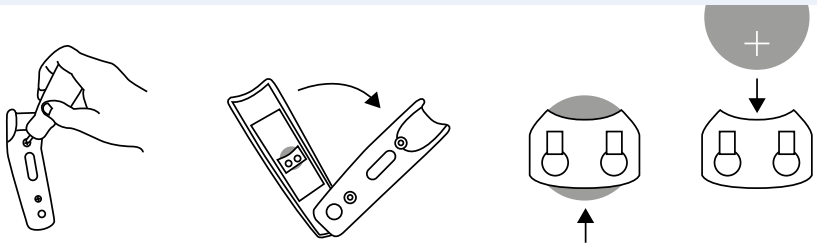
- Immerse the tube and mouthpiece in a container filled with:
  - Either 70% isopropyl alcohol, for 5 min
  - Or 3% hydrogen peroxide for 30 min
- Rinse with sterile water (it is possible to sterilise the water by boiling it)
- Dry the tube and the mouthpiece thoroughly in the vertical position to remove all traces of moisture and disinfectant product residues
- Wait until it is completely dry before putting the tube and the mouthpiece into the plastic bag
- Place the kit in the plastic bag checking that it belongs to the patient concerned

After washing or disinfecting, and before storing the tube and the mouthpiece in the plastic bag, it is important to rinse them thoroughly and dry them to remove any residual disinfectant.

6 Preventive Maintenance

No preventive maintenance is to be carried out on SIMEOX.
The only operation required is replacement of the remote control battery.
When the remote control battery is low, an orange visual indicator illuminates at the bottom right of the control pad .
It is then necessary to replace the battery.

- *It is important to use a battery of the type recommended by PHYSIO-ASSIST: the use of a mediocre quality battery may cause problems with operation, autonomy, even an explosion risk of the battery if it does not meet safety standards.*
- *At home, do not replace the batteries in the presence of a child: the battery and the screws of the housing could be ingested and cause serious, even fatal lesions.*



1. Provide yourself with a cross-headed screwdriver and unscrew the two screws at the back of the remote control
2. Open the remote control by turning the bottom cover.
3. Take out the used battery: push to remove the battery.
4. Replace with a battery of the same type:
   Energizer CR2032 or RENATA CR2032 MFR.
5. Insert the new battery observing the polarity indicated.
6. Push the battery all the way in to ensure optimal contact.
7. Close up the remote control housing with the two screws.

The used batteries must not be disposed of with the household waste. Please refer to the regulations in your country for the handling of used batteries.

7 Contacting us

In the event of an operational problem, or incident, please contact PHYSIO-ASSIST using the following contact details:

PHYSIO-ASSIST
31 Parc du Golf CS90519
13593 Aix-en-Provence
FRANCE

Tel : +33 (0)4 67 03 13 92

contact@physio-assist.com
www.physio-assist.com

8 Transporting Simeox

SIMEOX is equipped with a carry handle for its transport indoors.

Always ensure that the power cord is disconnected from the power outlet before moving Simeox.

To move SIMEOX from one place to another, it is delivered with a carrying bag designed specially to transport SIMEOX, its expiratory kits and its accessories.

- This carrying bag is watertight to protect against rain.
- It protects SIMEOX against moderate impacts during transport.
- It is equipped with storage pockets for the accessories (cord, remote control) and the expiratory kits.

When moving SIMEOX, always make sure to use the bag supplied: PHYSIO-ASSIST cannot be held responsible in the event of damage to SIMEOX caused by moving SIMEOX with another means of transport.

PHYSIO-ASSIST also offers the option of a stand on wheels for transport, equipped with a basket for the expiratory kits and castors with brakes.

9 Symbols used on the labels and packaging

To inform users, SIMEOX, the accessories and their packaging carry standardised symbols and pictograms.
You will find the explanation of these symbols below. Some symbols are specific to medical devices, a full explanation requires some knowledge of these standards.

Symbols featuring on SIMEOX or on the accessories

CE 0459 — CE marking, SIMEOX complies with the applicable European directives
0459: number of the notified body that issued the CE certificate

Alternating current

F2AH250V 5 x 20 mm — Type and dimensions of the protection fuse.

Name and address of the manufacturer

General safety sign: the user should refer to the user manual to acquaint themselves with the safety information

IP21 — The device is protected against solid objects of diameter 5.6 mm and greater, and water drops falling vertically

Parties appliquées de type BF
B = Body F= Floating

230V ~ 50Hz — Nominal acceptable supply voltage

Manual cleaning only.
For disinfection, refer to the "maintenance" section of the manual

REF — Reference of the device

SN — Serial number of the device

Bluetooth identification number of the device

Device using RF transmitters

Refer to the user manual for precautions for use

SIMEOX and its remote control contain printed circuit boards. At end-of-life, they must not be thrown in the dustbin, but recycled.

Class 2 electrical protection (double insulation)

To be used indoors only

WARRANTY SEAL PhysioAssist DO NOT REMOVE — Warranty seal: do not damage, do not remove.

Contains FCC ID xxxxxxxx — SIMEOX contains certified RFID and Bluetooth transmitters, identified by their FCC ID

Environmental limits symbols appearing on the Simeox packaging

On the packaging: storage and transport

Pressure limits not to be exceeded for storage and transport: 700hPa to 1060 hPA

Temperature limits not to be exceeded for storage and transport: -25°C à +70°C

Humidity level limits not to be exceeded for storage and transport: 15% to 93%

Symbols appearing only on the packaging of the expiratory kits

Batch number of the device

Use-by date (in the format YEAR/MONTH)

Phthalate-free plastic

Latex-free

Do not use if the packaging is damaged

Single use device.

Symbols appearing only on the SIMEOX packaging

Store in a dry place

Fragile, handle with care

Top, do not store or transport the other way up

10 Technical specifications

10.1 Compliance with standards and regulations

SIMEOX is a class IIa medical device that complies with the requirements of Directive 93/42/EEC on medical devices.

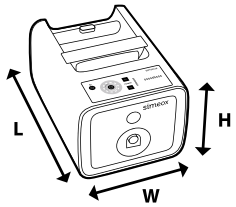
As such it complies with the following standards:

- EN 14971 on risk analysis for medical devices
- EN 60601-1 on the safety of medical electrical devices
- EN 60601-1-2 on the Electromagnetic Compatibility of medical electrical devices
- EN 60601-1-6 on the usability of medical electrical devices
- EN 60601-1-11 on the use of medical electrical devices in the home
- EN 62304 on medical device software
- IEC 62366-1 on the usability engineering to Medical Devices
- EN 10993-1 on the biocompatibility of materials in contact with the user

SIMEOX is manufactured under an ISO 13485 certified quality system.
SIMEOX also complies with the "RoHS" Directive 2011/65/EU on the restriction of the use of certain dangerous substances, with the "REACH" regulation 1970/2006 on the registration and evaluation of chemical substances, and with the "RED" Directive 2014/53/EU on radio equipment.
EC certificates of conformity and EC declarations of conformity to European Directives are available upon request.

10.2 Weight and dimensions

- L = 280 mm / 11"
- W = 212 mm / 8" 1/3"
- H = 175 mm / 7"
- Weight: 5.1 kg / 11 lbs



10.3 Materials used that may come into contact with the patient

Within the meaning of the required standards, all parts of SIMEOX are called "applied" as they are liable to make contact with the patient.

SIMEOX casing: polyurethane acrylic paint.

SIMEOX control pad: Autotex Softouch®

Remote control casing: PC/ABS (polycarbonate and acrylonitrile-butadiene-styrene)

Expiratory kit mouthpiece: Phthalate-free, latex-free, rubber-free biocompatible polypropylene.

Expiratory kit filter: 3 mm thick membrane

made of polypropylene fibres retaining up to 99.99% of bacteria and viruses.

The filter does not contain latex or bisphenol.

Expiratory kit tube: Phthalate-free, latex-free, Bisphenol A-free PVC

10.4 Operating life

The operating life of SIMEOX, if it is used and maintained in compliance with the recommendations in this manual, is five years.

10.5 Compatible accessories

10.5.1 Expiratory kits:

- Single patient kit with disposable mouthpieces, 3 uses, in a box of 10 kits, reference: TUB03_EU
- Single patient kit with disposable mouthpieces, 10 uses, in a box of 10 kits, reference: TUB10_EU
- Single patient kit with reusable mouthpieces, 25 uses, in a box of 10 kits, reference: TUB25_EU

10.5.2 Accessories:

- Carrying bag (supplied), reference SAC01
- Wrist strap (supplied), reference DRAG01
- Wheeled stand (option), reference PIEDROULANT01

10.6 Communications

Warning! Because of its Bluetooth, Bluetooth Low Energy and RFID components, SIMEOX can be subject to interference from other products, even if they comply with CISPR emission requirements.
SIMEOX uses wireless communications in the following bands:

- To communicate via Bluetooth with a tablet, SIMEOX uses GFSK modulation for an effective radiated power of 3mW on the band [2.400 GHz-2.4835 GHz].
- To communicate via RFID with the consumable, SIMEOX uses ASK modulation for an effective radiated power of 0.2512µA/m in the frequency 13.56MHz.
- To communicate with its remote control, SIMEOX uses a Bluetooth BLE interface: [2.400 GHz-2.4835 GHz] with a bandwidth of 2MHz per communication channel.

10.7 Stipulated environmental conditions

SIMEOX is intended to be used: in healthcare facilities, in medical or paramedical practices, at home. The conditions of use are the following (SIMEOX could not operate in accordance with its specifications if these are not present):

- Temperature limits at the place of use: +5 to + 40°C
- Humidity limits at the place of use: 15% to 93%
- Atmospheric pressure at the place of use: 700hPa to 1060hPa

When SIMEOX is subjected to extreme temperatures (low or high) make sure to wait at least 4 hours before using, to allow its components to return to a temperature that allows for its optimal use.

10.8 Electrical characteristics

10.8.1 Supply voltages:

SIMEOX_EU : 230 V AC 50 Hz

- The SIMEOX _EU is designed and manufactured to operate within the supply voltage limits of -15%/+10% set by European standards, that is 195 VAC to 253 VAC.

SIMEOX_NA : 120 V AC 60 Hz

- The SIMEOX_NA is designed and manufactured to operate within the supply voltage limits of -15%/+10% set by North American standards, that is 102 VAC to 132 VAC

10.8.2 Applied parts (according to standard EN 60601-1):

In compliance with standard EN 60601-1

When used at home, the patient being the user, all accessible parts of SIMEOX are considered applied parts.

These are Type BF applied parts.

11 Electromagnetic compatibility

SIMEOX is intended to operate in the following environments:

- In healthcare facilities, in medical or paramedical practices
- At home

The essential performance of SIMEOX defined for magnetic compatibility, according to the result of the Risk Analysis is as follows:

1. The device must remain operational during the tests.
2. If the outlet is physically blocked, either by simulation of an obstruction for example, the patient's tongue, or by the measuring instrument, SIMEOX should switch to status "outlet is blocked" if the negative pressure level is above the limit of 160 mBar, and once in "outlet is blocked" status, should maintain this status, regardless of the disturbances to which the device is subjected.

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- *Using this device near or stacked on other appliances should be avoided because this could cause a malfunction. If this use is necessary, this device and the other appliances should be monitored to check they are operating normally.*
- *Portable RF communication appliances should not be used (including peripherals such as antenna cables and external antennae) closer than 30 cm (12 inches) to any part of SIMEOX including the cables specified by the manufacturer. Otherwise, the performance of these appliances could be impaired.*
- *The use of accessories, transducers and cables other than those specified or supplied by PHYSIO-ASSIST can cause an increase in electromagnetic emissions or a reduction in the immunity of this device and cause inappropriate operation.*

DIRECTIVES AND DECLARATION OF THE MANUFACTURER - EMISSIONS AND IMMUNITY	
Emission tests	Compliance
RF Emissions CISPR 11	Group 1
RF Emissions CISPR 11	Class B

MANUFACTURER'S DECLARATION – IMMUNITY TO RADIATED DISTURBANCES		
Phenomenon	Applied standard	Immunity level
Magnetic field at mains frequency - (50/60 Hz)	IEC 61000-4-8	30 A/m 50Hz
Radiated RF disturbances	IEC 61000-4-3	80 MHz-2.7GHz Home care environment: 10 V/m 80% / 1 kHz
Radiated electromagnetic fields at radio wave frequencies	IEC 61000-4-3	380 - 390 MHz - 27 V/m; PM 50%; 18 Hz 430 - 470 MHz - 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz - 9 V/m; PM 50%; 217 Hz 800 - 960 MHz - 28 V/m; PM 50%; 18 Hz 1700 - 1990 MHz - 28 V/m; PM 50%; 217 Hz 2400 - 2570 MHz - 28 V/m; PM 50%; 217 Hz 5100 - 5800 MHz - 9 V/m; PM 50%; 217 Hz
Electrostatic Discharges (ESD)	IEC 61000-4-2	Contact : ±8 kV - Air : ±15 kV

MANUFACTURER'S DECLARATION – IMMUNITY TO CONDUCTED DISTURBANCES		
Phenomenon	Applied standard	Immunity level
Conducted disturbances caused by radio frequency fields	IEC 61000-4-6	150 kHz-80 MHz 3 V ISM/Radio frequencies 6 V 80% / 1kHz
Fast transient burst	IEC 61000-4-4	5/50 ns, 100 kHz; ±2 kV
Surges	IEC 61000-4-5	1.2/50 (8/20) µs line to line: ±1.0 kV
Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11	0% UT for 0.5 cycle (1 phase) 0% UT for 1 cycle 70% UT for 25/30 cycles (50/60 Hz)
Voltage dips, short interruptions and voltage variations on power supply input lines	IEC 61000-4-11	0% UT for 250/300 cycles (50/60 Hz)
UT is the AC mains voltage prior to application of the test level		

12 In the event of breakdown

No maintenance of SIMEOX is to be carried out by the user.

In the event of breakdown, never try to intervene: SIMEOX does not contain any part to be replaced by the user, and interfering with a device that is turned on could cause an electric shock.

In the event that SIMEOX malfunctions, call on PHYSIO-ASSIST or an approved repair centre.

The housing of SIMEOX is protected by a warranty seal.

Only PHYSIO-ASSIST and approved repair centres can replace this seal.

If this seal is broken or removed, proving that a non-authorised intervention has been carried out:

- *The SIMEOX warranty is automatically voided, the device must be handled by PHYSIO-ASSIST or an approved repair centre.*
- *You are held responsible in the event of an accident.*

In the event of malfunction, the user can however carry out simple manipulations to confirm that the fault is indeed attributable to SIMEOX.

SYMPTOM	PROBABLE CAUSE(S)	ACTION TO BE UNDERTAKEN
SIMEOX no longer starts at all, the orange light does not illuminate	1- Defective power supply 2- Power cord damaged 3- Possible failure of SIMEOX electronics	1- Check the power supply is functioning correctly 2- Disconnect SIMEOX from the mains and check the power supply cord. 3- If the symptom persists: possible failure of the SIMEOX electronics ● Contact PHYSIO-ASSIST or an approved centre
SIMEOX starts but stops unexpectedly	Inappropriate power supply: SIMEOX is intended to operate with a power supply that conforms to standards, in the case of a power supply that does not conform to standards, or in the event of repeated short power outages, SIMEOX switches to “safety” mode. Wait a few minutes and try again.	Have your power supply checked by a specialist. If the supply complies with European standards, and the symptom persists: possible failure of the SIMEOX electronics. Contact PHYSIO-ASSIST or an approved centre
Compressor noise as soon as it is turned on	Failure of the SIMEOX electronics	Contact PHYSIO-ASSIST or an approved centre
SIMEOX does not recognise the PHYSIO-ASSIST expiratory kits	The consumable is no longer usable: try with a new consumable. If the symptom persists: possible failure of the SIMEOX electronics	Contact PHYSIO-ASSIST or an approved centre
SIMEOX seems to operate but no negative pressure pulse output	Internal failure of SIMEOX (electronics, compressor, etc.)	Contact PHYSIO-ASSIST or an approved centre
SIMEOX operates but the operating noise is irregular and loud	Internal failure of SIMEOX (electronics, compressor, etc.)	Contact PHYSIO-ASSIST or an approved centre
SIMEOX no longer responds to the remote control. It is impossible to pair SIMEOX and the remote control.	Replace the remote control battery. If the symptom persists: possible failure of the SIMEOX electronics or of the remote control.	Contact PHYSIO-ASSIST or an approved centre
When checking the lights on starting the device, one light does not illuminate	Control pad needs to be replaced	Contact PHYSIO-ASSIST or an approved centre

13 Warranty conditions

SIMEOX is guaranteed under the following conditions:

- Any use that does not comply with the recommendations of this manual voids the warranty.
- Removing or breaking the warranty seal voids the warranty.

PHYSIO-ASSIST guarantees the Purchaser that the Products supplied will be, in the context of normal use, free from design, component and manufacturing faults, and substantially compliant with their specifications for a period of 24 months from delivery.
"Normal use" specifies storage, installation, initial operation, use and maintenance that comply with PHYSIO-ASSIST specifications and expressly excludes uses made outside the indications specified in this user manual.
PHYSIO-ASSIST's obligation under this warranty will be limited to the repair or replacement, at PHYSIO-ASSIST's discretion, of all Product faults that appear before the expiry of the warranty period above.
When PHYSIO-ASSIST chooses to repair Products, the Purchaser must return the Products to be repaired to PHYSIO-ASSIST's premises at the Purchaser's expense. As regards to the Products that have been repaired or replaced by PHYSIO-ASSIST below, PHYSIO-ASSIST guarantees these articles until the end of the original warranty period.

PHYSIO-ASSIST's obligations under the terms of this agreement are subject to the following conditions:

(i) That PHYSIO-ASSIST is paid in full by the Purchaser for the Products: making the purchaser the owner of the device

(ii) That PHYSIO-ASSIST is informed by the Purchaser of the Product fault within 7 days after the appearance of the fault

(iii) That PHYSIO-ASSIST has a reasonable possibility of inspecting the Product presumed to be faulty, at the expense of the Purchaser

(iv) That the Purchaser uses exclusively PHYSIO-ASSIST accessories and expiratory kits

(v) That SIMEOX has been used in compliance with the recommendations in this manual

(vi) That the warranty seal has not been broken, nor removed, so indicating a non-authorised intervention on the device.

The warranty obligations of PHYSIO-ASSIST do not extend to faults or failures caused by wear, accidents, non-compliant use, the use of disposable products or accessories not specified for use with the Products, unreasonable conditions of use (variable temperatures, voltage and supply limitations), negligence, lack of maintenance or cleaning, repair or modification of the products (including with reference to product packaging and labelling) which have been carried out without the approval of PHYSIO-ASSIST. PHYSIO-ASSIST disclaims all liability for the costs of disassembly, transport, reassembly and of retesting for any product affected by this warranty.

14 End-of-life, recycling

14.1 Expiratory kits

Expiratory kits can potentially be contaminated by patient mucus and can therefore be considered Medical Waste.

It is the responsibility of the user to refer to the local Medical Waste regulations for the treatment method.

14.2 Remote control batteries

Used batteries must not be disposed of with the household waste, but recycled.

It is the responsibility of the user to refer to the local regulations on the recycling of Batteries and Accumulators for the disposal method.

14.3 SIMEOX

When SIMEOX has reached the end-of-life stage, it must not be disposed of with the household waste.

The rules for disposal are as follows:

- If the devices are potentially infected, they are considered Medical Waste and must be treated accordingly in a specific circuit.
- If the devices are not infected, the regulations from the Directive 2012/19/EU also apply to non-infected medical devices: SIMEOX and its remote control must be treated as Electrical and Electronic Equipment Waste (EEEW).

It is the responsibility of the user to contact the supplier or PHYSIO-ASSIST to find out about the action to be taken to recycle SIMEOX in compliance with the applicable regulation.

PhysioAssist

www.physioassist.com

PhysioAssist
31 Parc du Golf - CS 90519
13593 Aix-en-provence Cedex 3
FRANCE

tel +33 (0)4 67 03 13 92
contact@physio-assist.com

CE 0459

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