

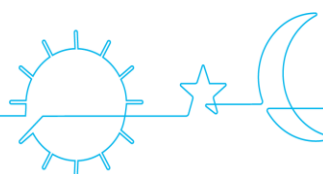
# Sefam S.Box

BY  
STARCK®



S.Box™ C

Manuel patient



en

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and



With SEFAM Access Lite, you can:

- Easily adjust your S.Box C,
- Easily monitor the evolution of the effectiveness of your treatment and other parameters of your health and well-being,
- Share this data with your healthcare professionals,
- Get access to information about your S. Box C.

With SEFAM Access Lite, engage in your treatment !

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# Product description

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Please read this manual carefully before using your SEFAM S.Box C to understand the usage constraints of the device.

## Intended purpose

The S.Box C is Positive Pressure devices connected by a flexible tube to a mask worn by the patient suffering from obstructive sleep apneas and hypopneas during sleep. The device delivers a continuous flow of air to obstruction of the upper airway during sleep.

## Indications

The S.Box C device is indicated for the treatment of obstructive sleep apnea and hypopnea syndrome (OSAHS).

## Contra-indications

The use of a positive pressure device is contraindicated in certain patients with one of the following pre-existing conditions:

- Severe bullous emphysema
- Pneumothorax
- Pneumocephalus, trauma or recent surgery with sequela of cranio-nasopharyngeal fistula.
- Decompensated cardiac insufficiency or hypotension, particularly in case of decreased blood volume or cardiac arrhythmia
- Dehydration
- Tracheotomy.

Furthermore, due to the fact that positive pressure affects the cardiac output in certain heart failure patients, it is recommended that patient blood pressure and heart rate are carefully monitored when starting treatment at an effective pressure. The risks and benefits of treatment by Continuous Positive Airway Pressure must be individually evaluated in such subjects. This evaluation must take into account the fact that the device can be adjusted to deliver pressures up to 20 cm H<sub>2</sub>O, and under certain defect conditions, static pressures up to 40 cm H<sub>2</sub>O are possible. The device must not be used then, if such pressure level presents a risk to the patient.

# Warnings/ Precautions

## WARNING:

Means in this manual that there is a risk of danger of injury or accident to yourself or others.

- Portable RF communications devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the SEFAM S.Box C including cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.
- Never use the appliance without checking that the air inlet filter is in place.
- Use the appliance only for the purpose recommended in this manual.
- The SEFAM S.Box C may only be used on medical prescription.
- The device is not intended to provide assistance with vital functions.
- Only use this device with the authorised accessories listed in this manual.
- Do not start treatment if you notice any fault with the device.
- To ensure correct maintenance and avoid any possibility of damage, only qualified personnel are authorised to carry out maintenance on the appliance. The user assumes full responsibility for any malfunction of the appliance caused by maintenance carried out by unqualified personnel.
- Any serious incident involving the S.Box C must be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.
- Place the device on a stable horizontal surface in a clean, dry environment. Do not use the device if it is adjacent to or placed on top of another device.
- Take care not to accidentally or intentionally obstruct the air outlet or any opening in the device or breathing circuit. Do not cover the appliance or place it too close to a wall. Do not introduce liquids or objects into the air outlet, as they could be propelled into the tube.
- Keep the appliance and its power supply module away from all sources of water. Only use the appliance and its accessories if they are dry and in working order.
- Keep the power cord away from any hot surface.
- If additional oxygen is required, scrupulously comply with the instructions and safety instructions relating to the use of oxygen.
- Do not use the appliance in the presence of flammable vapours and in particular the heated humidifier in the presence of flammable anaesthetic products, either independently or mixed with other gases (risk of explosion).
- Do not leave unnecessary lengths of tube on the bed. They could wrap around your head or neck when you sleep.
- Keep the appliance away from children and pets.
- The American HIMA (Health Industry Manufacturers Association) recommends that a minimum separation of 15 cm be maintained between a wireless telephone and a pacemaker in order to avoid any possible interference with the pacemaker. In this respect, the Bluetooth communication built into the SEFAM S.Box C should be regarded as a cordless telephone.
- Once the machine is operating and the mask is in place, check that the device is producing an airflow. If not, remove the mask immediately.
- Never obstruct the mask's exhaust port, which allows air to escape continuously and minimises the rebreathing of carbon dioxide. If the device is operating, the air produced will force the exhaled air through the mask's leak hole. However, if it is not working, there will not be enough fresh air produced in the mask and exhaled air may be rebreathed, which could lead to suffocation over several minutes and in certain circumstances.
- If the device malfunctions and the patient is fitted with a nasal mask, the resistance of the device is low enough to allow the patient to breathe out through the machine or simply open his mouth. If the patient is fitted with a face mask, the mask must have an anti-asphyxia valve device.
- Remove the mask in the event of a power cut or machine malfunction.

In case your device is equipped with a heated humidifier:

- The side cover must be removed and replaced with the humidifier, which includes the heating element and humidifier chamber.
- Care must be taken every time the heated humidifier is used to eliminate any risk of water entering the machine and causing irreversible damage. To do this, place the appliance on a horizontal, stable surface, taking care not to tilt it.
- Do not add any products to the water in the humidifier chamber (essential oils, etc.).

- Always empty the humidifier chamber before moving or transporting the appliance.
- The humidifier must not be used with nitric oxide. This could cause the humidifier to malfunction, leading to a serious deterioration in health.
- The use of a humidifier with a gas source (for example, a fan equipped with a compressor/turbine) that heats the gas supplied to the humidifier above a temperature of 35°C may lead to an alteration in the amount of humidification delivered, potentially causing serious deterioration in health.
- The heated humidifier has a plate that may be hot during normal operation, as may the bottom of the humidifier chamber. Avoid touching them.
- The humidifier chamber must be cleaned before using it for the first time or after any technical intervention, and then regularly as described in the "Cleaning and Maintenance" paragraph.
- Fill the humidifier chamber with water away from the appliance to prevent water dripping onto it.
- Do not use the appliance if you notice any leaks from the humidifier chamber, e.g. due to damage to the seal.
- The heated humidifier must not be used at an ambient temperature above 35°C, as the temperature of the air delivered to the patient could exceed 43°C. This could lead to irritation or burns of the upper airways.
- The addition of a heated humidifier may modify the performance of the device.
- There is a risk of air leakage if the humidifier chamber or side cover is incorrectly refitted, which could lead to a variation in the pressure applied compared with the prescribed pressure.
- Do not add intermediate parts or accessories to the humidifier that are not included in the instructions for use for the humidifier or accessory, otherwise the humidifier or accessory may not function correctly and may affect the quality of treatment or cause injury to the patient.
- Do not use the humidifier at altitudes above approximately 2500 m or outside a temperature range of +5°C to +35°C with the humidifier. Using the humidifier outside this temperature range or above this altitude may impair the quality of the treatment or cause injury to the patient.
- To prevent the tube or tube system from becoming disconnected during use, particularly during ambulatory use, you should only use tubes that comply with ISO 5367 or ISO 80601-2-74.
- Covering breathing tubes with a blanket or warming them in an incubator or with an electric ceiling heater may adversely affect the quality of treatment or cause injury to the patient.

#### CAUTION:

In this manual it means that there is the possibility of material damage to this device or any other.

- Place the device in a way that nobody can bump into it or trips over the power cord
- If the apparatus is placed on the floor, ensure that it is in a place free from dust, bedding, clothing or other objects that may obstruct the air intake.
- As this is an electrical medical device, when installing it you must comply with the electromagnetic compatibility instructions given in this manual.
- Like any medical electrical device, the device is likely to be disturbed by mobile or portable radio frequency communication devices (mobile phones, Wi-Fi...).

## Potential undesirable side effects

Potential undesirable side effects, which in some cases may require temporary discontinuation of treatment, include: unusual chest pain, severe headache, increased dyspnoea, dry airways or nose, skin sensitivity, runny or bloody nose (epistaxis), ear or sinus discomfort or pain, bloating, daytime drowsiness, mood changes, disorientation, irritability or memory loss.

## Target patient groups

S.Box C and its accessories may only be used for the treatment of obstructive sleep apnea-hypopnea syndrome (OSAHS) in patient over 30 kg and with spontaneously breathing.

## Intended users

The various potential users of this device are: patients weighing over 30 kg, healthcare professionals and homecare providers.

A specific manual is available for healthcare professionals and homecare providers.

Patients can receive rapid training from healthcare professionals or homecare providers. This prior training is not essential, but reading this instruction manual is necessary for correct use of the device.

## Environment of use

The SEFAM S.Box C is intended for use at home or in a care centre (hospital or clinic). It is designed to travel easily and can be used on aircraft (see " Transport of the device " paragraph).

It is not suitable for use in the immediate proximity of CT scanners, MRT devices or RF surgical equipment.

## Clinical benefits

The direct benefits of using S.Box C are :

- Restoration of normal breathing (residual AHI <10 events/hour)
- Improved sleep at night

Furthermore, in terms of indirect benefits, regular use of the positive pressure device every night will be accompanied by a reduction in sleepiness, cognitive deficits, deterioration in health, hypertension and metabolic disorders associated with OSAHS.

**Note :**  $IAH = IAH_{flow}$

## Device performance

The S.Box C medical device consists of an air compressor that generates a flow of positive pressure air throughout the respiratory cycle, of sufficient pressure to keep the upper airways open.

In this way, S.Box C effectively prevents repetitive obstruction by acting as a pneumatic splint for the upper airway. However, it does not permanently restore or correct the problems causing the obstruction, so they must be applied throughout the night for maximum effect.

# Presentation of the system

## Components of the system

The SEFAM S.Box C comes with the following components:

- S.Box SD card
- Inlet air filter
- S.Box power supply
- Flexible tube
- Side cover
- Patient manual
- S.Box carrying bag

The device can also be used with the following optional accessories. Contact your Home Healthcare Provider for further information on the accessories available. When using the device, follow the instructions supplied with the accessories.

- S.Box cigarette cable (24 VDC)
- S.Box heated humidifier
- S.Box modem
- PolyLink system
- S.Box heated tube with ATC (Adaptive Thermo Control) 15 mm in diameter
- Fine filter (disposable)
- S.Box Wi-Fi module
- Oximeter 3150 in Bluetooth or in BLE
- S.Box USB cable
- SEFAM Access Lite (application pour Tablette/Smartphone)
- Breeze mask

## Views of the device



Figure 1 – Vue de la face avant



Figure 2 – Vue de la face arrière d'un appareil équipé d'un humidificateur



Figure 3 – Vue de la face arrière d'un appareil équipé d'un couvercle latéral







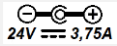

















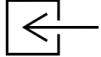




Figure 4 – Vue de l'élément chauffant et du logement accessoire



1	Start / standby button ①:	To switch the device on and off.
2	Touch screen display:	To view the information and access the settings.
3	Ramp button ∠:	Enables or disables the ramp function when the unit is operating.
4	Button to unlock humidifier chamber or side cover (black or grey):	To unlock and remove the humidifier chamber or the side cover from the machine.
5	SD card slot:	Slot for inserting the SD card.
6	USB connector:	Intended for use by the doctor or Home Care Provider.
7	Air inlet filter and grid:	Prevent dust from entering the device and the air flow path.
8	Power port:	To power the device by the power supply or by a cigarette lighter.
9	Heated tube connection:	To connect a S.Box heated tube with ATC.
10	Accessory slot:	Slot for a communication accessory (PolyLink system, S.Box modem or S.Box Wi-Fi module).
11	Heater plate (if humidifier is included):	Base of the heated humidifier used to heat the water in the humidifier chamber.
12	Humidifier chamber (if included):	Humidifier chamber in which the maximum water level is indicated.
13	Side cover (if included):	
14	Angled outlet connector:	Swivel connector for connecting the tube.

## Meaning of symbols

Symbol	Description	Symbol	Description
	Start / standby button.		Ramp button.
	Device is in accordance with the requirements of the European directive 93/42 /EC on medical devices.		Device can no longer be used, dispose separately from household garbage. See paragraph "End-of-life disposal of the device".
	Class II device.		Type BF device.
	24 V Direct Current power supply		Device composes an RF transmitter, non - ionizing radiation.
	Manufacturer.		Manufacturing date.
	Danger: hot surface.		On the humidifier chamber, this symbol indicates the maximum water level which should not be exceeded in the chamber.
	On the humidifier chamber, this symbol indicates that it is necessary to open the chamber and remove its cover before pouring water in from a recipient.		Do not pour water directly into the openings of the humidifier chamber.
	On the heater plate, this symbol indicates in which direction to push the latch to lock or unlock the heater plate.		Device protected against solid objects of more than 12 mm and against drops of water falling vertically.
	Unique Identifier of device		Medical Device
	On the packaging, this symbol means "Atmospheric pressure limit".		On the packaging, this symbol means "Relative humidity limit".
	On the packaging: this symbol means "Fragile" because the package must be handled with care.		On the packaging: this symbol means "Keep dry" because the package must be protected against moisture and water.
	On the packaging, this symbol means "Temperature limit".		Refer to the user manual.
	Air flow input. Do not clog.		Air flow output. Do not clog.
	Pay attention to the electrical connections.		

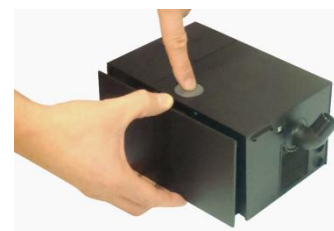
# Installation

## Standard installation

The apparatus must be positioned on a flat and stable surface. It comes with a pre-mounted side cover and according to the chosen configuration, it can also be delivered with a heated humidifier that replaces the pre-mounted side cover.

1. If you have a humidifier or/and a communicating accessory, remove the side cover from the device:

Press the button to unlock the cover (mark 4 in Figure 1) and at the same time, pull the cover with the integrated handle located under the cover away from the machine.




2. Install the communicating accessory (S.Box modem, S.Box Wi-Fi module or PolyLink system) into the accessory slot (mark 10 in Figure 4) – we herefor refer to the corresponding instructions in the installation and usage procedure.
3. Then place the cover on the rails in the side part of the device and push it against the device until you hear a "click".

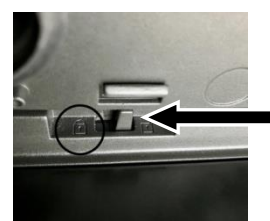
or

Install the heated humidifier (if included):

- A) Place the heater plate on the rails in the side part of the device and push it towards the machine.



- B) Lock the heater plate by pushing the latch to the left as indicated by .



- C) Place the base of the humidifier chamber on the heater plate and push the humidifier chamber against the device until you hear a "click".




#### 4. Connect the breathing tube:

Connect the end of the flexible tube to the angled outlet connector on the back of the device (Mark 14 in Figure 2).

If you have a S.Box heated tube with ATC, insert its power cable lead into the corresponding socket on the device (Mark 9 in Figure 2).



5. Prepare the mask by following the instructions in its operating instructions. Connect the mask to the end of the breathing tube.
6. Plug the power supply cord into the power inlet on the back of the device (Mark 8 in Figure 2) and connect the power supply plug to the electrical power grid.
7. When you turn on the power for the first time, the display light comes on and the logo of the SEFAM mobile apps  appears.

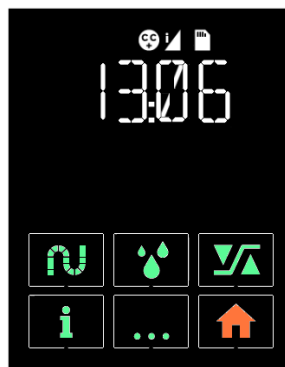
Then, the standby mode screen appears two seconds later, indicating the time.

The device is now ready for use.

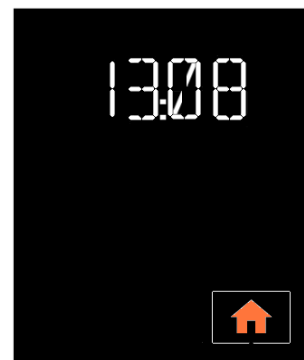
After two minutes in standby mode, without action on any touch key or any button, the hibernation mode screen appears.

The touch key "home"  permits:

- to return the screen from hibernation to standby screen
- to turn off the display from the standby screen.



Standby screen



Hibernation screen

#### WARNING :

- Risk of air leakage in the event of incorrect installation of the heated humidifier, which could cause the pressure applied to vary from the prescribed pressure.
- Correct fitting and positioning of the mask on the face is essential for the correct operation of this device.
- The humidifier chamber may be contaminated by body fluids or exhaled gases.

## Installation with cigarette lighter

The device can be powered by a cigarette lighter socket using a 24 V cable (optional) designed for this purpose. To do this, replace step 6 of the standard installation by the following step:

- Connect the cigarette lighter cable to the power input of the device (Mark 8 in Figure 2) and the other end of the cable directly to the cigarette lighter socket.

#### CAUTION:

- Use only the 24 V cigarette lighter cable recommended with the device.
- Assure the conformity of the voltage supplied by the cigarette lighter socket.
- Do not use the device with a 12 V or 13 V battery of a light vehicle.

## Filling the humidifier chamber (if applicable)

1. Unplug the SEFAM S.Box C device from the power supply or the electrical power grid.
2. To separate the humidifier chamber from the device, press the button to unlock the humidifier chamber (mark 4 in Figure 1) and at the same time, pull the humidifier chamber away from the device using the integrated handle.
3. Put the humidifier chamber away from the device and pull the opening clip upwards to release the upper part of the chamber, then put it aside.
4. Fill the bottom part of the chamber with water up to the maximum level mark indicated by **↑ MAX ↑**.
5. Put the upper part back on the base of the humidifier chamber by positioning the hinge properly, then press down on the upper part to close the chamber and lock it.
6. Place the humidifier chamber back on the heater plate, with the hinge side towards the inside of the machine, and push it against the device until you hear a "click".
7. Plug the SEFAM S.Box C device into the power supply or electrical power grid.



### CAUTION:

- Be careful not to exceed the maximum level mark.
- Fill the chamber only with water at room temperature, do not use hot or chilled water.
- It is recommended to use distilled water.
- **Do not add any product to the water in the chamber (essential oils, etc).**
- Do not use alkaline solution (physiological saline).

# Device configuration

## User interface description

The two mechanical buttons on the top of the device are used to manage its operation:

- Start / standby button : switches the device on or off.
- Ramp button : deactivates or activates the ramp function when the device is in operation.

When the device is in operation, information appears on the touch screen in front and you may be able to adjust certain settings.

The available parameters are:

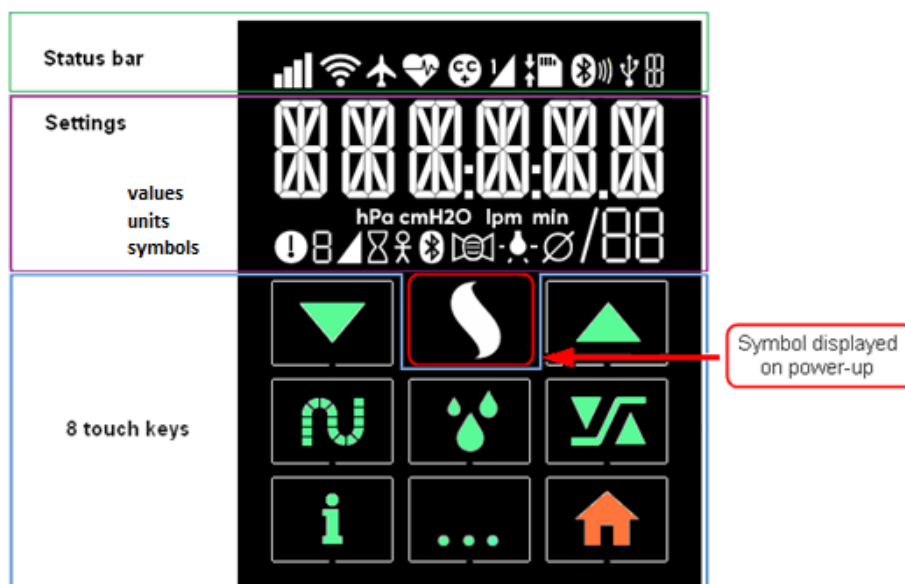
- settings for your treatment,
- general settings such as time or brightness,
- recorded compliance data.

The display may also indicate possible problems with the device or its accessories.

## General organization of the display

From top to bottom, the display is organized in three parts:














- a status bar
- a setting area
- a space with 8 touch keys and the symbol displayed on power-up.


















### Notes:

- The backlight of the display comes on when your hand approaches the display (Wave & Go feature) or when you tap the touch area or push one of the two operating buttons on the device.
- Displays illustrated in this manual are just used as examples.









## Meaning of symbols displayed

Symbol	Meaning	Symbol	Meaning
<b>Status bar</b>			
	GSM mobile phone network status. Flashes quickly during the transmission.		Wi-Fi Communication activated. Flashes quickly during the transmission.
	Airplane mode		Oximeter connected
	Comfort Control Plus CC+ function activated		T RAMP: time ramp active
	SD card inserted		I RAMP: intelligent ramp active
	Flashes slowly when data storing is in progress.		Bluetooth connection activated
	Flashes slowly when settings update is in progress.		Bluetooth transmission in progress
	USB connection activated (Bluetooth disabled)		

### Settings: values, units and symbols displayed


	Numbers or letters		Pressure unit: hecto Pascal or cm H <sub>2</sub> O
	Flow unit: liter per minute		
			Time unit: hour and minute
	Caution: the device detected an error or an incident		
	Machine hour counter		Setting of the ramp time
	Bluetooth		Usage hour counter
	Setting of the brightness of the display		Mask adjustment
			Diameter of tube


### Touch keys

	Scrolling-down touch key, allows to decrease the value of the displayed parameter		Scrolling-up touch key, allows to increase the value of the displayed parameter
	Touch key to adjust the S.Box heated tube with ATC setting (if installed)		Touch key to adjust the heated humidifier setting (if installed)
	Touch key to access the settings		Touch key to access information
	Multifunctional touch key		Home touch key



## Available features

### Mask Fit & Go

You can check the air tightness of your mask before starting the treatment and when the device is in standby mode. The residual mask leak information can be displayed by tapping the touch button .

Adjust your mask in case of undesired leak. Tap  to return to the standby screen.

### Mask unplugged feature



If you remove your mask, the device automatically reduces the flow. The machine will restore normal flow and pressure when you reconnect your mask or if you press the Start / standby button  or the ramp button . Otherwise, the machine will stop after 30 minutes. The feature can be used at night when you need to get up.


### Comfort Control Plus

The Comfort Control Plus (CC+) is intended to slightly increase the treatment pressure when you inhale and to decrease the pressure when you exhale to make your breathing more comfortable during the treatment. It can be activated during the ramp or the entire treatment. In both cases, three levels are available in order to get an optimal setting.

### Ramp

When activated, the ramp function makes it possible to gradually increase the pressure to help you fall asleep. The delivered pressure increases progressively from a lower initial pressure (ramp pressure) up to the prescribed pressure for a duration called 'ramp time'. There are two types of ramp:

- Time ramp (T RAMP): the ramp time is determined by your Home Care Provider. The symbol  is displayed in the status bar.
- Intelligent ramp (I RAMP): the ramp time is determined automatically by the device. The pressure rise up to the prescribed pressure occurs as soon as the device starts to detect obstructive breathing events indicating that you have fallen asleep. The symbol  is displayed in the status bar.

The ramp feature starts automatically when the apparatus is switched on (if the ramp time is  $\neq 0$ ). It can be deactivated (then reactivated) by pressing the ramp button .

## Device settings

The setting can be done via the touch keys if the unit is in standby or in use (depending on settings).

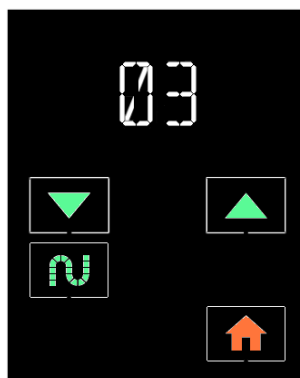




## 1. Heating capacity of the S.Box heated tube with ATC (if installed)

Tap the touch key



in standby or operation mode.



You can decrease or increase the displayed value of the heating power by tapping the key  or .

Possible settings: OFF (no heating), 01 to 05 and AUTO (if a humidifier is also present).

The AUTO mode makes the heating of the heated tube progressive as a function of the heating power level of the heated humidifier.

This setting is only possible if your device is equipped with a S.Box heated tube with ATC.

Tap  to return to the standby or operation screen.

## 2. Humidification level (if humidifier installed)

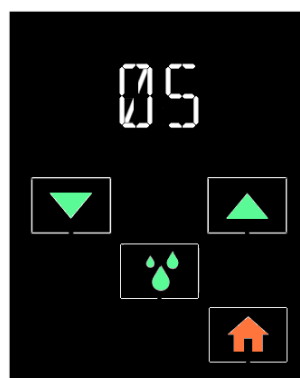
Tap the touch key





in standby or operation mode.



View of the display:



You can decrease or increase the value of the humidification level by tapping the key  or .

Possible settings: OFF (no humidification) and 01 to 10.

This setting is only possible when your device is equipped with a humidification system.

Tap  to return to the standby or operation screen.

## 3. Mask Fit & Go: control airtightness of the mask

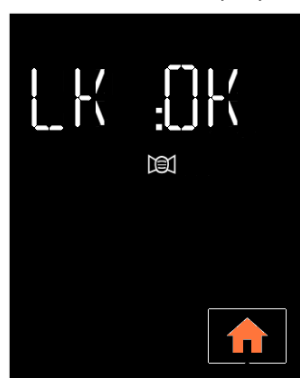
Tap the touch key



in standby mode.




View of the display:




Residual mask leak information can be viewed, but not changed.




Possible displays: LK:OK, LK:NOK.

In case of undesired leak (LK:NOK), re-adjust your mask.

Tap  to return to the standby screen. The display will turn off automatically after two minutes without tapping a key.

## 4. Settings menu

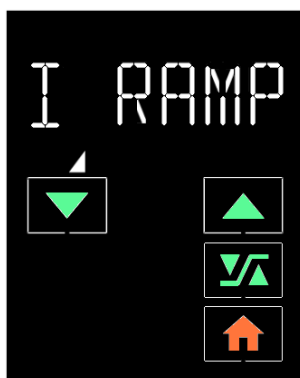
To access the settings, tap the touch key  when the device is in standby mode. In the following sequence of settings:

- Tapping on  or  allows you to decrease or increase the value of the parameter or to deactivate or activate the displayed function,
- Tapping on  allows you to access the next display,

The display turns off automatically after two minutes without pressing a key or by tapping .

①  
Tap the touch key

  
in standby mode.



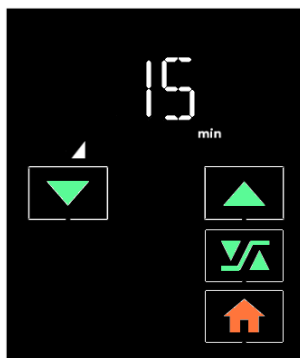
**I Ramp** (Intelligent Ramp) if it has been selected by your Home Care Provider.

You can activate or deactivate this function

by tapping the key  or  displayed.



Possible settings: I RAMP and OFF.

or



**Ramp time** if T Ramp (Time Ramp) has been selected by your Home Care Provider.

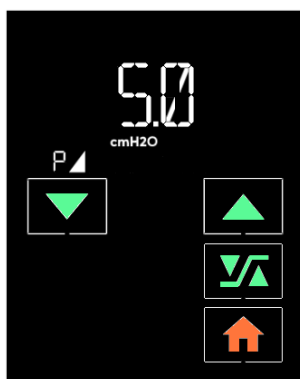
You can decrease or increase the value

displayed by tapping the key  or  or disable the ramp feature in selecting **OFF**.

Possible settings: OFF and from 5 min to the maximum ramp time set by your Home Care Provider.



②  
Tap the touch key





**Ramp pressure** (ramp start pressure).

This parameter is displayed if a ramp has been selected by your Home Care Provider and if he/she did not lock your access to this setting.



You can decrease or increase the value displayed by tapping the key  or  repeatedly.

Possible settings: from 4 cm H<sub>2</sub>O to the pressure set

**3**  
Tap the touch key

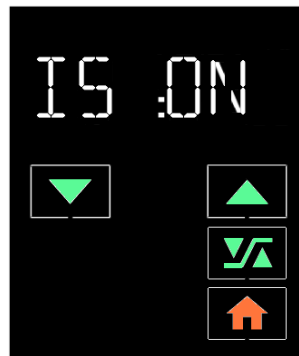


### CC+ (Comfort Control Plus)



This function is displayed if it has been activated by your Home Care Provider and if he did not lock your access to this setting. You can deactivate (OFF) or activate (ON) this function by tapping the key  or .

Possible settings: CC+: ON and CC+: OFF.

**4**  
Tap the touch key

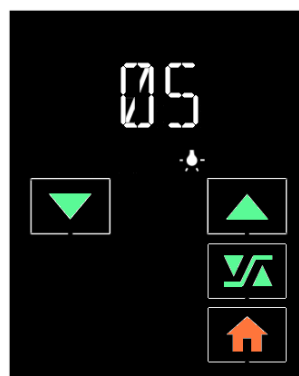


### IS (Intelligent Start)



This function is displayed if it has been activated by your Home Care Provider and if he did not lock your access to this setting. You can deactivate (OFF) or activate (ON) this function by tapping the key  or .

Possible settings: IS: ON and IS: OFF.

**5**  
Tap the touch key



### Brightness



You can decrease or increase the brightness of the display by tapping the touch key  or  as many times as needed.

Possible settings: 01 to 10.

**6**  
Tap the touch key



### BT (Bluetooth wireless communication)

You can deactivate (OFF) or activate (ON) this function by tapping the key  or .

Possible settings: BT: ON and BT: OFF.

### CAUTION:

The Bluetooth wireless connection must be enabled:

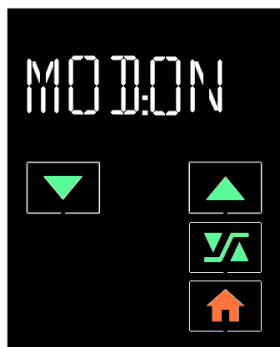
- for real-time acquisition of signals from the Nonin pulse oximeter on the SD card
- to recover compliance data recorded in the device via a Bluetooth connection
- to make adjustments via tablet / smartphone applications (refer to the corresponding instructions for use).

If your device is equipped with a communicating accessory (PolyLink system, S.Box modem or S.Box Wi-Fi module), the corresponding display appears at this level in the settings menu. Refer to the installation of the relevant accessory described in the corresponding instructions for use.



**7**  
Tap the touch  
key



or



Connecting the S.Box modem (if installed)



You can deactivate (OFF) or activate (ON) the S.Box modem connection by tapping the key  or .

Possible Settings: MOD: ON and MOD: OFF.

**7**  
Tap the touch  
key



Connecting the S.Box Wi-Fi module (if installed)

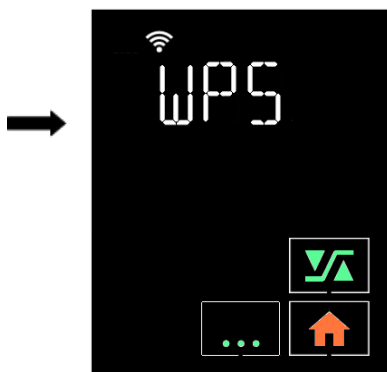
You can deactivate (OFF) or activate (ON) the Wi-Fi module connection by tapping the key  or .

Possible settings: WIFI: ON and WIFI: OFF.

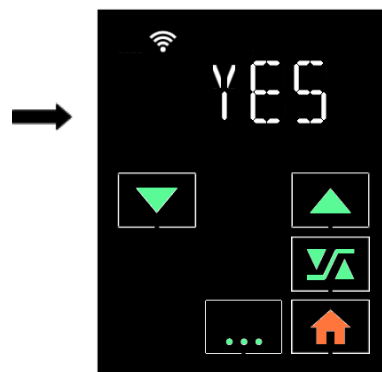
The symbol  blinks slowly at the top of the screen.






Only when the Wi-Fi module is installed inside the SEFAM S.Box C device and the Wi-Fi connection activated, you can access the **WPS automatic configuration** which allows connecting to the local network.

**8**  
Tap the touch  
key

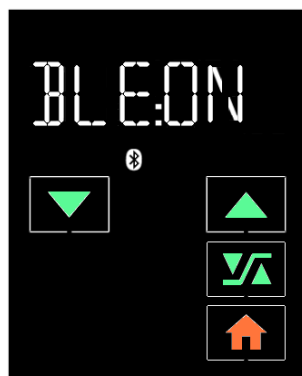


Tap the touch  
key





Select **YES** on the screen by using the touch key  or . You then have about two minutes to press the **WPS** button on your Wi-Fi router and enable connecting to the network with the key . A progress bar  appears until the connection to the network is effective. The symbol  blinks quickly at the top of the screen, then becomes permanent. Then you go back to the **WPS** screen and you can resume the settings menu.

Or  
**7**  
 Tap the touch key  

**BLE communication** (BLE = Bluetooth Low Energy)

You can deactivate (OFF) or activate (ON) the communication by tapping the key  or .

Possible Settings: BLE: ON and BLE: OFF.

#### CAUTION:

The Bluetooth Low Energy wireless connection must be enabled for acquisition of signals from the PolyLink system or from an oximeter 3150 BLE-0101.

**8**  
 Tap the touch key  




**SP02** (Pulsed Oxygen Saturation of Hemoglobin).

The device searches for an oximeter and the display flashes alternately with six dashes as long as no oximeter is associated.


Once the oximeter detected, the last six digits of its Bluetooth address flash alternately with SP02.

#### CAUTION:

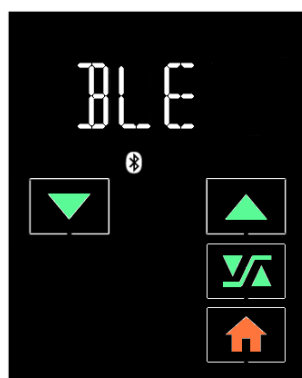
Make sure that the last six digits of the Bluetooth address (BDA) match those of the oximeter you want to pair.

You can deactivate the communication by tapping on  or .

#### Notes:

- This display appears only if the Bluetooth communication has been previously enabled or if a PolyLink module for S.Box C is present in the device and the BLE communication enabled.
- Follow the instructions in the user guide to install the oximeter and oximetry sensor (if present), and wait for the communication to take place (approximately one minute).
- Replace the batteries if a low level (  ) is displayed on the oximeter.



**9**  
 Tap the touch key  

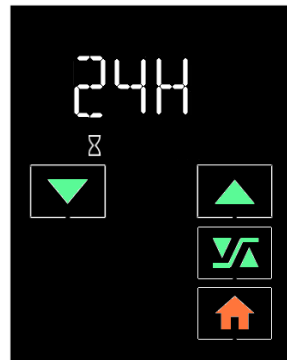
**Communication with the PolyLink BLE module**

The device searches for the BLE module and the display blinks alternately with six dashes as long as no module is associated.



Once detected, the last six digits of the Bluetooth address of the PolyLink system flash alternately with BLE.

You can disable the communication by tapping the key  or .

10  
Tap the touch key

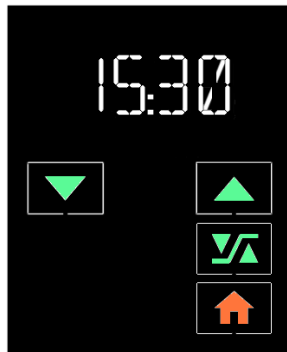


#### Choosing the format of the time display



The time display is set to 24 hours by default. You can select another format by tapping the key  or .

Possible Settings: 24H and 12H.

11  
Tap the touch key




#### Clock

The hour is flashing in the display. You can set it by tapping the key  or  as many times as necessary.

Tap .




The minutes will then flash. Adjust the minutes as well as the hours.

Tap  to return to the standby screen.

## 5. Information menu

The compliance information can be viewed but not modified.

To access it, tap the touch key  when the device is in standby mode. In the following sequence:

-  allows accessing a memorised compliance period, then compliance information recorded during this period and technical information about the device.
-  allows selecting a period of use and moving to the next display.
-  allows going back to the standby display.

#### Information concerning a period of use:

A period of 24-hour use is set from noon to the next noon.

1  
Tap the touch key



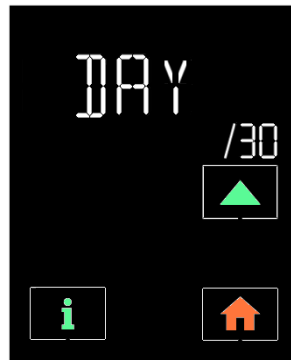
in standby mode.



#### Accessing a period of use

This screen appears only if at least two periods of 24-hour use have been recorded in the device.

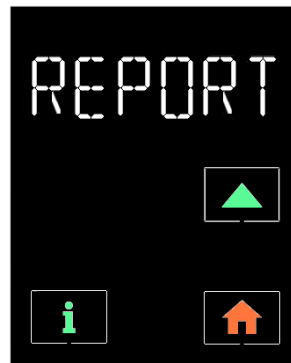
2  
Tap the touch key




### Selecting one of the last periods of use

The value displayed on the right side of the display (30 in the example) represents the number of the last periods of 24-hour use which have been memorized, within the limit of 30 days.

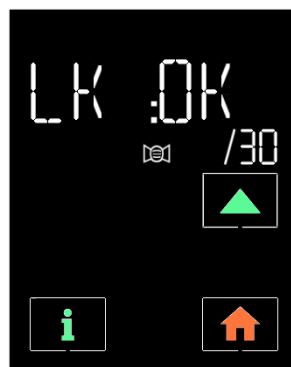
3  
Tap the touch key



### Accessing the compliance information report

The key  allows displaying successively the compliance data recorded during the period of use.

4  
Tap the touch key

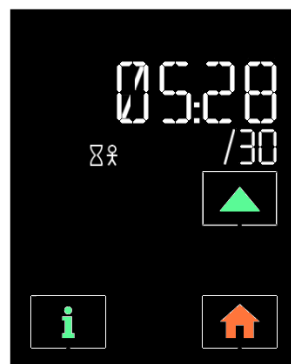


### Average level of unintentional leakage in the mask during the period of use.

Possible displayed information:  
LK: OK, LK: NOK.

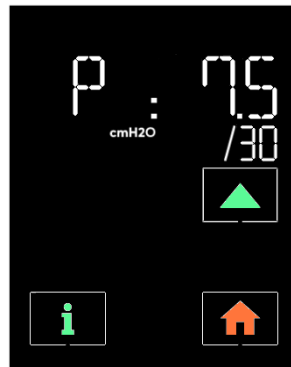
The value shown on the right side represents in each display the number of the last periods of 24-hour use.

5  
Tap the touch key



**Usage hour counter:** time during which you have been breathing in the mask during the period of use.

6  
Tap the touch key



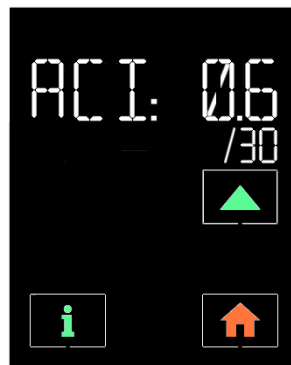
Average pressure delivered during the period of use.

7  
Tap the touch key



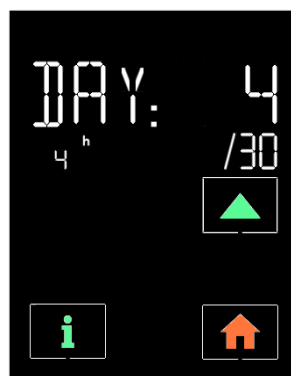
AHI: Index of Apneas and Hypopneas detected and classified as **obstructive** during the period of use.

8  
Tap the touch key



ACI : Index of Apneas detected and classified as **central** during the period of use.

9  
Tap the touch key




Number of the last days of use for which the compliance is higher than 4 hours per day (within the limit of 30 days)

This screen appears only if the number of 24-hour periods recorded in the device is more than 01.



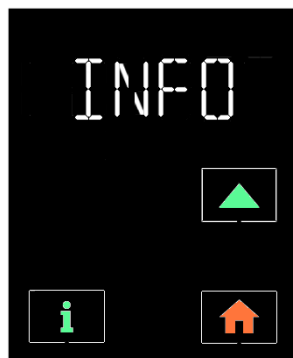
## Technical information concerning the device:

Tapping the touch key  will display, after the previous ones, the technical information concerning the device.

⑩  
Tap the touch key



Views of the display:



Accessing the technical information concerning the device.

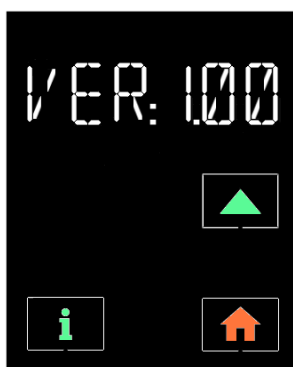
Tap the key  to display the information.

⑪  
Tap the touch key



Identification number of six digits specific to the patient is automatically assigned by the device.

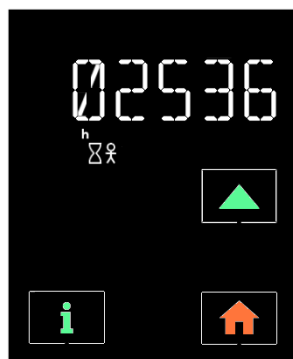
⑫  
Tap the touch key



Software version

This is the version of the embedded software of the device. It can be read but not modified.

⑬  
Tap the touch key



Total usage hour counter

This counter calculates the total time during which you have been breathing into the mask.

14  
Tap the touch  
key



Total machine hour counter





This counter calculates the total operating time of the device.

Tap the touch key  or  to exit the menu.

## 6. Status menu

This menu is accessible when the device is in operation and when a PolyLink system or an oximeter 3150 has been installed and linked. The information may be visualised consecutively but may not be modified.

To access the status menu, tap the  touch button while the device is on. In the sequence below:

-  accesses the next display.
-  then  returns you to the previous display.
-  leaves the current menu.

1  
Tap the touch  
button



when the device  
is in operation.

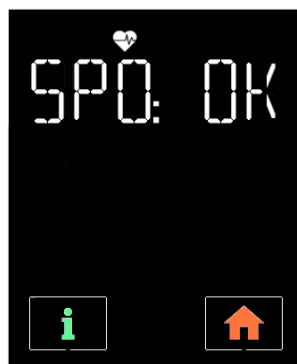


SD card status

Possible displays: SD: OK and SD: \_ \_ \_.

If SD: \_ \_ \_ is displayed, check that the SD card is present and properly inserted in the memory card slot.

2  
Tap the touch  
button

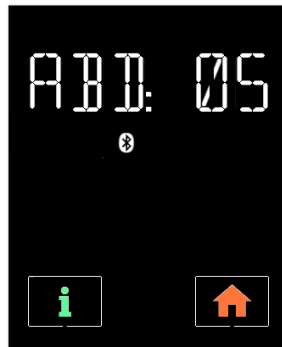


Status of the oximeter

Possible displays: SPO: OK and SPO: \_ \_ \_.

If SPO: \_ \_ \_ is displayed, check that the oximeter sensor has been properly installed and the communication with the oximeter is correct.

③  
Tap the touch  
button

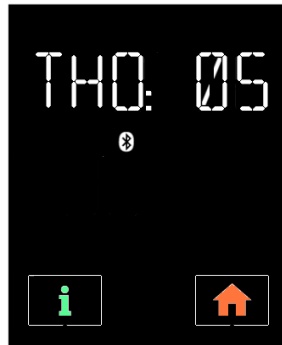


### Status of the abdominal effort sensor

Possible displays: ABD: XX and ABD: \_ \_ \_  
(XX = 01 to 10)

If ABD: \_ \_ \_ is displayed, check that PolyLink effort/position kit is turned on, the abdominal effort sensor is connected and that its tension is correct.

④  
Tap the touch  
button

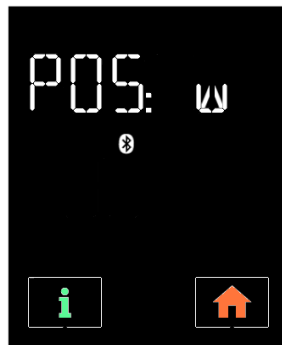


### Status of the thoracic effort sensor

Possible displays: THO: XX and THO: \_ \_ \_  
(XX = 01 to 10)

If THO: \_ \_ \_ is displayed, check that PolyLink effort/position kit is turned on, the thoracic effort sensor is connected and that its tension is correct.

⑤  
Tap the touch  
button



### Status of the body position sensor

Possible displays:

POS: (lying on back)

POS: (lying on stomach)

POS: (lying on right side)

POS: (lying on left side)

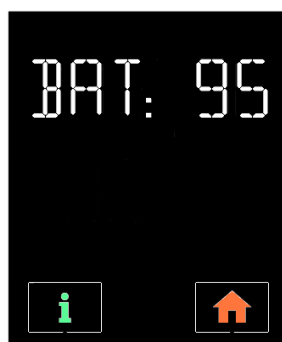
POS: (standing)

POS: (sensor inverted)

and POS: \_ \_ \_

If POS: \_ \_ \_ is displayed, check that the PolyLink system is installed correctly that that the PolyLink effort/position kit is turned on.

⑥  
Tap the touch  
button




### Status of the internal battery for the PolyLink efforts/position kit

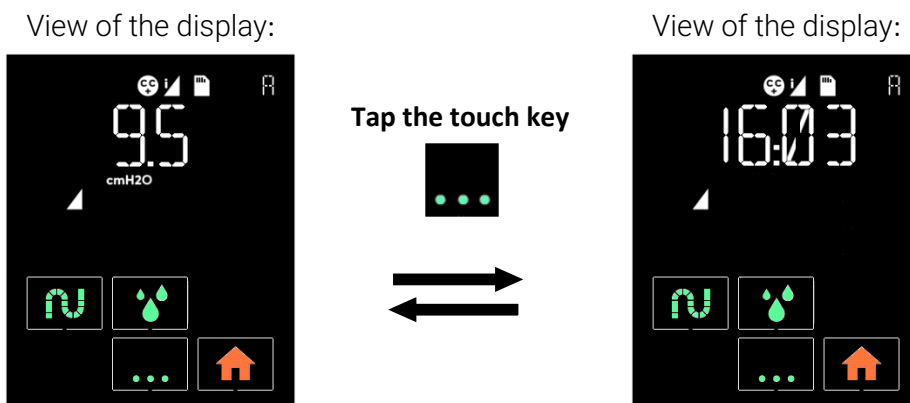
Possible displays: BAT : X  
(X = 0 to 100)

If the displayed value is slow, recharge the internal battery using the USB charger (see the procedure for installation of the PolyLink system).

Tap to exit the status menu.

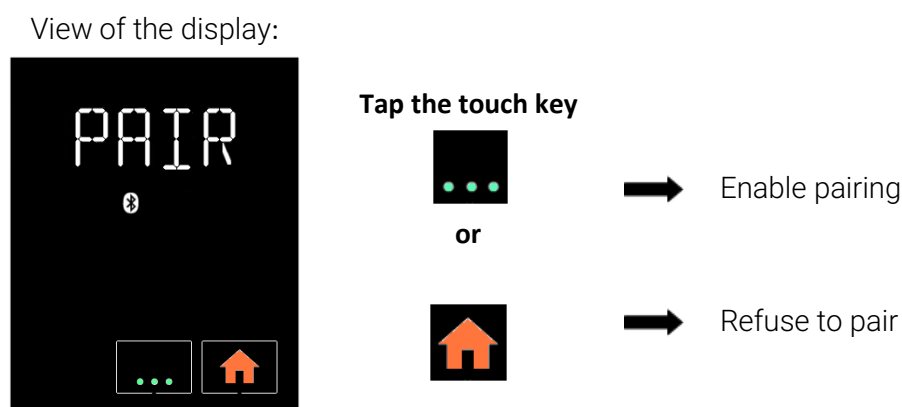
## 7. Viewing the clock during the treatment

When the SEFAM S.Box C device is working, the delivered pressure is displayed. Tap the key  to view the clock, and vice versa to come back to the delivered pressure.



## 8. Pairing a Bluetooth communication tool device


When you are using **SEFAM Access** application on a Bluetooth enabled device (such as a Smartphone or a tablet) and you connect it to the SEFAM S.Box C in standby mode via Bluetooth wireless communication, a message appears on the display of the machine at the first pairing:



The display disappears after 30 seconds.

## 9. Airplane mode

In an airplane or in public places such as hospitals, wireless functionalities can cause interference and disrupt the operation of some devices. To avoid this problem, the airplane mode can be used on the


device. The wireless communications with the machine are then interrupted and the symbol  appears on the status bar. To do this, make sure that Bluetooth wireless communication is disabled, as well as the PolyLink system, S.Box modem or S.Box Wi-Fi module. Otherwise, follow the instructions in the settings menu and set these connections on OFF.



The SEFAM S.Box C device complies with the Federal Aviation Administration RTCA/DO-160G section 21 category M.

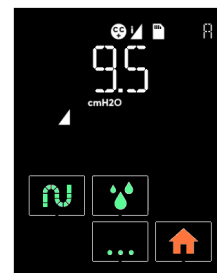
# Use



## Starting treatment

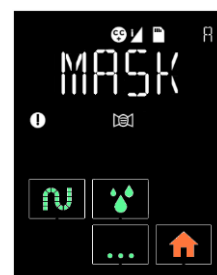
1. Put on your mask as described in the corresponding user instructions. If the Intelligent Start feature has been activated, the device will start during your first breaths in the mask.


You can also hold down the start / standby button  to begin treatment. Recording of compliance data and of treatment effectiveness begins immediately in the device memory and on the SD card when present.

2. Then, the display of the device indicates the delivered pressure and if the ramp is enabled (symbol  or  in the status bar). The displayed symbols indicate which features and accessories are activated (see paragraph "Meaning of symbols displayed").



3. If the message "MASK" appears on the screen, that means your mask is not properly connected. Reposition it properly to minimize the leak as much as possible, then press the start / standby button  or the ramp button . The apparatus will restore the set pressure and the message will disappear.



4. Lie down and place the breathing tube so that it can follow your movements while you are sleeping.
5. If your device is equipped with a heated humidifier, it starts automatically when the appliance is switched on. You can increase or decrease the humidification level using the touch key , (see paragraph "2. Humidification level").

### WARNING:

After a power failure, the appliance will recover the same parameters and operating mode as the ones before the power failure occurred (start / standby).

## Stopping treatment

1. Remove the mask.
2. Hold down the start / standby button  to switch off the device. If it is installed, the heated humidifier stops simultaneously.

## Use when oxygen is added (optional)

### WARNING

- The oxygen source should be placed at least one metre from the appliance.
- Do not smoke in the presence of oxygen.
- Do not inject oxygen through the device's air inlet.
- Scrupulously follow the instructions for starting and stopping treatment.
- Stop the flow of oxygen when the machine is not operating. If the oxygen supply is maintained when the appliance is switched off, the oxygen delivered to the breathing circuit may accumulate in the appliance and create a fire hazard.
- The maximum flow rate of oxygen used must not exceed 8 l/min.

### CAUTION

At a fixed oxygen flow, the concentration of inhaled oxygen varies depending on the settings of pressure, your breathing pattern, type of mask and leakage rate. This applies to most Continuous Positive Airway Pressure devices.

## Installation with an oxygen adapter (optional)

In case of additional supply of oxygen, you definitely have to use a non-return valve equipped with a specific valve to prevent the accumulation of oxygen in the device.

This valve must be fitted between the device and the breathing circuit.

Refer to the manufacturer's instructions for installation, cleaning and maintenance of the valve.


## Starting and stopping treatment

1. In order to prevent oxygen from entering the device, it is essential that it is in operation and that it generates an air flow before opening the oxygen flow.
2. Similarly, in order to prevent oxygen from entering the device, it is essential to stop the flow of oxygen before switching off the device.


## Using an SD card

An SD card is used to store the most recent compliance data memorized by the machine, or to update the settings of your device.



## Inserting the card

When the device is operating, switch it off by holding down the start / standby button . Insert the SD card in the corresponding slot: the symbol  appears on the top of the screen. If it is blinking, it means that the card is improperly inserted or non-functional. Reinsert it properly.

## Updating the settings

If the Home Care Provider configured the SD card to update the settings of the device, the machine will start automatically once the card is inserted in the slot and the symbol  blinks slowly on the top of the screen. Leave the SD card in the slot after the update is finished. This operation can be performed only once.



## Backing up the data

If the data is recorded within the device, the data backup starts automatically when you insert the memory card into the machine, turn on the power and stop treatment. The  symbol blinks slowly in the status bar on the screen and the display changes: an animation appears at the top, showing three blocks  that move towards the right until the data storage is complete. Do not disconnect the power supply and do not remove the memory card.





While the data is being stored, the device continues to be operational and the information remains accessible on the display of the unit.

### CAUTION:

- Do not remove the SD card during the treatment as data is recorded in real time.
- If the symbol  or  is blinking slowly on the top of the screen, it means that a settings update or a data backup is in progress. Do not remove the SD card.

## Removing the card

Once the recording is finished, switch off the apparatus by holding down the start / standby button . Wait for the symbol  to stop blinking on the screen (up to 2 minutes) and remove the card.

# In case of problems






## Helpful tips

Problem	Possible cause	Suggestion
Your nose is cold	Room temperature is too low. The air delivered is too cold.	Increase the room temperature. Ask your Home Care Provider to provide you with a S.Box heated tube with ATC.
Running nose.	Reaction from air flow and pressure.	Contact the medical-technical support or your doctor.
Your nose or throat is dry or irritated.	The air is too dry  Lack of water in chamber (if included).	Use the humidifier when device equipped with one. Increase the humidification level (see paragraph "2. Humidification level"). Check the water level in the chamber. If necessary, fill it (see paragraph "Filling the humidifier chamber").
Pain in the nose, sinus or ears.	Sinus infection or nasal congestion.	Contact your doctor immediately.
Redness of your skin in contact with the mask.	The headgear is too tight or it has the wrong size. Allergic reaction to mask components	Adjust the headgear. Contact your doctor or Home Care Provider to try different sizes. Stop using the mask. Contact your doctor or the Home Care Provider.
Dryness or irritation of eyes.	Air leak around the mask.	Reposition the mask. Ask your doctor or Home Care Provider to try different sizes of masks.
The device delivers air which is too hot.	Air inlet filters are dirty. The air inlet is clogged. The room temperature is too high.	Clean or replace the air inlet filters (see paragraph "Cleaning and Maintenance"). Keep all linen and clothing away from the device. Lower the room thermostat. Make sure the device is away from sources of heat. Unplug the S.Box heated tube with ATC (if present).
The appliance does not deliver the correct pressure on the display.	A ramp is activated.  The selected ramp does not suit you.	Check that the ramp indicator is displayed. If necessary, deactivate the ramp function (see paragraph "Ramp"). Contact your Home Care Provider.
The device seems to be disturbed and not functioning properly.	Too much electro-magnetic disturbance.	Keep the device away from sources of interference such as halogen lamps, mobile phones, etc.



Problem	Possible cause	Suggestion
Discomfort due to excessive pressure sensation.	Pressure of the device.	Adjustment of nasal pressure takes some time. Use the I Ramp to help you fall asleep (see paragraph "Ramp"). Relax and breathe slowly through your nose.
Re-occurrence of symptoms of sleep apnea syndrome.	The device is not set on the correct pressure or is not working properly. Your physical condition or pressure needs have changed.	Ask the Home Care Provider to check how it operates.  Contact your doctor.
The device does not turn on (no display).	The power supply is not connected properly. Absence of mains.  The internal fuse of the device is defective.	Check the connections between the device, the power supply and the mains plug.  Use another device (e.g., lamp, radio etc.) to check if the electrical outlet is working. Contact your Home Care Provider.
White deposits appear in the humidifier chamber.	These are traces of lime scale from tap water.	Rub the traces with a sponge and a mild detergent. Soak the humidifier chamber in a solution consisting of one volume of white vinegar and 9 volumes of water (see paragraph "Cleaning and Maintenance"). Rinse thoroughly with tap water. Wipe the outer part with a clean cloth.
Water droplets appear in the breathing tube, the S.Box heated tube with ATC or the mask.	A few drops of water are normal, especially in winter. The water level is too high in the chamber (if included). Condensation of water vapor is excessive.	Decrease the humidification level (see paragraph "2. Humidification level").  Check that the water level in the chamber does not exceed the maximum, otherwise empty the excess water. Put the breathing tube under a blanket.
Water was spilled into the device.		Unplug the device and allow it to dry for at least 24 hours. Reconnect the device and make sure it is working properly.
The temperature of the heated tube is too low.	The heat level of the tube is set on OFF.	Set the heat level between 01 and 05 (see paragraph "1. Heating capacity of the S.Box heated tube with ATC").
The humidifier does not appear to heat the water.	The humidification level is set on OFF.	Set the humidification level between 01 and 10 (see paragraph "2. Humidification level").

## Device messages

Message on the display	Possible cause	Proposed solution
	The mask is disconnected.	Check the connection between the mask, the breathing tube and the device. This message disappears once you breathe into your properly reconnected mask or press the ⓘ or ⚙ button. Otherwise, the machine will stop after 30 minutes.
 This symbol flashes on screen.	The device detected an operating error in the heated humidifier.	Check that the heated humidifier is properly installed in the device (see paragraph "Standard installation"). The device is operating without the heated humidification function. Unplug the machine from all power sources. Plug it in again and turn it on. If the problem persists, contact your Home Care Provider.
 This symbol flashes on screen.	The device has detected a malfunction of the heated tube.	Check the tube connections to the device. Unplug the device from all power sources. Plug it in again and turn it on. If the problem persists, contact your Home Care Provider.
 This symbol blinks quickly on your display status bar.	The SD card is either not inserted or not properly inserted in the device. The SD card is locked. The SD card is 90% full or more. SD card error.	Insert the SD card properly into the SD card slot (mark 5 in Figure 2). If the symbol continues to blink, contact your Home Care Provider.  Unlock the SD card and reinsert it into the SD card slot.  Contact your Home Care Provider.  Contact your Home Care Provider.
 <p>The error code blinks. (XX = 2 figures).</p>	The unit detected an operating error.	Disconnect the power supply from the mains. Plug it in again and turn on the device. If the error persists, contact your Home Care Provider.

# Cleaning and Maintenance

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No maintenance is required apart from periodic cleaning.

For more details on accessory maintenance, refer to the instructions for use for the mask, breathing circuit, heated tube and communicating accessory used.

## WARNING:

Unplug the device from the power supply. Always remove the breathing tube and the humidifier chamber from the device before cleaning.

## CAUTION:

- For cleaning, only use materials suited for this purpose.
- Do not use aggressive detergent, scouring sponge or hard bristle brush.

## Daily

### Humidifier chamber (if humidifier is installed)

- Remove the humidifier chamber:
  - To remove the humidifier chamber from the device, press the button to unlock the humidifier chamber and at the same time, pull the humidifier chamber using the integrated handle.
  - Put the humidifier chamber away from the device and pull the opening clip upwards to release the upper part of the chamber. Empty the water if any.
- Rinse with clean water.
- Allow to dry by draining, away from the sun.
- Re-install the humidifier chamber, once it is dry.
  - Fill the bottom part of the humidifier chamber, then press down on the upper part to close the chamber and lock it.
  - Place the humidifier chamber back on the heater plate, hinge side towards the inside of the machine, and push it against the device until you hear a "click".

## Weekly

### Humidifier chamber (if humidifier is installed)

- Remove the humidifier chamber:
  - To remove the humidifier chamber from the device, press the button to unlock the humidifier chamber and at the same time, pull the humidifier chamber using the integrated handle.
  - Put the humidifier chamber away from the device and pull the opening clip upwards to release the upper part of the chamber. Empty the water if any.
- Clean the different parts of the chamber with warm water and a mild detergent (e.g. using 3 drops of dishwashing liquid diluted in water).
- Rinse thoroughly with water to remove any trace of detergent.
- Allow to dry by draining, away from the sun.
- Re-install the humidifier chamber, once it is dry.
  - Fill the bottom part of the humidifier chamber, then press down on the upper part to close the chamber and lock it.
  - Place the humidifier chamber back on the heater plate, hinge side towards the inside of the machine, and push it against the device until you hear a "click".

#### Notes:

- Do not leave stagnant water in the chamber in order to prevent the development of micro-organisms.

### Washable filter

- Remove the air intake grid.
- Pull the filter towards you to remove it.
- Wash the filter with lukewarm water and a mild detergent (e.g. using a drop of dishwashing liquid diluted in water).
- Rinse thoroughly to remove any trace of detergent.
- Drying the filter: press the filter in a clean absorbent cloth, then, let it dry totally away from the sun.
- Once dried, place the filter at the back of the device and put back the air intake grid. Do not use a partially dry filter.

## Monthly

### Device

- Clean the outside of the device with a damp cloth (rag, paper towel) sprinkled with a little water and a drop of mild detergent.
- Remove traces of detergent by repeating this procedure with a new cloth, (rag, paper towel) slightly moistened with only water.
- Wipe the device completely dry with a dry cloth (rag, paper towel).

### Air inlet filters

- The optional fine filter cannot be washed. It must be changed once a month or more, if it is visibly dirty.
- Change filters as soon as they are torn or stained.
- It is recommended to change the washable filter every 6 months.

### Humidifier (if installed)

- Once the humidifier chamber has been cleaned, the patient can let it soak for 15 minutes in a solution of 9 volumes of water and one volume of white vinegar.
- Rinse thoroughly with water to remove any trace of vinegar.
- Allow to dry by draining, away from the sun.
- When the humidifier chamber has been removed and emptied, the heated plate can be cleaned by following same cleaning procedure as the device. Reinstall it once it is dry.
- Put the humidifier chamber back in place.
  - Fill the humidifier chamber, then press down on the upper part to close the chamber and lock it.
  - Place the humidifier chamber back on the heater plate, hinge side towards the inside of the machine, and push it against the device until you hear a "click".

#### Notes:

- The different parts of the humidifier chamber can also be cleaned in a dishwasher (maximum 70°C or 158°F).
- Do not leave stagnant water in the chamber in order to prevent the development of micro-organisms.

#### WARNINGS:

- Check if the heater plate is properly dried before plugging the device.
- Never use the device without making sure that the air inlet filter is present.
- Do not use spray detergent. Harmful residues could enter and remain in the air outlet, the air inlet filter or inside of the device, which could cause air way irritation.
- Never use concentrated bleach higher than 0.1%. For example: pour 200 ml of bleach to 2.6% in 5 liters of cold water.

- The tank is the only part of the gas pathways running through the humidifier that can become contaminated with body fluids or contaminated substances carried by expired gases, both normal and single-fault condition.

## Transport of the device

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Unplug the power module and disconnect all accessories from the device. Store the device and accessories in the carry bag.

### Device with heated humidifier

If your device is equipped with a humidifier, press the button to unlock the humidifier chamber and at the same time, pull the chamber using the integrated handle. Then, away from the device, pull the opening clip upwards to release the upper part of the chamber, then put it aside. Empty the water. Then unlock the heater plate by pushing the latch to the right and remove it. Pack it, with the humidifier chamber, in the designated compartment of the travel bag. Place the cover on the rails in the side part of the device and push it against the device until you hear a "click". Pack the device in the bag.

#### CAUTION:

It is absolutely necessary that you empty the humidifier chamber before moving or transporting the device, in order to prevent any risk of water entering the machine, which can cause irreversible damage.

### Air travel

If you are travelling by plane, it is advisable to take your manual with you to facilitate check-in and security formalities at airports.

You can take the appliance and its accessories with you as hand luggage in their carry-on bag, but it is advisable to protect them well in a rigid case if they have to travel in the luggage hold.

If you are travelling to a country where the voltage is different from that normally used, it may be necessary to bring a different power cord or an adapter to connect your appliance to the electrical sockets in that country.

# Technical characteristics

## Performance of the device

Pressure range:	4 to 20 cm H <sub>2</sub> O Adjustable by steps of 0.5 cmH <sub>2</sub> O
Maximum pressure at the patient-side connection port in single fault condition:	40 cm H <sub>2</sub> O
Maximum adjustable pressure:	20 cm H <sub>2</sub> O
Duration of ramp:	0 to 45 minutes ± 1 minute Adjustable in 5 minute steps
Sound pressure level measured according to standard ISO 80601-2-70:2020:	26.0 dBA with side cover 27.5 dBA with humidifier
Patient-side connection port:	Conical connector 22 mm in diameter
Expected life of the device:	5 years (for a typical use of 8 hours a day)
Air inlet filters:	Optional high-efficiency filter. Disposable fabric HEPA filter, which is 90% effective for particles > 3 microns.

Values determined under ATPD (Ambient Temperature and Pressure, Hygrometry) conditions.

Time required for the device to warm from the minimum storage temperature between uses until it is ready for its intended use when the ambient temperature is 20 °C:	At least one hour
Time required for the device to cool from the maximum storage temperature between uses until it is ready for its intended use when the ambient temperature is 20 °C:	At least one hour

## Humidifier performance

Humidification rate:	> 12mg H <sub>2</sub> O/l at the maximum setting for a leakage rate < 60 l/min.
Heating time:	45 minutes
Pressure drop depending on flow:	1.3 cm H <sub>2</sub> O at 1 l/sec
Humidifier chamber compliance:	11 ml / kPa (humidifier chamber empty) 8 ml / kPa (humidifier chamber full)
Maximum operating pressure:	20 cm H <sub>2</sub> O
Maximum gas temperature coming from the breathing tube:	43°C (109°F)

The humidification rate includes a measurement uncertainty of 2.7%.

Values determined under ATPD (Ambient Temperature and Pressure, Hygrometry) conditions.

## Conditions of use

Pressure range:	700 hPa to 1060 hPa
Temperature:	+5°C to +40°C (+41°F to +104°F) with side cover +5°C to +35°C (+41°F to +95°F) with humidifier
Relative humidity:	Between 15 % and 90 % without condensation
Altitude range:	Approximately 0 – 2 500 m (0- 8200ft approx)
Maximum temperature of applied parts:	51°C (or 124°F)
Time of contact of the patient with applied parts:	< 1 minute

## Transporting and storage conditions


Pressure range:	700 hPa to 1060 hPa
Temperature:	-25°C to +70°C (-77°F to +158°F)
Relative humidity:	Up to 90 % without condensation

## Electrical characteristics

### Device

Input voltage:	24.0 V $\pm$ 20 %
Maximum power consumption:	75 W during a mask disconnection
Current consumption at 20 cmH <sub>2</sub> O with a 4-mm leak:	0.42 A (minimum configuration: SEFAM S.Box C only) 1.99 A (maximum configuration: SEFAM S.Box C with humidifier set to 10 and heated tube set to 05)
RF emission type (SEFAM S.Box C®):	Bluetooth version 2.1+ EDR
Frequency band:	2400 to 2483.5 MHz (ISM band)
Maximum power:	4 dBm
RF emission type (PolyLink):	Bluetooth Smart (BLE 4.1)
Frequency band:	2402 to 2480 MHz (ISM band)
Maximum power:	5.3 dBm
RF emission type (optional S.Box C® modem):	HSDPA, WCDMA, EDGE, UMTS
Frequency band:	850MHz, 1900 MHz (for US version) 900MHz, 2100MHz (for European version) 800MHz, 850MHz, 2100MHz (for Japanese version)
Maximum power:	+33 dBm
RF emission type (optional S.Box C® Wi-Fi module):	Wi-Fi 802.11b/g/n
Frequency band:	2412 to 2484 MHz (ISM band)
Maximum power:	+18 dBm

## Power supply

Power supply class II:	
Input voltage:	100 – 240 VAC, 50 - 60 Hz
Power supply provided:	MDS-090BAS24 A (outlet depending on the country)
Input current:	2 - 1 A
Output voltage:	24 V

### WARNING:

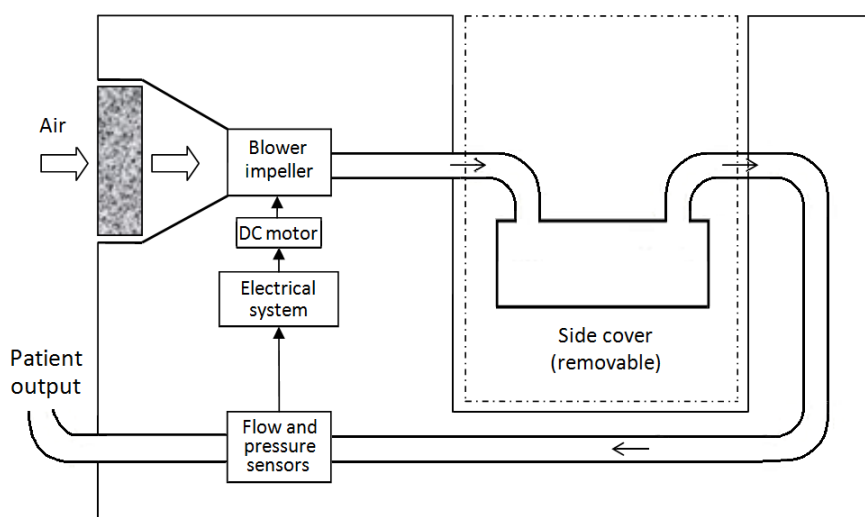
- Use only the plug-in power supply provided with the device
- The power supply is not intended to be repaired. In case of a breakdown, please contact your home care provider for a replacement.
- The 24 V<sub>DC</sub> input is protected against voltage reversals.

## Physical characteristics

Dimensions (L x W x H):	245 x 140 x 110 mm with side cover (9,6 x 5,5 x 4,3 inch) 245 x 185 x 110 mm with humidifier (9,6 x 7,3 x 4,3 inch)
Carrying bag dimensions (L x W x H):	305 x 245 x 180 mm (12 x 9,6 x 7,1 inch)
Carrying case dimensions (L x W x H):	350 x 310 x 190 mm (13,8 x 12,2 x 7,5 inch)
Weight (without power supply):	1.4 kg with side cover (3,1 lbs) 1.7 kg with humidifier (3,7 lbs)
Power supply weight:	0.5 kg (1,1 lbs)
Operational volume (minimum volume of gas in the humidifier chamber):	730 ml
Usable volume of water in humidifier chamber	350 ml
Maximum liquid level:	Indicated by <b>↑ MAX ↑</b> on humidifier chamber

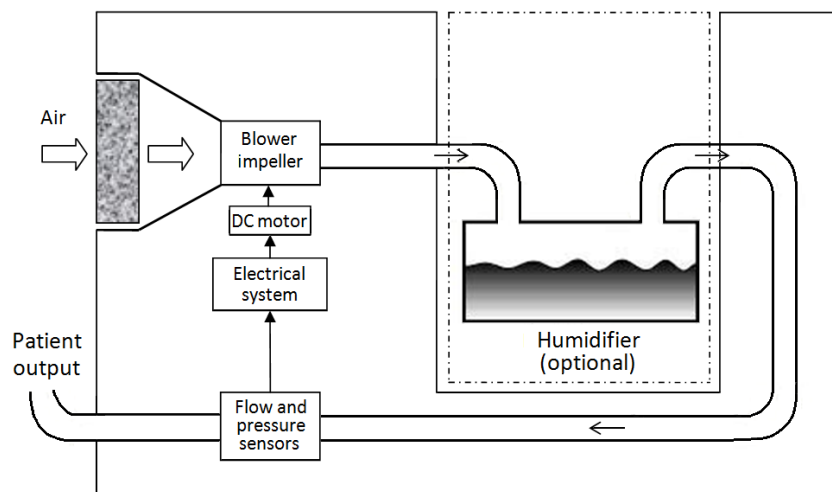
## Functional diagram of the internal pneumatic circuit

### Device with side cover





## Device with humidifier



## CE marking

Date of CE marking of SEFAM S.Box C: 2021

## End-of-life disposal of the device

In accordance with European Directive 2012/19/EU, this appliance constitutes electrical and electronic equipment whose waste must be collected and treated separately from household waste.

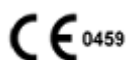
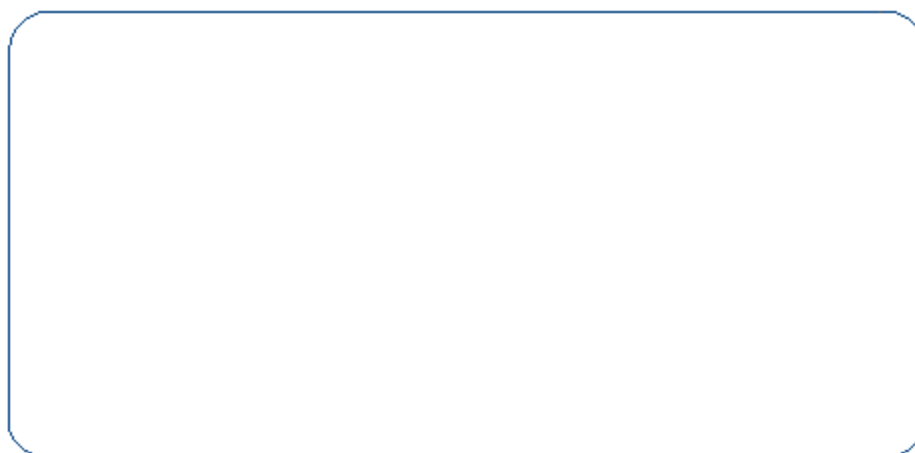
Recycling electrical equipment preserves natural resources and avoids any risk of pollution. To this end, SEFAM fulfils its obligations relating to the end-of-life of SEFAM S.Box C devices by financing Recylum's recycling channel dedicated to WEEE Pro, which takes them back free of charge (more information on [www.recylum.com](http://www.recylum.com)).

Improper treatment of a device at the end of its lifetime can have harmful consequences for the environment.





Coordonnées de votre Prestataire de Santé A Domicile



Fabricant :

SEFAM  
144 AV CHARLES DE GAULLE  
92200 NEUILLY SUR SEINE  
FRANCE

Site de fabrication :

SEFAM  
10 ALLEE PELLETIER DOISY  
54600 VILLERS-LES-NANCY  
FRANCE