CONTENTS

Before you start

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

Safety guidelines

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

- The SEFAM S.Box can only be used on prescription. Under no circumstances should you change the prescribed settings without the agreement of your healthcare professional.
- Use the device only for the prescribed use as indicated in this manual. The advice given in this manual does not replace the instructions of your healthcare professional.
- This device is not intended to provide assistance to vital functions.
- The device should be used only with the circuits, masks, fittings and accessories recommended by a physician or provided by your Home Care Provider. Make sure that you have the user guide for each accessory and read them carefully.
- Contact your Home Care Provider if you think that the device or any of its accessories is damaged, malfunctioning or has a defect.
- Do not attempt to open or modify the device (risk of electric shock). The maintenance of this device is entirely the responsibility of qualified personnel. Please contact your Home Care Provider.
- Any serious incident that occurs in relation to use of the S.Box must be communicated to the manufacturer and the competent authority for the Member State in which the user and/or patient is located.
- Use only the power supply provided with the device.
- If necessary, the device can be disconnected from the power supply by unplugging the power cord. Make sure the power cord is easily accessible.
- If the device is connected to a multi-socket outlet, do not connect the system to any other multi-socket outlet or extension cable.
- Place the device on a stable horizontal surface and in a clean and dry environment. Do not use the device if it is adjacent or on another appliance.
- Be careful not to accidentally or intentionally block the air outlet or any opening of the device or the breathing circuit. Do not cover the device or place it too close to a wall. Do not put any liquid nor objects into the air outlet as they may be propelled into the tube.
- Keep the device and its power supply away from all sources of water. Use the device and its accessories only if they are dry and in good working condition.
- Keep the power cord away from hot surfaces.
- If additional oxygen must be used, follow and respect carefully the safety instructions concerning the use of oxygen.
- Do not use the device, particularly the heated humidifier, in the presence of flammable vapors, flammable anesthetic agents, independently or mixed with other gases (risk of explosion).
- Once the machine is in operation and the mask is in place, make sure the unit produces an air flow. If not, remove the mask immediately and contact your Home Care Provider.
- Never block the leak vent of the mask which allows the continuous evacuation of the air and minimizes the re-inhalation of carbon dioxide. If the device is in operation, the generated air flow pushes out the exhaled air through the mask's vent hole. On the other hand, if the device is not in operation, there will not be enough fresh air produced in the mask, and the exhaled air may be re-inhaled, which under certain circumstances could lead to a phenomenon of suffocation in a few minutes.
- If the device has a malfunction and the patient is equipped with a nasal mask, the resistance of the device is low enough to allow the patient to exhale through the machine otherwise the patient can simply open his/her mouth. If the patient is equipped with a face mask, the mask should have an anti-asphyxia valve.
- Remove the mask in the event of a power outage or malfunction of the device.
- Do not leave unnecessary lengths of tube on the bed. They could wrap around your head or neck when you are asleep.

- Keep the device away from children and pets.
- The Health Industry Manufacturers Association (HIMA) recommends maintaining a minimum separation of 15 cm between a wireless phone and a pacemaker in order to avoid possible interference with the pacemaker. The Bluetooth communication in the SEFAM S.Box device must be considered as a wireless phone.

In case your device is equipped with a heated humidifier:
- Precautions should be taken when using the heated humidifier to prevent the risk of water entering the machine causing irreversible damage. Place the device on a horizontal and stable surface and be careful not to tilt it.
- The heated humidifier as well as the bottom of the humidifier chamber has a plate that can be hot in normal operation. Avoid touching these parts.
- The humidifier chamber must be cleaned before its first use or after any technical intervention, then regularly following the procedure described in the paragraph "Cleaning and Maintenance " on page 30.
- Always empty the humidifier chamber before moving or transporting the device.
- Fill the humidifier chamber away from the device to prevent water from spilling over it.
- Do not add any product to the water in the chamber (essential oils, etc).
- Do not use the device if there is a leak in the humidifier chamber due to, for example, the deterioration of the gasket.
- The heated humidifier should not be used at room temperature above 35°C as the air temperature delivered to the patient may exceed 43°C. There is a risk of irritation or burning of the upper airways.
- The performance of the device may change if a heated humidifier is added.
- There is a risk of air leakage when the humidifier chamber or side cover is improperly reassembled, which may cause a variation in the applied pressure versus the prescribed pressure.

| 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.
- Like any medical electrical device, the device is likely to be disturbed by mobile or portable radio frequency communication devices (mobile phones, Wi-Fi…).

When traveling

When traveling with your device, refer to the instructions of "Transporting the device" page 14 and in case of airline travel, contact your Home Care Provider to prepare the trip. It is advised to bring the patient manual along with you to facilitate the formalities of registration and security in airports.

You can take with you, as hand luggage, the device and its accessories packed in their travel bag, but it is recommended to protect them inside a rigid suitcase if they are in the checked luggage compartment.

If you travel to a country where the voltage is different from the voltage usually used, it may be necessary to take another power cord or an adapter to connect your device to the electrical outlets in this country.

Recommended use

The SEFAM S.Box is designed for the treatment of Obstructive Sleep Apnea–Hypopnea Syndrome (OSAHS) in patients over 30 kg, who breathe spontaneously. It can be used at home or in healthcare centers (hospital or clinics). It is designed for hassle free travelling and can be used in an airplane.

The S.Box heated humidifier is an accessory designed to warm and add moisture to the air flow delivered to the patient by the SEFAM S.Box device, for the treatment of Obstructive Sleep Apnea–Hypopnoea Syndrome (OSAHS). It is intended for use by adult patients in either the homecare or the hospital environment.

Contra-indications

Studies have shown that using positive pressure can be contraindicated in certain patients with one of these pre-existing medical 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
- Dehydratation.
- Tracheotomy.

Side effects

If any of the following symptoms appear, while using the device, which may in certain cases require temporary cessation of treatment, please contact your healthcare professional: unusual chest pain, severe headache, increased dyspnea, dryness of the airways or nose, skin sensitivity, running or bleeding nose (Epistaxis), discomfort or pain in the ear or sinuses, bloating, daytime sleepiness, mood changes, disorientation, irritability or loss of memory.

Components of the system

The SEFAM S.Box 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 Care Provider for more information on the available accessories. When using them, follow the instructions given with the accessories.

- ★ S.Box cigarette cable (24 VDC)
- ★ S.Box heated humidifier
- ★ S.Box modem
- ★ SEFAM S.Box by Starck carrying case
- ★ S.Box heated tube with ATC (Adaptive Thermo Control) 15 mm in diameter
- ★ Fine filter (disposable)
- ★ Oximeter 3150
- ★ S.Box Wi-Fi module
- ★ PolyLink system
- ★ SEFAM Access (tablet / smartphone application)

Description

Views of the device

Figure 1 – Front view

Figure 2 – Rear view of a device with a humidifier

Figure 3 – Rear view of a device with a side cover
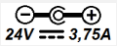
Figure 4 – View of the heater plate and accessory location

1	Start / standby button ⏻:	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:	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 your 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.

Definition of symbols

| Symbol	Description	Symbol	Description
	Start / standby button.		Ramp button.
CE 0459	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 "End-of-life disposal of the device" page 38.
	Class II device.		Type BF device.
24V 3,75A	24 V Direct Current power supply	((•))	Device composes an RF transmitter, non - ionizing radiation.
	Manufacturer.		Manufacturing date.
	Danger: hot surface.	↑ MAX ↑	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.	IP21	Device protected against solid objects of more than 12 mm and against drops of water falling vertically.
	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.

Installation

Standard installation of the device

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.
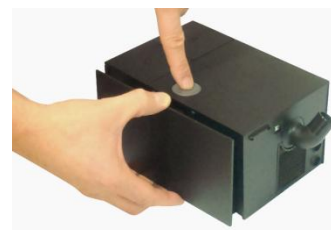
2. Install the communicating accessory (S.Box modem, S.Box Wi-Fi module or PolyLink system) into the accessory slot (mark 10 in Figure 4) – we herefor refer to the corresponding instructions in the installation and usage procedure.

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".
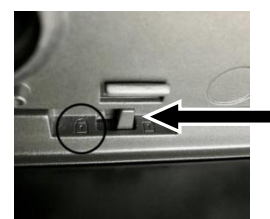
or

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".

WARNING:

If the heated humidifier is not properly installed, there is a risk of air loss which can cause a variation of the applied pressure versus the prescribed pressure.

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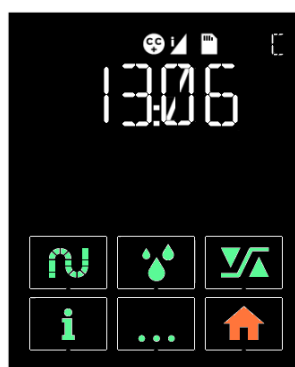
   Then, the standby mode screen appears two seconds later, indicating the time.

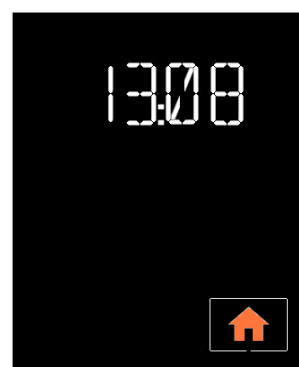   The device is now ready for use.

   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

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.

Installation for power via the 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.

Use

Filling the humidifier chamber (if installed)

1. Unplug the SEFAM S.Box 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 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).

Starting treatment

1. Put on your mask as described in the corresponding user instructions. If the Intelligent Start feature has been activated by your Home Care Provider, 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 the table " Description of symbols " page 16).

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.
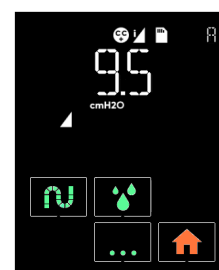
4. Lie down and place the breathing tube so that it can follow your movements while you are sleeping.

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 " How to set the device " page 17).

> | WARNING: |
>
> After a power failure, the appliance will recover the same parameters and operating mode as the ones before the power failure occured (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.

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 you 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 automatically determined by the device. The pressure rise (in CPAP mode) or the activation of the pressure up/down commands (in Auto CPAP mode) 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 starts automatically when the apparatus is switched on (if the ramp time is not zero). It can be deactivated by pressing the ramp button ◿.

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. Follow the instructions given by the Home Care Provider before using this card.

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. If the problem persists, contact your Home Care Provider.

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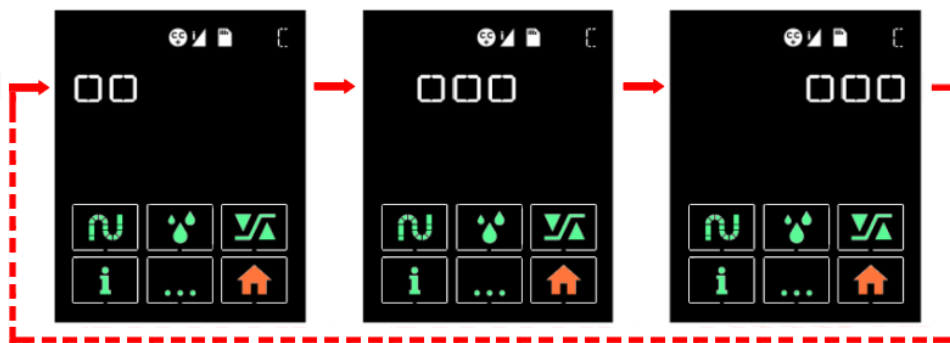
While the data is being stored, the device continues to be operational and the information remains accessible on the display of the unit.

CAUTION:

- Do not remove the SD card during the treatment as data are 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. You can now send it to your Home Care Provider.

Transporting the device

Unplug the power supply and disconnect all accessories from the device. Pack the apparatus and the accessories in the travel 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.

Information and settings

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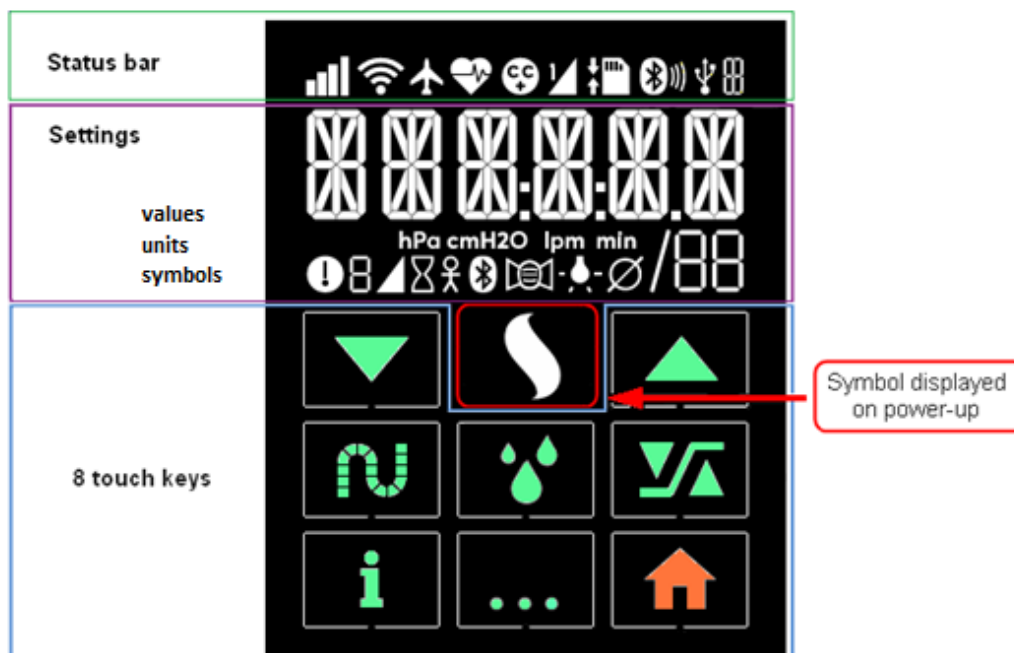- settings for your treatment,
- general settings such as time or brightness,
- recorded compliance data.

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.

Description of symbols displayed

Symbol	Meaning	Symbol	Meaning
	Status bar		
	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		Time ramp T RAMP activated Intelligent ramp I RAMP activated
	SD card inserted Flashes slowly when data storing is in progress. Flashes slowly when settings update is in progress.		Bluetooth connection activated Bluetooth transmission in progress
	USB connection activated		Operation mode C: CPAP A: APAP (Auto-CPAP)
	Settings: values, units and symbols displayed		
	Numbers or letters	hPa cmH2O	Pressure unit: hecto Pascal or cm H_2O
lpm	Flow unit: liter per minute	h min	Time unit: hour and minute
	Caution: the device detected an error or an incident		Setting of the ramp time
	Machine hour counter		Usage hour counter
	Bluetooth		Mask adjustment
	Setting of the brightness of the display	Ø	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		Touch key to adjust the heated humidifier setting
	Touch key to access the settings	i	Touch key to access information
	Multifunctional touch key		Home touch key

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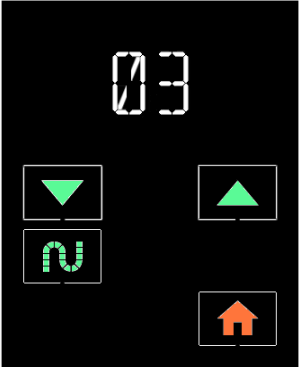
The setting can be done via the touch keys if the unit is in standby or in use (depending on settings).

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

View of the display:

Tap the touch key

in standby or operation mode.

03

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.
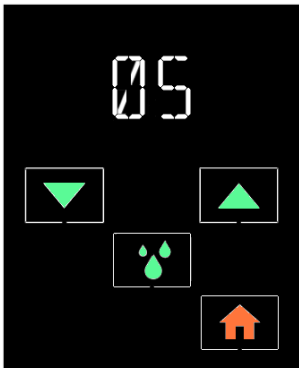
Tap 🏠 to return to the standby or operation screen.

2. Humidification level (if humidifier installed)

View of the display:

Tap the touch key

in standby or operation mode.

05

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

View of the display:

Tap the touch key

in standby mode.

LK :OK

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 .

Views of the display:

❶ **Tap the touch key** ⏎ in standby mode.	**I RAMP**	**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	**15** min	**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 ▲. Possible settings: OFF and from 5 min to the maximum ramp time set by your Home Care Provider.
❷ **Tap the touch key**	**5.0** cmH2O P	**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_2O to the pressure set in CPAP mode. ▪ from 4 cm H_2O to the maximum pressure set in APAP (Auto-CPAP) mode.

Views of the display:

❸

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.

❹

Tap the touch key

➡️
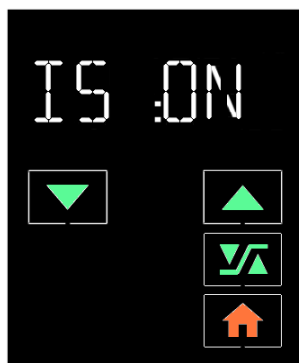
IS (Intelligent Start)

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.

❺

Tap the touch key

➡️
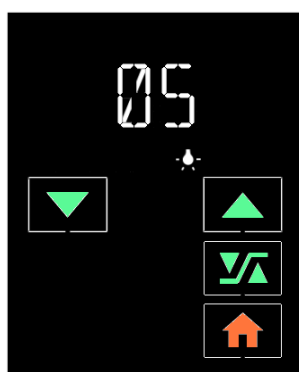
Brightness

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.

❻

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).

Views of the display:

❼

Tap the touch key

➡️

SPO2 (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 detected, the six digits of the PIN code of the oximeter flash alternately with SPO2.

| CAUTION: |

Make sure that the PIN code is the one of the oximeter that you want to pair.

You can deactivate the communication by tapping on 🔽 or 🔼.

Notes:

★ This display appears only if the Bluetooth communication has been enabled previously

★ 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.

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.

❽

Tap the touch key

➡️
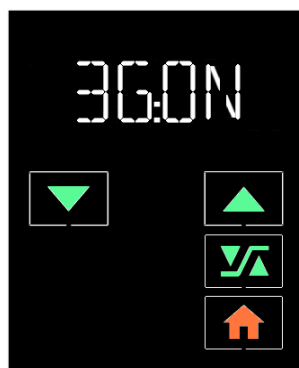
3G:ON

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: 3G: ON and 3G: OFF.

or

❽

Tap the touch key

➡️

WIFI :ON

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 device and the Wi-Fi connection activated, you can access the **WPS automatic configuration** which allows connecting to the local network.

Tap the touch key	Views of the display:	Tap the touch key	View of the display:
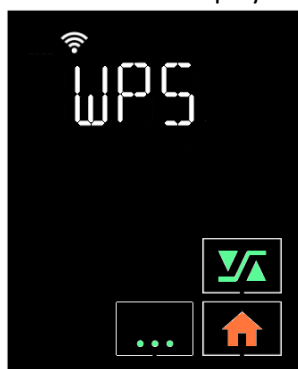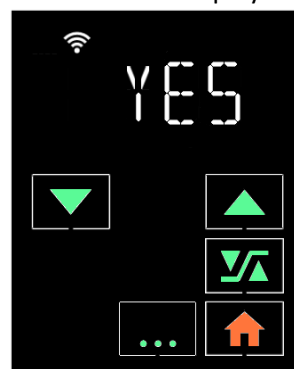
Select **YES** on the screen by using the touch key ▼ or ▲. You then have about two minutes to press the **WPS** button on your Wi-Fi router and enable connecting to the network with the key `...`. A progress bar ▯▯▯▯ appears until the connection to the network is effective. The symbol 🛜 blinks quickly at the top of the screen, then becomes permanent.

Then you go back to the **WPS** screen and you can resume the settings menu.
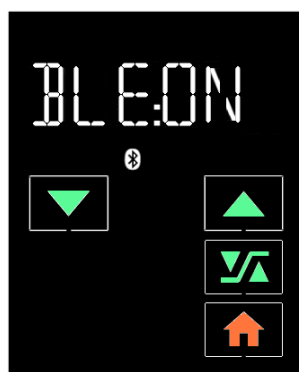
or		
❽		**BLE communication** (BLE = Bluetooth Low Energy)
Tap the touch key		You can deactivate (OFF) or activate (ON) the communication by tapping the key ▼ or ▲.
		Possible Settings: BLE: ON and BLE: OFF.

CAUTION:

The Bluetooth Low Energy wireless connection must be enabled for acquisition of signals from the PolyLink system.
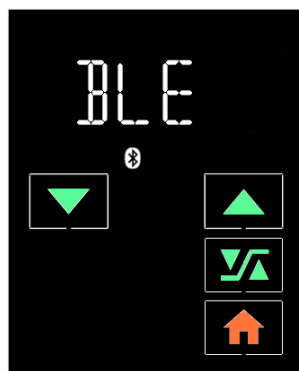
Tap the touch key		**Communication with the PolyLink BLE module**
		The device searches for the BLE module and the display blinks alternately with six dashes as long as no module is associated.
		Once detected, the last six digits of the Bluetooth address of the PolyLink system flash alternately with BLE.
		You can disable the communication by tapping the key ▼ or ▲.

Views of the display:

❾

Tap the touch key
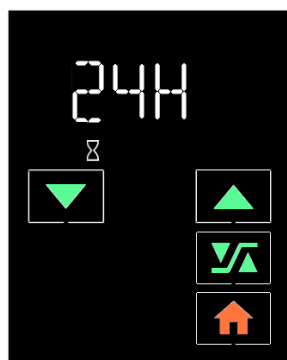
Choosing the format of the time display

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.

❿

Tap the touch key
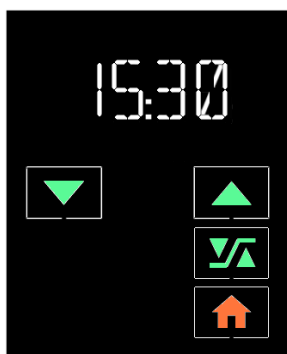
Clock

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 **i** when the device is in standby mode. In the following sequence:

- ★ **i** 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.

❶

Tap the touch key

i

in standby mode.
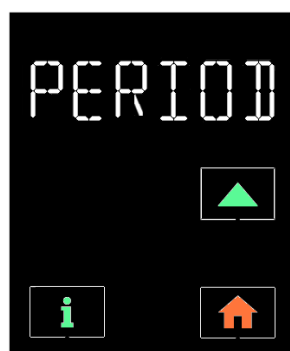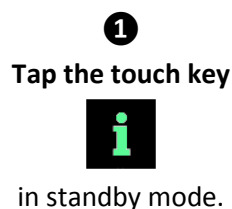
Accessing a period of use

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

❷

Tap the touch key

▲

➡️

DAY
/30
▲

i **🏠**
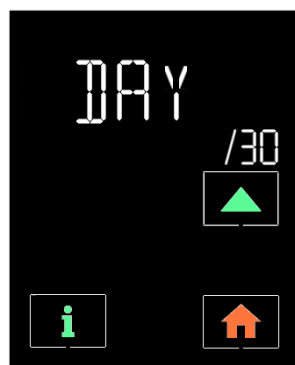
Selecting one of the last periods of use

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.

❸

Tap the touch key

i

➡️

REPORT
▲

i **🏠**
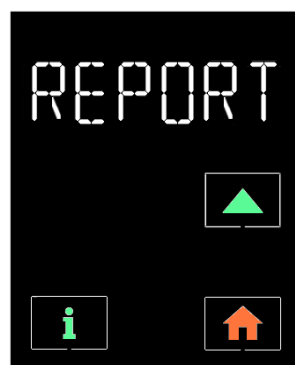
Accessing the compliance information report

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

❹

Tap the touch key

▲

➡️

LK :OK
/30
▲

i **🏠**
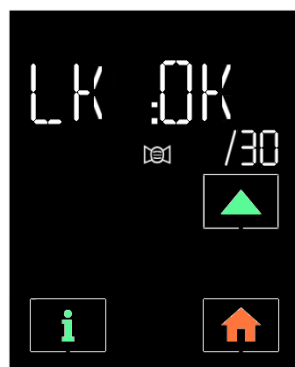
Average level of unintentional leakage in the mask during the period of use.

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.

❺

Tap the touch key

▲

➡️

05:28
/30
▲

i **🏠**

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

❻

Tap the touch key

▲

→

P : 7.5
cmH2O
/30
▲
i 🏠
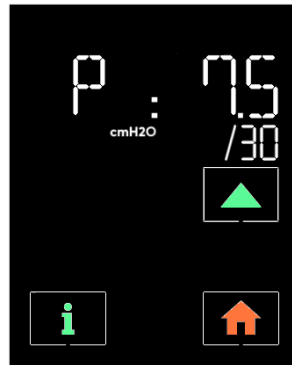
Average pressure delivered during the period of use.

❼

Tap the touch key

▲

→

AHI: 4.5
/30
▲
i 🏠

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

❽

Tap the touch key

▲

→

ACI: 0.6
/30
▲
i 🏠

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

❾

Tap the touch key

▲

→

DAY: 4
4 h /30
▲
i 🏠
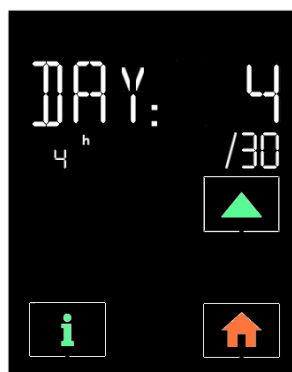
Number of the last days of use for which the compliance is higher than 4 hours per day (within the limit of 30 days)

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 **i** will display, after the previous ones, the technical information concerning the device.
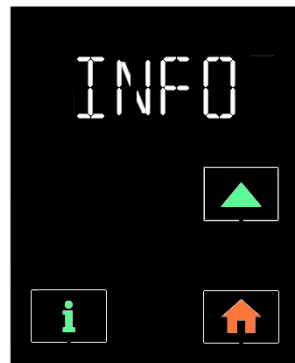
❿ **Tap the touch key** i	Views of the display: **INFO**	**Accessing the technical information concerning the device.** Tap the key ▲ to display the information.
⓫ **Tap the touch key** ▲	**123456** id	**Identification number** of six digits specific to the patient is automatically assigned by the device.
⓬ **Tap the touch key** ▲	**VER: 1.00**	**Software version** This is the version of the embedded software of the device. It can be read but not modified.
⓭ **Tap the touch key** ▲	**02536** h	**Total usage hour counter** This counter calculates the total time during which you have been breathing into the mask.
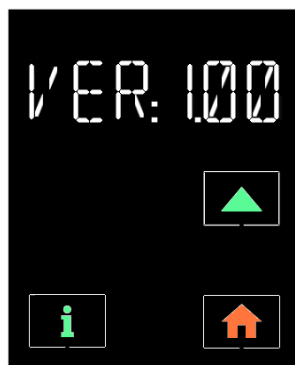
⓮

Tap the touch key

➡

02543
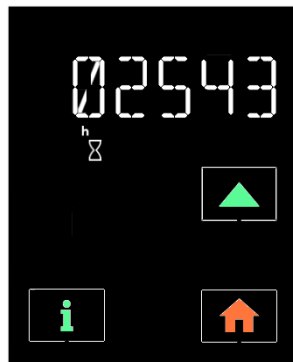
Total machine hour counter

This counter calculates the total operating time of the device.

Tap the touch key **i** 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 **i** touch button while the device is on. In the sequence below:

- **i** accesses the next display.

- ◺ then **i** returns you to the previous display.

- **🏠** leaves the current menu.

❶

Tap the touch button

i

when the device is in operation.

➡
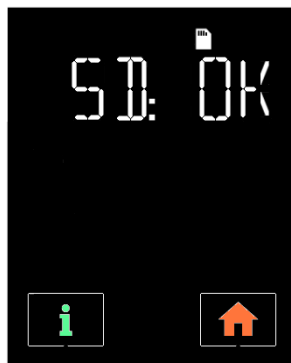
SD: OK

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.

❷

Tap the touch button

i

➡
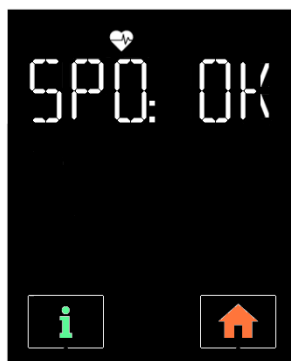
SPO: OK

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.

❸

Tap the touch button

i

➡️

ABD: 05
🔵

i   🏠
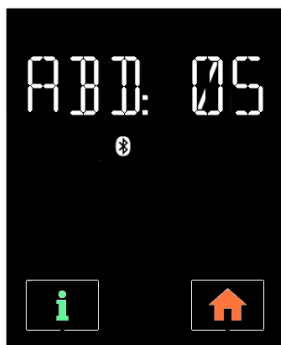
Status of the abdominal effort sensor

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.

❹

Tap the touch button

i

➡️

THO: 05
🔵

i   🏠
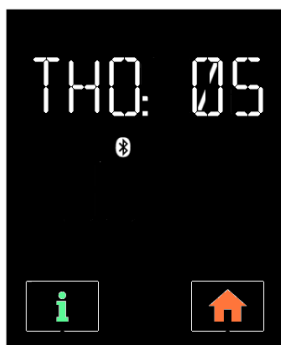
Status of the thoracic effort sensor

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.

❺

Tap the touch button

i

➡️

POS: ⩗
🔵

i   🏠

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.

❻

Tap the touch button

i

➡️

BAT: 95

i   🏠

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 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.

View of the display:		View of the display:
	Tap the touch key 	
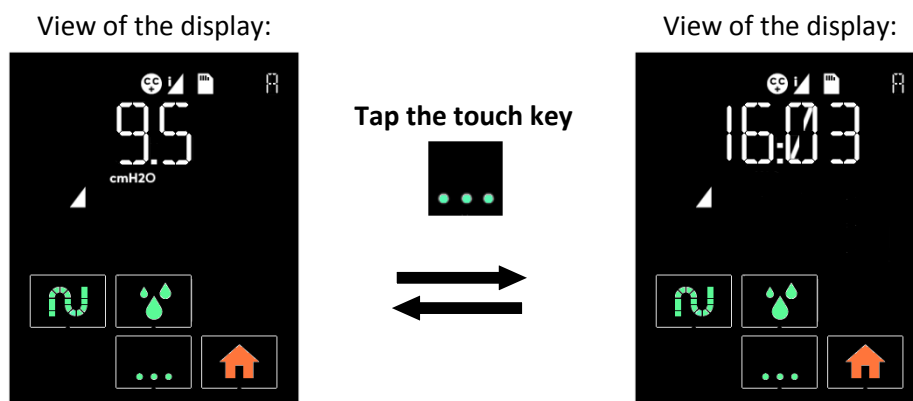
8. Pairing a Bluetooth communication tool device

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 in standby mode via Bluetooth wireless communication, a message appears on the display of the machine at the first pairing:

View of the display:

Tap the touch key

 ➡ Enable pairing

or

 ➡ Refuse to pair
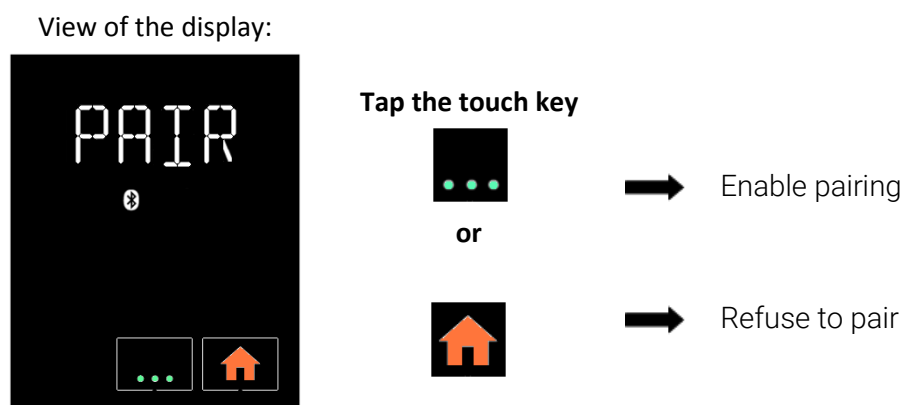
The display disappears after 30 seconds.

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 device complies with the Federal Aviation Administration RTCA/DO-160G section 21 category M.

Using the device when adding oxygen (optional)

- Always follow the instructions of the medical professionals or the Home Care Provider in case of using oxygen. The source of oxygen should be placed more than one meter away from the device.
- Do not smoke in the presence of oxygen.
- Do not inject oxygen through the air inlet of the device.
- Follow carefully the instructions for starting and stopping treatment.
- If you are using oxygen, stop the oxygen flow when the device is not working. If the supply of oxygen is maintained while the device is switched off, the oxygen delivered in the breathing tube can accumulate inside the device and create a risk of fire.

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.

Cleaning and Maintenance

No specific maintenance other than periodic cleaning is required.

Please refer to the instructions for use of your mask, the breathing tube, the S.Box heated tube with ATC and the communicating accessory used for more details on cleaning and maintaining them.

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:

★ The different parts of the humidifier chamber can also be cleaned in a dishwasher (maximum 70 ° C).

★ 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.
  - o Fill the humidifier chamber, then press down on the upper part to close the chamber and lock it.
  - o 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".

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.

In case of problems

Helpful tips

Problem	Possible cause	Suggestion
Your nose is cold	Room temperature is too low.	Increase the room temperature.
	The air delivered is too cold.	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	Use the humidifier when device equipped with one. Increase the humidification level (see section "How to set the device" page 17).
	Lack of water in chamber (if included).	Check the water level in the chamber. If necessary, fill it (see section "Filling the humidifier chamber (if installed)" page 11).
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.	Adjust the headgear. Contact your doctor or Home Care Provider to try different sizes.
	Allergic reaction to mask components	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.	Clean or replace the air inlet filters (see chapter "Cleaning and " page 30).
	The air inlet is clogged.	Keep all linen and clothing away from the device.
	The room temperature is too high.	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.	Check that the ramp indicator is displayed. If necessary, deactivate the ramp function (see section "How to set the device" page 17).
	The selected ramp does not suit you.	Contact your Home Care Provider.

Problem	Possible cause	Suggestion
The device seems to be disturbed and not functioning properly.	Too much electromagnetic disturbance.	Keep the device away from sources of interference such as halogen lamps, mobile phones, etc.
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 section "Ramp" page 12). Relax and breathe slowly through your nose.
	The device is set in Auto-CPAP mode.	The pressure level has been prescribed by your doctor, it can only be changed by medical prescription. If you feel that the pressure from the device has changed, contact your Home Care Provider to have it checked.
Re-ocurrence of symptoms of sleep apnea syndrome.	The device is not set on the correct pressure or is not working properly.	Ask the Home Care Provider to check how it operates.
	Your physical condition or pressure needs have changed.	Contact your doctor.
The device does not turn on (no display).	The power supply is not connected properly.	Check the connections between the device, the power supply and the mains plug.
	Absence of mains.	Use another device (e.g., lamp, radio etc.) to check if the electrical outlet is working.
	The internal fuse of the device is defective.	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 "Cleaning and Maintenance" page 30). 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.	Decrease the humidification level (see section "How to set the device" page 17).
	The water level is too high in the chamber (if included).	Check that the water level in the chamber does not exceed the maximum, otherwise empty the excess water.
	Condensation of water vapor is excessive.	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.

Problem	Possible cause	Suggestion
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 section "How to set the device" page 17).
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 section "How to set the device" page 17).

Device messages

Message on the display	Possible cause	Proposed solution
MASK	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 ① 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 "Standard installation of the device" page 9). 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 mal-function 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.
ERxx The error code blinks. (XX = 2 figures).	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.

Technical characteristics

Performance of the device

Pressure range:	4 to 20 cm H_2O Adjustable by steps of 0.5 cmH_2O
Maximum pressure at the patient-side connection port in single fault condition:	40 cm H_2O
Maximum adjustable pressure:	20 cm H_2O
Duration of ramp:	0 to 45 minutes ± 1 minute Adjustable in 5 minute steps
Sound pressure level measured according to standard NF EN ISO 17510-1: 2009:	27.5 dBA with side cover
	28.5 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_2O/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_2O 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_2O
Maximum gas temperature coming from the breathing tube:	43°C

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 with side cover
	+5°C to +35°C with humidifier
Relative humidity:	Between 15 % and 90 % without condensation
Altitude range:	Approximately 0 – 2 500 m
Maximum temperature of applied parts:	51°C
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
Relative humidity:	Up to 90 % without condensation

Electrical characteristics

Device

Input voltage:	24.0 V ± 20 %
Maximum power consumption:	75 W during a mask disconnection
Current consumption at 20 cmH$_2$O with a 4-mm leak:	0.42 A (minimum configuration: SEFAM S.Box only)
	1.99 A (maximum configuration: SEFAM S.Box with humidifier set to 10 and heated tube set to 05)
RF emission type (SEFAM S.Box®):	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® 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® 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_{DC} input is protected against voltage reversals.

Physical characteristics

Dimensions (L x W x H):	245 x 140 x 110 mm with side cover
	245 x 185 x 110 mm with humidifier
Carrying bag dimensions (L x W x H):	305 x 245 x 180 mm
Carrying case dimensions (L x W x H):	350 x 310 x 190 mm
Weight (without power supply):	1.4 kg with side cover
	1.7 kg with humidifier
Power supply weight:	0.5 kg
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 ⬆ **MAX** ⬆ on humidifier chamber

CE marking

Date of CE marking of SEFAM S.Box: 2017

Regulatory Requirements

Risks concerning this medical device are evaluated according to the ISO 14971 standard, specifically with regard to global residual risk.

The SEFAM S.Box complies with the following Directives and standards:

- Directive 93/42/CEE of the European Parliament and of the Council concerning medical devices, modified by the European Directive 2007/47/CE.
- Directive 2014/53/EU of the European Parliament and of the Council on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment.
- Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
- Directive 2012/19/EU of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE).
- Federal Aviation Administration RTCA/DO-160G section 21 category M.
- IEC 60601-1:2005 + AC1:2006 + AC2:2007 + Amd1:2012: Medical electrical equipment. Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
- IEC 60601-1-2:2015: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
- ISO 80601-2-70-1:2015: Medical electrical equipment -- Part 2-70: Particular requirements for basic safety and essential performance of sleep apnea breathing therapy equipment.
- EN ISO 8185:2009: Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems.

End-of-life disposal of the device

In European Union this device has to be considered as an electrical and electronic piece of equipment as defined in Directive 2012/19/EU, and must be collected and processed separately from household waste for disposal as indicated by the symbol of the crossed out garbage bin (see "Definition of symbols" page 8).

In other countries, this device must be processed following local regulation.

Unsuitable disposal of the device at the end of its life could harm the environment.

Contact your home care provider.