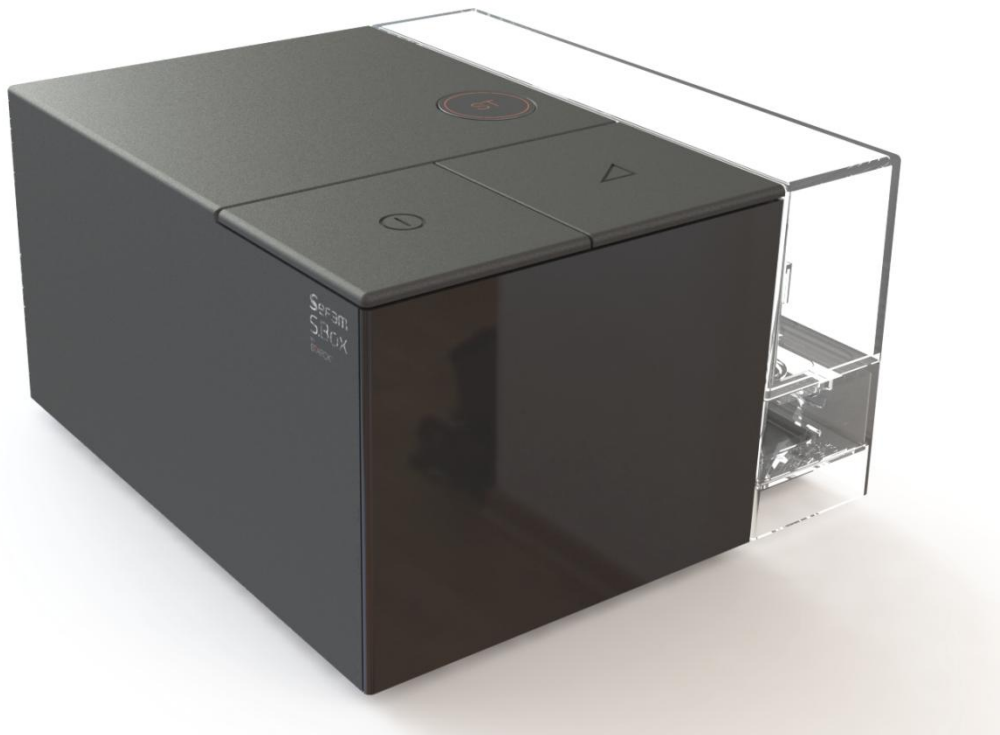


Sefam S.Box

BY
STARCK®

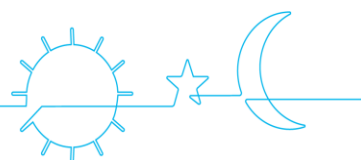


OPTIONAL HEATED HUMIDIFIER

S.Box™ Duo **S**

S.Box™ Duo **ST**

Patient Manual



en

Download the FREE application



on your Smartphone or on your tablet



and



With **SEFAM Access**, you can:

- Easily adjust your S.Box Duo S or your S.Box Duo ST,
- 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 Duo S or your S.Box Duo ST.

With **SEFAM Access**, participate in your treatment !

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Before you start

Please read this manual carefully before using your S.Box Duo S or S.Box Duo ST 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 S.Box Duo S and S.Box Duo ST 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 advices given in this manual do 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, for any problem detected.
- Any serious incident that occurs in relation to use of the S.Box Duo S or S.Box Duo ST must be communicated to the manufacturer and a competent authority of the Member State of your location.
- Place the device on a stable horizontal surface and in a clean and dry environment. Do not use the device if it is adjacent to another electrical/electronic device or over another appliance.
- 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.
- 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 or any object into the air outlet of the device, as they may be propelled into the tube.
- Keep the device and its power supply away from all sources of water / liquids. Use the device and its accessories only if they are dry and in a good working condition.
- Keep the power cord away from a hot surface.
- If oxygen enrichment is required, follow the safety instructions carefully, concerning the use of oxygen.
- Do not use the device, particularly the heated humidifier, in the presence of flammable gases, flammable anesthetic agents, which may be independent or mixed with other gases, as there is a risk of explosion, or fire.
- While the machine is operational and the mask is applied on the face, make sure the unit produces an air-flow. If it does not, remove the mask immediately and stop using the device. Contact your Home Care Provider, to inform this.
- Never block the exhalation vents on the mask which allows continuous exhaust of air, which minimizes rebreathing of carbon dioxide. While the device is operational, the generated air-flow pushes out the exhaled air through the vent-holes of the mask. On the other hand, while the device is not operational, there will not be enough fresh air produced in the mask, and the exhaled air may be rebreathed, which can cause suffocation and/or any adverse effect on health 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, and alternatively the patient can simply open his/her mouth to breathe in and out. If the patient is equipped with a face mask, the mask should have an anti-asphyxia valve, for safety of the patient in case of malfunction of the device.
- Remove the mask immediately in case of power outage or malfunction of the device.

- Do not leave unnecessary lengths of the tube on the bed because they could wrap around your head or neck.
- Keep the device away from children and pets.
- The Health Industry Manufacturers Association (HIMA) recommends maintaining a minimum separation of 15 cm between a cordless phone and a pacemaker in order to avoid possible interference with the pacemaker. The Bluetooth communication in the S.Box Duo S or S.Box Duo ST device must be considered as a wireless phone.

If your device is equipped with a heated humidifier:

- Precautions should be taken while using a heated humidifier to prevent a 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 when reservoir is filled with water.
- The heated humidifier as well as the bottom of the humidifier chamber has a plate that can be very hot when in operation. Avoid touching these parts.
- The humidifier chamber must be cleaned before its first use or after any technical intervention, as well as regularly in time, following a procedure described in the paragraph "Cleaning and Maintenance" on page 29.
- Always detach the humidifier chamber and empty it, before moving or transporting the device.
- Fill the humidifier chamber with water keeping it far away from the device to prevent water spilling on the device.
- Do not add any type of liquid in the water, used in the chamber (e.g. essential oils, or aerosol medications etc).
- Do not use the device if a leak is detected in the humidifier chamber, e.g. due to a deterioration of the gasket, or a crack due to fall of the chamber.
- The heated humidifier should not be used when room temperature is above 35°C, because the temperature of air delivered to the patient may exceed 43°C. This can cause irritation or burning of the upper airways.
- The performance of the device may alter if a heated humidifier is installed.
- There is a risk of air leak when the humidifier chamber or side cover is not attached properly, 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.
- After storing or transporting the device, ensure it is used in compliance with the conditions of use specified in this manual.
- Like all medical electrical devices, the device is vulnerable to interference from mobile and portable radiofrequency communication equipment (mobile phones, Wi-Fi...).
- The device has to be controlled to check the proper operation, whenever it is located near to a AM, FM or broadcast antennas.

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 S.Box Duo S and S.Box Duo ST devices are designed for the Non-Invasive Ventilation of patients weighing more than 30 kg, suffering from a Ventilatory Disorder or Sleep Apnea Syndrome (SAS), but not dependent on respiratory assistance.

They can be used mainly in Home Healthcare Environment or in a sleep center (hospital or clinics). They can travel easily and be used in airplane.

They are not suitable to be used in close proximity to CT scanners, MRT devices, RF surgical devices or in transportation vessels (on land, sea or in the air).

The S.Box heated humidifier is an accessory designed to warm and add moisture to the air flow delivered to the patient by the S.Box Duo S or S.Box Duo ST device. It is intended for use by adult patients in either the homecare or the hospital environment.

Contraindications

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
- Dehydration.
- Tracheotomy.

Adverse 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), pain in the ear or sinuses, bloating, daytime sleepiness, mood changes, disorientation, irritability or loss of memory.

Components of the system

The S.Box Duo S or S.Box Duo ST comes with the following components:

- S.Box power supply
- Side cover
- Patient manual
- Flexible tube
- S.Box SD card
- Air inlet filter
- 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)
- Fine filter (disposable)
- S.Box modem
- Oximeter 3150 in Bluetooth or in BLE
- S.Box heated tube with ATC (Adaptive Thermo Control) 15 mm in diameter
- S.Box USB cable
- S.Box by Starck carrying case
- S.Box heated humidifier
- S.Box Wi-Fi module
- PolyLink system
- SEFAM Access (tablet / smartphone application)

Description

Device Overview



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

- | | |
|--|---|
| <p>1 Start / standby button :</p> <p>2 Touch screen display:</p> <p>3 Ramp button :</p> <p>4 Button to unlock humidifier chamber or side cover:</p> <p>5 SD card slot:</p> <p>6 USB connector:</p> <p>7 Air inlet filter and grid:</p> <p>8 Power port:</p> <p>9 Heated tube connection:</p> <p>10 Accessory slot:</p> | <p>To switch the device on and off.</p> <p>To view the information and access the settings.</p> <p>Enables or disables the ramp function when the unit is operating.</p> <p>intended for unlocking the side cover or the humidifier chamber and removing it from the machine. It also identifies the model of the device: S or ST.</p> <p>Slot for inserting the SD card.</p> <p>Intended for use by your doctor or Home Care Provider.</p> <p>Prevent dust from entering the device and the air flow path.</p> <p>To power the device by the power supply or by a cigarette lighter.</p> <p>To connect a S.Box heated tube with ATC.</p> <p>Slot for a communication accessory (PolyLink system, S.Box modem or S.Box Wi-Fi module).</p> |
|--|---|

- 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 Outlet elbow connector: Swivel connector for connecting the tube.

Definition 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 "End-of-life disposal of the device" page 37.
	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.		

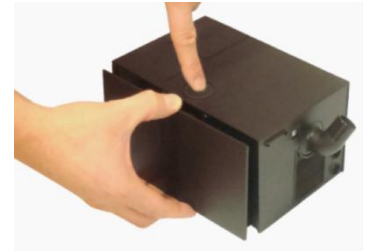
Installation

Standard installation 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".

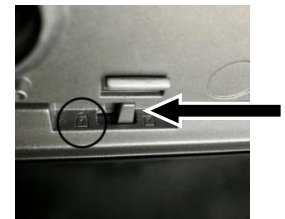
or

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 SEFAM mobile apps  appears.

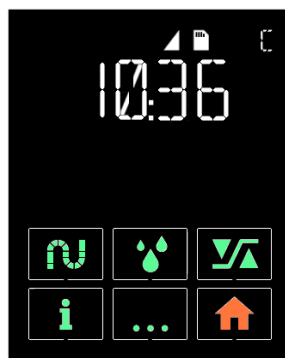
Then, the standby mode screen appears two seconds later, indicating the time.

The device is now ready for use.

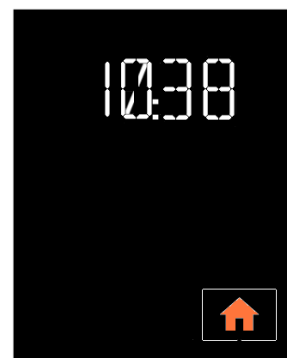
After two minutes in standby mode, without action on any touch key or any button, the hibernation mode screen appears.

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

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 socket

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 S.Box Duo S or S.Box Duo ST device from the power supply or 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 S.Box Duo S or S.Box Duo ST 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 of 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 press and hold 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  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.

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 16).

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 of treatment

1. Remove the mask.
2. Press and hold 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

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.

Ramp



When enabled, the time ramp feature makes it possible to gradually increase the pressure to help you fall asleep: the delivered pressure increases from a lower initial pressure called "comfort pressure" up to the appropriate treatment pressure (during the ramp time.). In BPAP (bilevel) mode, the pressure is reduced to the comfort pressure and then raised up to the inspiratory and expiratory pressure levels.

If it is active (≠ OFF), the ramp feature starts when the device is switched on. It can be disabled (then reactivated) 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

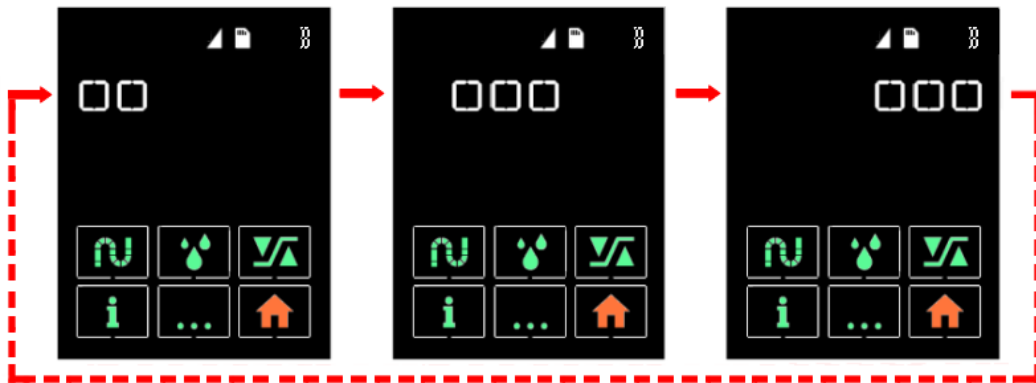
When the device is operating, switch it off by holding down the start / standby button . Insert the SD card in the corresponding slot: the symbol  appears on the top of the screen. If it is blinking, it means that the card is improperly inserted or non-functional. Reinsert it properly. If the problem 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 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. 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
	USB connection active (Bluetooth disabled)		Ramp active (T RAMP)
	Inspiratory pressure		Operation mode
	Expiratory pressure		C: CPAP B: BPAP (bilevel)
	SD card inserted		Bluetooth connection active
	↓ Flashes slowly when data storing is in progress.		Bluetooth transmission in progress
	↑ Flashes slowly when settings update is in progress.		

Settings: values, units and symbols displayed

	Numbers or letters		Pressure unit: hecto Pascal or cm H ₂ O
	Flow unit: liter per minute		
	Caution: the device detected an error or an incident		Time unit: hour and minute
	Machine hour counter		
	Bluetooth		Setting of the ramp time
	Setting of the brightness of the display		Usage counter
			Spontaneous cycle indicator (operation in BPAP [bilevel] mode)
			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 setting of heated tube (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

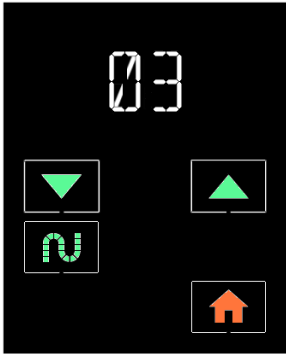
How to set the device



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)

Tap the touch key

 in standby or operation mode.

Views of the display:




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

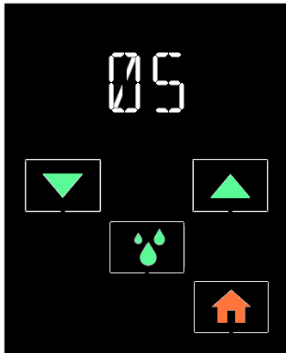
Possible settings: OFF (no heating), 01 to 05 and AUTO (if a humidifier is also present).
 The AUTO mode makes the heating of the heated tube progressive as a function of the heating power level of the heated humidifier.



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.




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

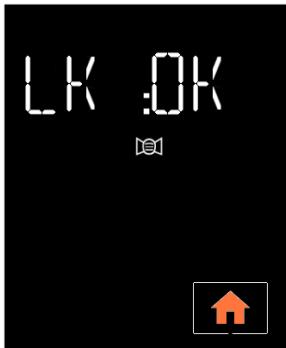
Possible settings: OFF (no humidification) and 01 to 10.

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.









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

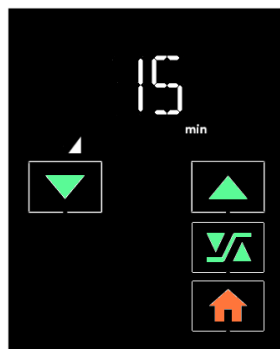
To access the settings, tap the touch key  when the device is in standby mode. In the following sequence of settings:

- 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,
- maintaining the ramp button  pressed, then tapping simultaneously the touch key  allows coming back to the previous display.

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



Views of the display:

1
Tap the touch key  in standby mode.



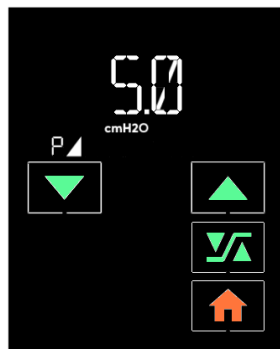
Ramp time: time taken by the device to reach the prescribed pressure.

This parameter is displayed if the ramp has been enabled by your Home Care Provider.

By tapping the key  or  as many times as necessary, you can decrease or increase the value displayed or disable the ramp feature in selecting **OFF**.



Possible settings: OFF and from 05 min to the ramp time set by your Home Care Provider.

2
Tap the touch key .



Comfort pressure: pressure level produced when the ramp starts up.

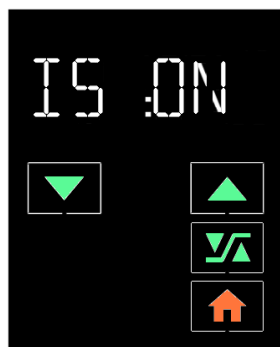
This parameter is displayed if the ramp time is \neq OFF and if your Home Care Provider did not lock your access to this setting.

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

Possible settings:



- from 4 cm H₂O to the set pressure in CPAP mode.
- from 3 cm H₂O to the expiratory pressure in BPAP (bilevel) mode.

3
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.

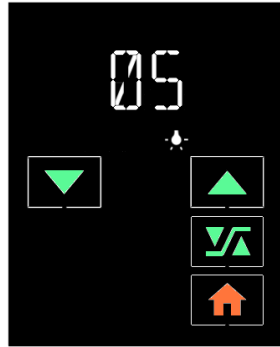
You can deactivate (OFF) or activate (ON) this function by tapping the key  or .

Possible settings: IS: ON and IS: OFF.



4 Tap the touch key



Views of the display:

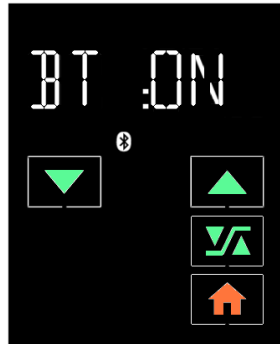


Brightness



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.

5 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:

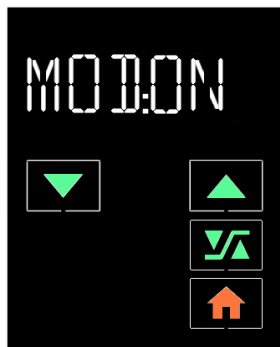
The Bluetooth wireless connection must be enabled:



- 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 (S.Box modem, S.Box Wi-Fi module or PolyLink system), 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.

A) Connecting the S.Box modem (if installed)

6 Tap the touch key



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



Possible Settings: MOD:ON and MOD:OFF.

or

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

6 Tap the touch key

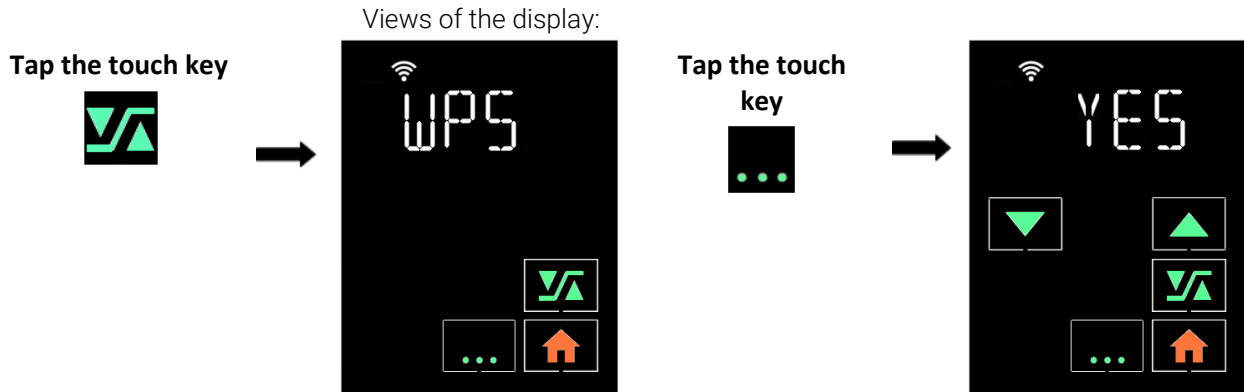







You can disable (OFF) or enable (ON) the Wi-Fi module connection by tapping the key  or .

Possible settings: WIFI:ON and WIFI:OFF.

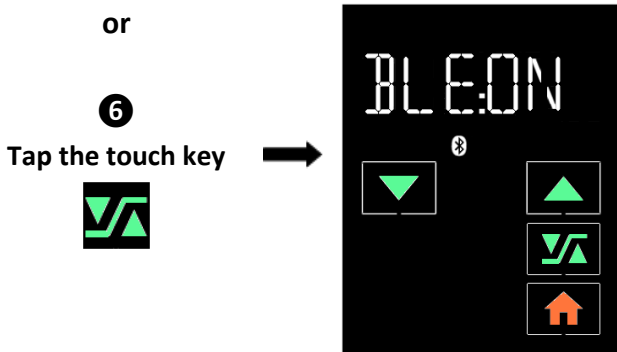
The symbol  blinks slowly at the top of the screen.



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



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.

C) BLE communication (BLE = Bluetooth Low Energy)

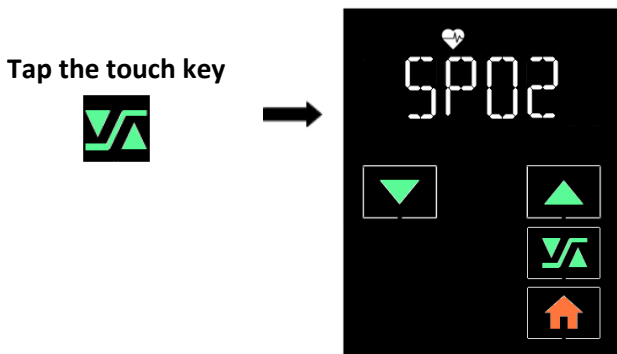


You can disable (OFF) or enable (ON) the communication by tapping the key  or .


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.



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 the oximeter detected, the last six digits of its Bluetooth address flash alternately with SPO2.

CAUTION:

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

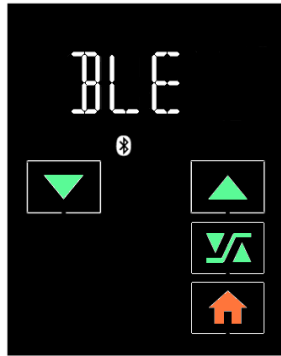
If the number is not the correct one, start a new search by tapping the key  or .

Notes:

- This display appears only if the Bluetooth communication has been previously enabled or if a PolyLink module 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.

Views of the display:

Tap the touch key



Communication with the PolyLink BLE module

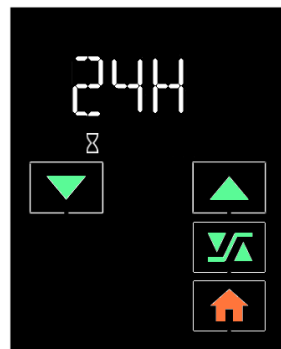
The device searches for the BLE module and the display blinks alternately with six dashes as long as no module is associated.





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

If the number is not the correct one, start a new search by tapping the key  or .

7 Tap the touch key

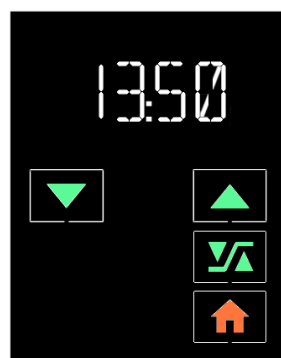


Choosing the format of the time display


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.


8 Tap the touch key




Setting the 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.
- maintaining the ramp button  pressed, then tapping simultaneously the touch key  allows coming back to the previous display.
-  allows selecting a period of use and moving to the next display.
-  allows leaving the menu.

Information concerning a period of use:

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


Views of the display:

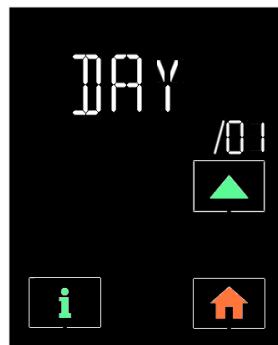
1
Tap the touch key  in standby mode.




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 

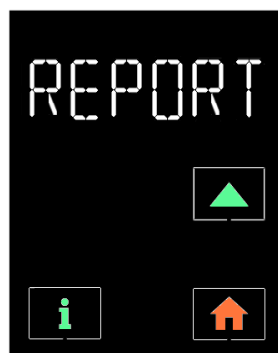


Selecting one of the last periods of use


The value displayed on the right side of the display represents the number of the last periods of 24-hour use which have been memorized, within the limit of 30 days (20 in the example below). The key  allows changing the period of use.



3
Tap the touch key 

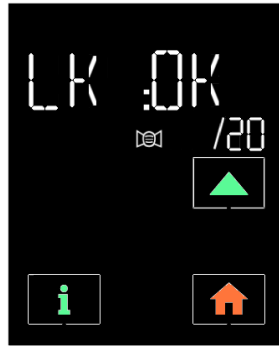


Accessing the compliance information report

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

Views of the display:

4
Tap the touch key



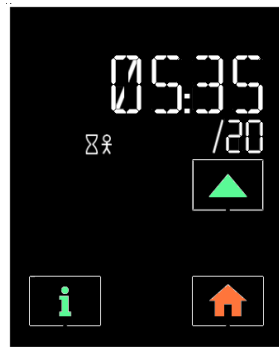
Average level of unintentional leakage in the mask during the period of use.

Possible displayed information:

LK: OK, LK: NOK.

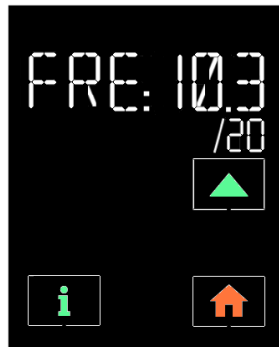
The value shown on the right indicates each time the number of the last 24-hour periods of use.

5
Tap the touch key



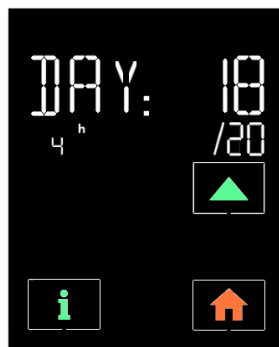
Average compliance value: time during which you have been breathing in the mask during the period of use.

6
Tap the touch key





Average breath rate delivered during the period of use.

7
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)

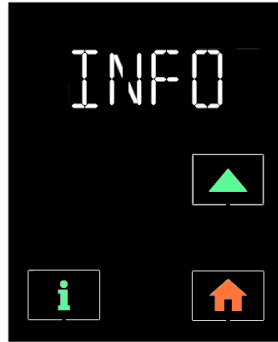
This screen appears only if the number of 24-hour periods recorded in the device is more than 01.

Tapping the touch key  will display, after the previous ones, the technical information concerning the device, and the touch key  allows leaving the menu.


Technical information concerning the device:

Views of the display:

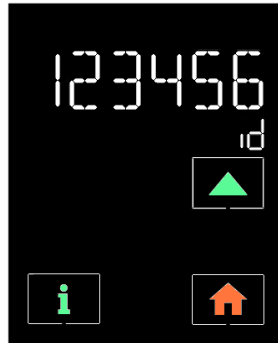
8
Tap the touch key



Accessing the technical information concerning the device.

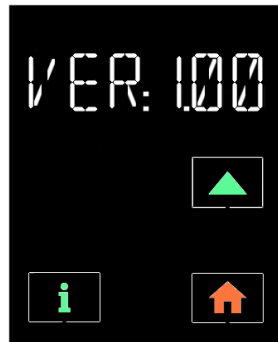
Tap the key  to display the information.

9
Tap the touch key



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

10
Tap the touch key



Software version

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

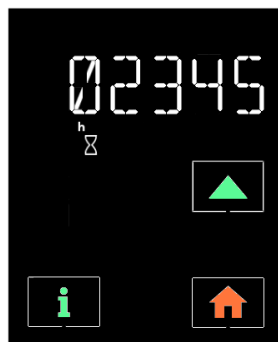
11
Tap the touch key



Total usage hour counter

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

12
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.

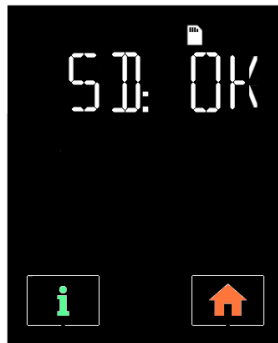
To access the status menu, tap the  touch button while the device is on. In the sequence below:

-  accesses the next display.
- maintaining the ramp button  pressed, then tapping simultaneously the touch key  allows coming back to the previous display.
-  leaves the current menu.

①
Tap the touch
button



when the device
is in operation.

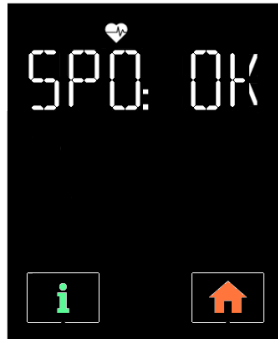


SD card status

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

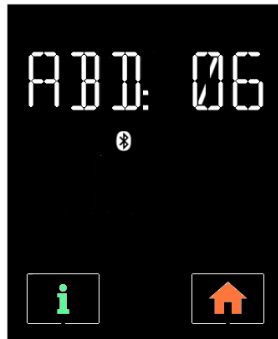


Status of the oximeter

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

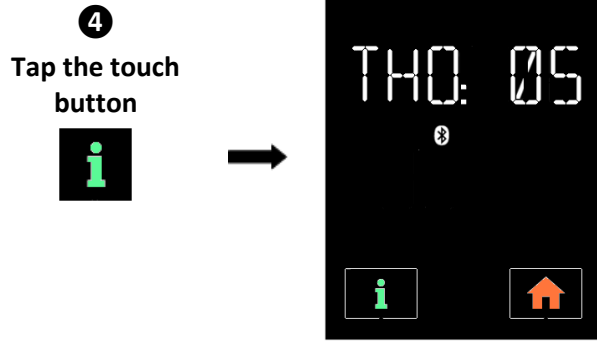


Status of the abdominal effort sensor

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.

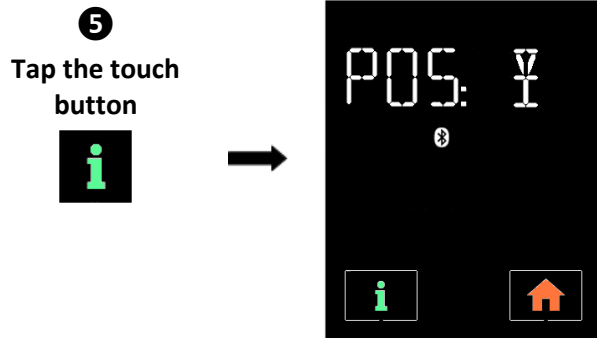
Views of the display:



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.





Status of the body position sensor


Possible displays:


POS:  (lying on back)


POS:  (lying on stomach)

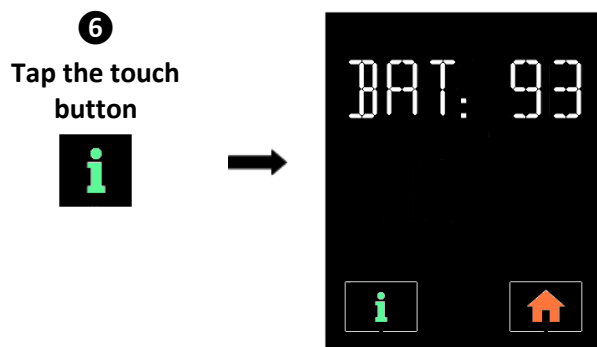
POS:  (lying on right side)

POS:  (lying on left side)

POS:  (standing)

POS:  (sensor inverted)

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




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

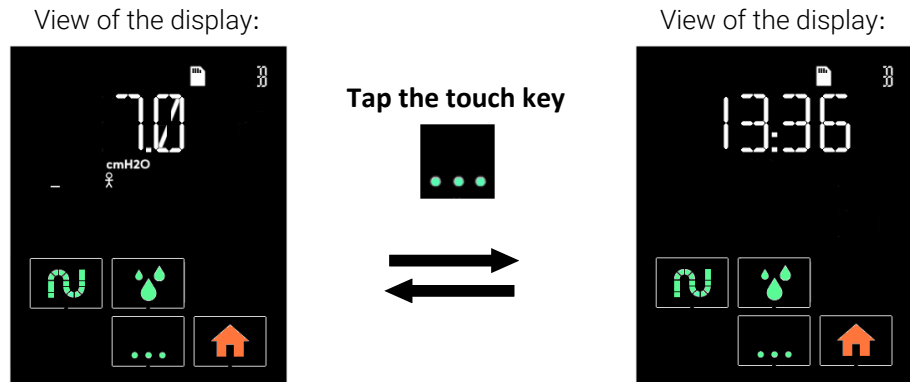
Possible displays: BAT : X
(X = 0 to 100)

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.

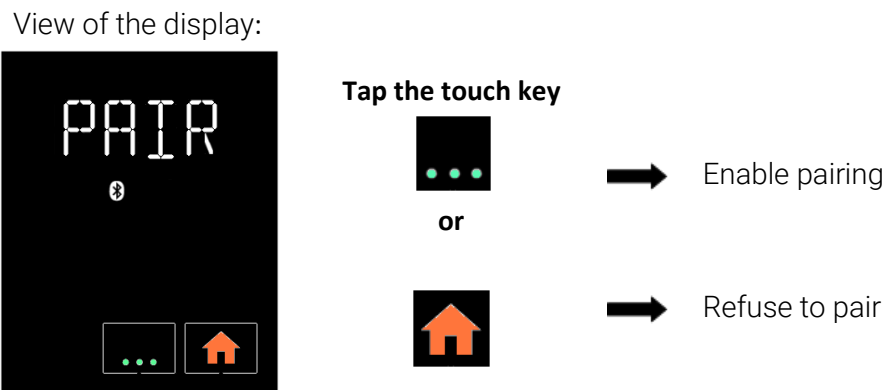
7. Viewing the clock during the treatment

When the S.Box Duo S or S.Box Duo ST 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 S.Box Duo S or S.Box Duo ST 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 S.Box Duo S or S.Box Duo ST device complies with the Federal Aviation Administration RTCA/DO-160G section 21 category M.

Using the device with oxygen enrichment (optional)

WARNING:

- 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.
- The maximum flow rate of oxygen 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 of 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 of 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.
 - 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".

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	The 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.
Runny nose.	Reaction to air flow and pressure levels.	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 the chamber (if included).	Use the humidifier when your device is equipped with one. Increase the humidification level (see section "How to set the device" page 16). Check the water level in the chamber. If necessary, complete it (see section "Filling the humidifier chamber (if installed)" page 11).
Pain in 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 its size is wrong. 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 irritated eyes.	Air leak around the mask.	Reposition the mask. Ask your doctor or Home Care Provider to try different sizes of masks.
The air delivered by the device 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 chapter "Cleaning and Maintenance" page 29). Keep all linen and clothing away from the device. Lower the room thermostat. Make sure the device is away from any source of heat. Unplug the S.Box heated tube with ATC (if installed).
Recurrence of symptoms of sleep apnea syndrome.	The device is not set to the correct pressure or is not operating properly. Your physical condition or pressure needs may have changed.	Ask the Home Care Provider to check how it operates. Contact your doctor.
The device does not deliver the correct pressures (on display).	The ramp is enabled.	Check that the ramp indicator is displayed. If necessary, disable the ramp feature (see section "How to set the device" page 16).

Problem	Possible cause	Suggestion
Discomfort due to excessive pressure sensation.	Device pressure. The device is set in BPAP (bilevel) mode.	Adjustment of nasal pressure takes some time. Use the pressure increase ramp to help you fall asleep (see section "Ramp" page 12). Relax and breathe slowly through your nose. The pressure levels were prescribed by your doctor and can only be changed by medical prescription. If you feel that the device pressure has changed, contact your Home Care Provider to have it checked.
The device does not turn on (no display).	The power supply is not properly connected. 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 that current is available at the electrical outlet. Contact your Home Care Provider.
The device seems to be disturbed and does not work correctly.	Too much electro-magnetic disturbance.	Keep the device away from sources of interference such as halogen lamps, mobile phones, etc.
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 16).
Water droplets appear in the breathing tube, the heated tube or the mask.	A few drops of water are normal, especially in winter. The water level is too high in the chamber (if included). The condensation of water vapor is excessive.	Decrease the humidification level (see section "How to set the device" page 16). 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.
White deposits appear in the humidifier chamber.	These are traces of lime scale from the 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 29). Rinse thoroughly with tap water. Wipe the outer part with a clean cloth.
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 operating 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 section "How to set the device" page 16).

Displayed 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.
	An overly high frequency has been detected.	Check the circuit connection 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 flashes on screen.	The device detected an operating error in the humidifier.	Check that the 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 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 flashes quickly on the display status bar.	<p>The SD card is either not inserted or not properly inserted in the device.</p> <p>The SD card is locked.</p> <p>The SD card is 90% full or more.</p> <p>SD card error.</p>	<p>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.</p> <p>Unlock the SD card and reinsert it into the SD card slot. Contact your Home Care Provider.</p> <p>Contact your Home Care Provider.</p>
 <p>The error code flashes. (XX = 2 figures).</p>	An operating error is detected. The device goes into Standby mode and the menus cannot be accessed.	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 cmH ₂ O to 20 cmH ₂ O in CPAP mode 3 cmH ₂ O to 25 cmH ₂ O in BPAP (bilevel) mode Adjustable by steps of 0.5 cmH ₂ O
Maximum pressure at the patient-side connection port in single fault condition:	40 cm H ₂ O
Maximum adjustable pressure:	20 cm H ₂ O in CPAP mode 25 cmH ₂ O in BPAP (bilevel) mode
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: 2015:	26.0 dBA with side cover 27.5 dBA with humidifier
System resistance for an air flow of 60 l/min at the patient-side connection aperture in power supply fault condition:	3.3 cm H ₂ O without humidifier 4.1 cm H ₂ O 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 ₂ 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 ₂ 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 ₂ O
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: S.Box Duo S or S.Box Duo ST only) 1.99 A (maximum configuration: S.Box Duo S or S.Box Duo ST with humidifier set to 10 and heated tube set to 05)
RF emission type (S.Box Duo S or S.Box Duo ST):	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 S.Box Duo S: 2021

Date of CE marking of S.Box Duo ST: 2021

Regulatory Requirements

Risks concerning this medical device are evaluated according to the ISO 14971:2019 standard, specifically with regard to global residual risk.

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

The S.Box Duo S or S.Box Duo ST complies with the following Directives and standards:

- Directive 93/42/EEC 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.
- CEI 60601-1:2005 + A1:2012: Medical electrical equipment. Part 1: General requirements for basic safety and essential performance.

- CEI 60601-1-2:2014 + A1:2020: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
- IEC 60601-1-6:2010: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 80601-2-70:2015: Medical electrical equipment -- Part 2-70: Particular requirements for basic safety and essential performance of sleep apnea breathing therapy equipment.
- ISO 80601-2-74:2017: Respiratory tract humidifiers for medical use -- Particular requirements for respiratory humidification systems.
- ISO 80601-2-79:2018: Medical electrical equipment -- Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment.

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.

Contact of your Home Care Provider



Manufacturer:

SEFAM
144 AV CHARLES DE GAULLE
92200 NEUILLY SUR SEINE
FRANCE

Manufacturing plant:

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

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M-164DFU03-80 version 2

Manuel patient S.Box Duo S/S.Box Duo ST anglais

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