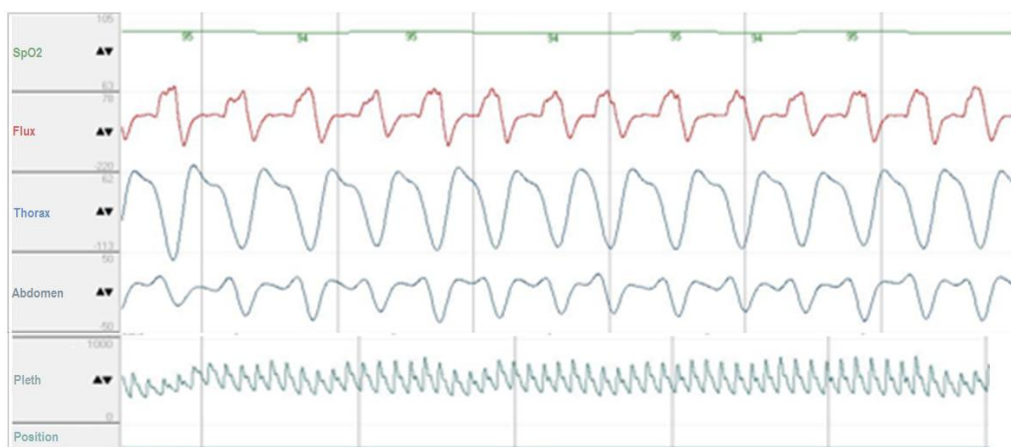
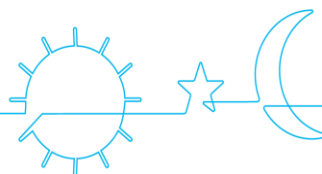


PolyLink



CONTROL POLYGRAPHY WITH THE S.BOX DEVICE

Procedure for Installation and usage



Manufacturer:

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Before you start

Please read this procedure carefully before using the PolyLink kit so that you fully understand the operation limitations of this accessory.

Safety guidelines

WARNING:

In this manual, it means that there is a risk of danger of injury or accident to yourself or others.

- The PolyLink kit must be used under medical supervision for the recommended use indicated in this procedure. Follow the recommendations given by your physician.
- The PolyLink kit is an accessory of the S.Box device. So before installing it, read the safety guidelines and the instructions for installation indicated in the S.Box patient manual. In particular, place the S.Box device on a stable horizontal surface and in a clean and dry environment.
- The PolyLink kit must be used only with the S.Box Positive Pressure device. Make sure that you have the instructions for use for each item and read them carefully.
- The PolyLink kit is not intended to provide assistance for vital functions.
- In addition to the clinical examination, the PolyLink kit allows the physician to assess the treatment efficiency of the patient by S.Box Positive Pressure Device.
- Keep the S.Box device and the PolyLink kit away from any source of water. Use them only if they are dry and in good working condition.
- Do not attempt to modify the elements of the PolyLink kit. The maintenance of this equipment is entirely the responsibility of a qualified person. Contact your Health Professional.
- Keep the PolyLink kit away from children and pets.
- The PolyLink kit complies with the electromagnetic compatibility regulation for medical devices. If you use any critical medical device such as a pacemaker, contact your physician and the manufacturer of this device for more precautions.
- Do not use the PolyLink kit in locations containing flammable or explosive materials.

CAUTION:

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

- Contact your Health Professional if you suspect that this accessory or one of its elements is defective, damaged or not working properly.
- In case of problem, the PolyLink kit must be sent back in its original packaging.
- Like any electrical device, the PolyLink kit is likely to be disturbed by mobile or portable radio frequency communication devices (mobile phones, etc.).
- The Polylink kit is not suitable for a usage near HF electrosurgical equipment.
- To ensure the proper operation of the PolyLink kit against electromagnetic disturbances, the two parts of the PolyLink kit must not be opened. In case of default for closing a casing, contact the Health Professional who provided you the PolyLink kit. Not respecting the requirements of use may result in a performance degradation related to electromagnetic disturbances.

Recommended use

The PolyLink kit is an accessory of the S.Box CPAP device, intended to be used by patients suffering from sleep respiratory disorders and treated only by this device. It allows acquiring and transmitting to the S.Box device the signals of respiratory effort and body position via a wireless communication.

It can be used at home or in care center and allows the clinical teams to monitor the treatment efficiency of the patient. There is no contra-indication or precaution of clinical use specific to usage of the PolyLink kit.

The Pulse Oximeter WristOx2 can also be used with the S.Box device to complete a control Polygraphy. In this case, follow the recommendations of the manufacturer.

Description

List of authorized accessories

The PolyLink complete kit Ref. M-116700 is delivered in a box that includes the following items:

	Reference		Reference
PolyLink module for S.Box	M-216730-00	PolyLink effort/position kit with its support	M-216730-02 M-216730-03
PolyLink effort sensor – Thorax	1369	PolyLink effort sensor – Abdomen	1368
2 belts for effort sensor	1350	PolyLink SD card	M-315890-01
USB charger of effort/position kit	M-416710-00	Power cord for USB charger	M-216730-01
PolyLink transport bag	M-816705-00	Procedure of Installation	M-167DFU00-10

WARNINGS:

- Use only the authorized accessories given in the list above or compliant with the standard EN ISO 17510-2:2007.
- WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other devices should be observed to verify that they are operating normally.
- WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- WARNING: RF portable communication devices (including equipments such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) from any part of the PolyLink kit, including cables specified by the manufacturer. Otherwise, the performance of these devices may be affected.

Overview of PolyLink elements

PolyLink module for S.Box: intended to be inserted in the S.Box device that powers it. It allows retrieving the data of position and of respiratory efforts via a wireless communication.

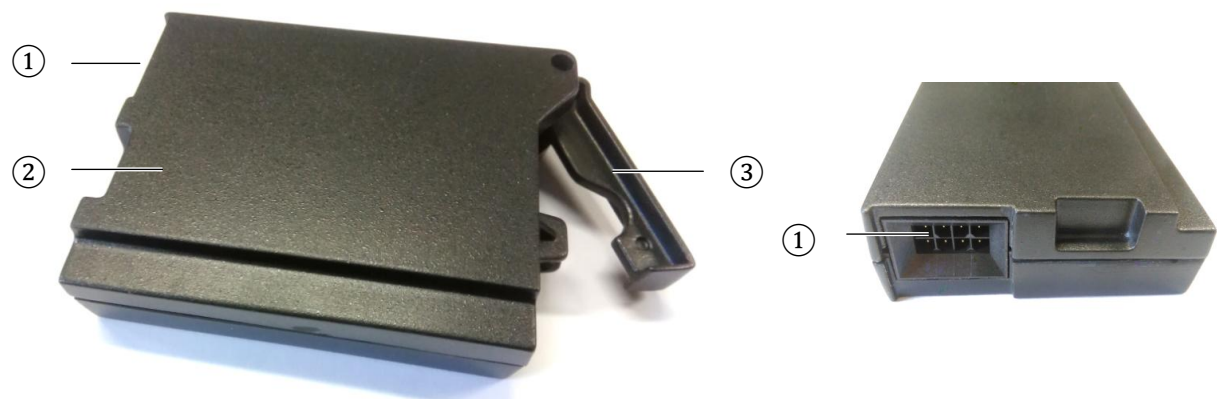


Figure 1 – Views of the PolyLink module for S.Box

- ① Electrical connector for plugging the PolyLink module into the S.Box device
- ② Plastic case of the module
- ③ Lever to remove the module from the S.Box device

PolyLink effort/position kit: integrates the position sensor and allows acquisition and transfer of signals of respiratory effort and of body position to the PolyLink module for S.Box. It is powered by an internal battery and fits into a support.

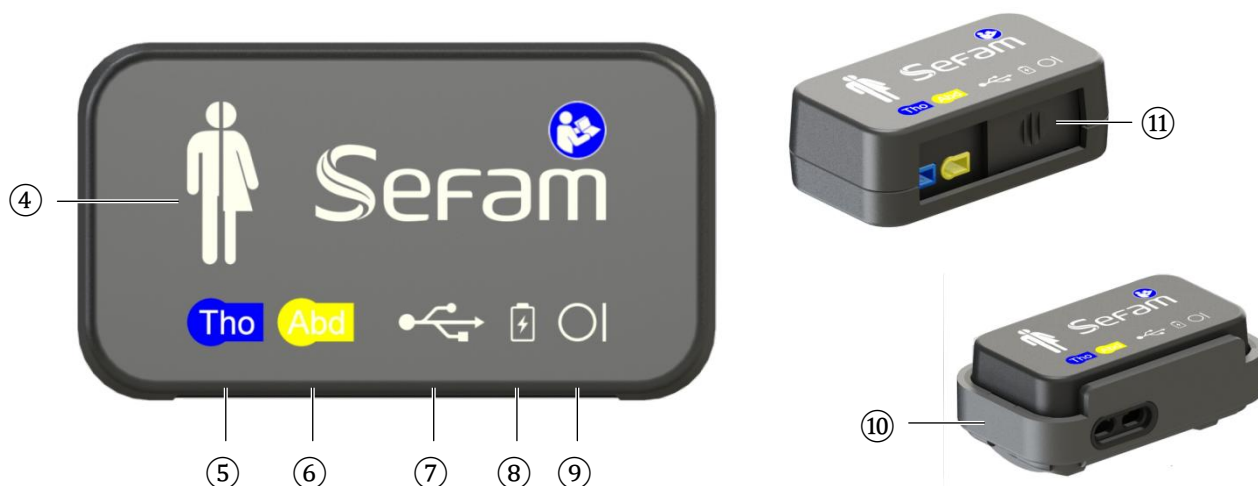


Figure 2 – Views of the PolyLink effort/position kit alone and in its support

- ④ indicates how the PolyLink effort/position kit must be placed in its support.
- ⑤ indicates where the Thorax effort sensor must be connected (blue colour).
- ⑥ indicates where the Abdomen effort sensor must be connected (yellow colour).
- ⑦ indicates where to plug the USB power cord of the charger used to charge the internal battery of the PolyLink effort/position kit.
- ⑧ indicates the charge state of the internal battery.
- ⑨ indicates the positions "On" (right) and "Off" (left) of the switch on the PolyLink effort / position kit.
- ⑩ support in which the PolyLink effort/position kit must be inserted. It is used to position and maintain the effort sensor on the thorax belt and to store the surplus cables.
- ⑪ sliding door: depending on its position, you can either switch on / switch off or charge the PolyLink effort / position kit, or plug the respiratory effort sensors in.

Respiratory effort sensors: are delivered with their belts and allow the measurement of thoracic and abdominal respiratory efforts. Each sensor must be connected to the PolyLink effort/position kit via a cable terminated with a colour connector (blue or yellow). Read the user manuals before installing the sensors.

If you are using a pulse oximeter WristOx2 in addition to the PolyLink kit, refer to the corresponding user instructions for the overview and installation of this equipment.

Definition of symbols

Symbol	Description	Symbol	Description
	Symbol indicating the connector of the PolyLink effort/position kit where must be connected the thorax effort sensor.		Symbol indicating the connector of the PolyLink effort/position kit where must be connected the abdomen effort sensor
	PolyLink effort/position kit alone protected against solid foreign objects of ≥ 12.5 mm diameter; not protected against the penetration of water with harmful effects		PolyLink effort/position kit in its support protected against the penetration of solid objects larger than 12 mm and against dripping water tilted at 15° from the vertical
	Symbol indicating the position "On" of the switch on PolyLink effort / position kit		Symbol indicating the position "Off" of the switch on PolyLink effort / position kit
	Symbol indicating the charge state of the internal battery of the PolyLink effort/ position kit		USB connection
	Class II device		Non ionizing radiation symbol
	Manufacturer		Manufacturing date
	Reference of the PolyLink module for S.Box		Serial number
	Device in accordance with the requirements of the European directive 93/42/EC on medical devices		Device no longer in use, to be disposed separately from household garbage. See "Disposal of device no longer in use" page 16.
	On the packaging: this symbol means "Keep dry" because the package and equipment must be protected against moisture and water		On the packaging, this symbol means "Fragile" because the package must be handled with care
	On the packaging, this symbol means "Atmospheric pressure limit"		On the packaging, this symbol means "Relative humidity limit"
	On the packaging, this symbol means "Temperature limit"		Specific warning (see "Safety guidelines" page 4)
	Read the user manual		

Installation

Insertion of the PolyLink module in the S.Box device

Refer to the patient manual for the instructions concerning the installation of the S.Box device before inserting the PolyLink module into the device, as described hereafter:

1. Unplug the S.Box device from the power supply or from the electrical power grid.
2. Remove the side cover or the humidifier from the device:
 - Press the button for unlocking the cover or the humidifier chamber and pull simultaneously the cover or the chamber towards you by using the corresponding integrated handle.
 - In addition, if the S.Box is equipped with a humidifier, unlock the heater plate by pushing the latch to the right and remove it.
3. Raise the lever of the PolyLink module and slide the module into the accessory location, making sure to position the connector upwards. Once it is in place, lock the module by pushing the lever down.

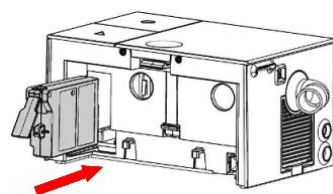



Figure 3 – Insertion of the module into the device

4. Re-place the side cover or the humidifier into the device:
 - Reinsert the cover on the rails in the side part of the device and push it against the device until you hear a "click".
 - If the S.Box is equipped with a humidifier, reinsert the heater plate on the rails in the side part of the device and push it against the device. Re-lock the heater plate by pushing the latch to the left. Install the base of the humidifier chamber on the heater plate and push the chamber against the device until you hear a "click".
5. Plug the S.Box device into the power supply or electrical power grid.

Implementation of the effort/position kit and sensors

1. Attach the support to the Thorax effort belt.
2. With a thin tip like that of a pen, turn on the PolyLink effort/position kit by setting the switch to **On** (sliding door to left) and check that the LED is lit in green, indicating that the internal battery is charged.

If the LED is lit in orange or in red, recharge the internal battery according to the instructions in the corresponding paragraph, page 9).

3. Insert the PolyLink effort/position kit into its support positioning it in the direction indicated by  on the kit, the side with symbols facing outward (A).
4. Install the two effort sensors on the thorax and abdomen following the instructions of the user manuals provided.
5. Connect the cable of the thorax sensor (blue connector) and the cable of the abdomen sensor (yellow connector) to the ports of same colours of the PolyLink effort/position kit (B).

A



B



Figures 4 : Implementation of the effort/position kit (A) and sensors (B)

WARNINGS:

- It is recommended to wear night clothing.
- Do not leave unnecessary lengths of belts on the bed. They could wrap around your head or around your neck when you are asleep.

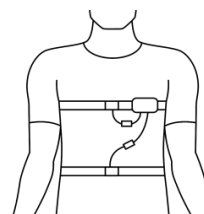


Figure 5 –General diagram of kit and sensors position

Recharging the internal battery of the kit

1. Connect the USB power cord of the charger to the corresponding port of the effort / position kit.
2. Plug the USB charger into the electrical power grid.
3. Keep the kit plugged until the internal battery is recharged and the LED becomes green.

Use

Operation configurations

The PolyLink kit has two operation configurations:

- The PolyLink effort/position kit transmits the signals of thorax and abdomen efforts, as well as the patient's body position, to the PolyLink module for S.Box. Electromagnetic disturbances may temporarily interrupt the transmission of data without danger for the user.
- The internal battery for the PolyLink effort/position kit is recharged by the USB charger. In this configuration, electromagnetic disturbances may temporarily interrupt the charge of the battery without danger for the user.

Communication with the PolyLink kit

The communication of the S.Box device with the PolyLink kit is performed directly by the device.

When the PolyLink module is installed in the S.Box device, the following display appears in the settings menu for the patient (see " How to set the device " in the patient manual).

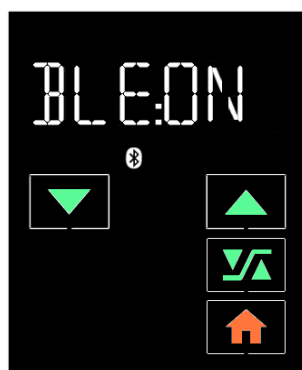
Tap the touch key





as many times as
necessary



View of the display:



BLE communication (BLE = Bluetooth Low Energy)

You can enable (ON) or disable (OFF) 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 effort/position kit.

Tap the touch
key





Views of the display:



Communication with the PolyLink effort/position kit


The S.Box device searches the PolyLink effort/position kit and the BLE display flashes alternately with six dashes as long as no kit is paired.

When the kit is detected, the BLE display flashes alternately with the last six alphanumeric characters of the Bluetooth address indicated on the rear side of the kit, **683B73** as shown in the example.

If the 6 characters displayed do not match the PolyLink effort / position kit used, a new search is possible by tapping the key  or .

Status menu

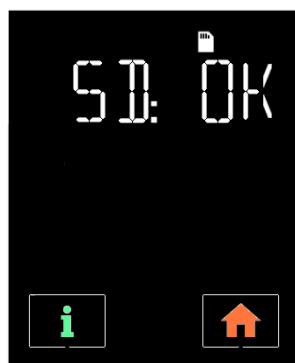
This menu is available from the firmware version 1.7 of the S.Box device. It is accessible when the S.Box device is in operation and when a PolyLink system or a pulse oximeter WristOx2 has been installed and paired. The information can be viewed successively but cannot be modified.

To access it, tap the  touch button when the S.Box device is on.

1
Tap the touch
button



when the device
is in operation.

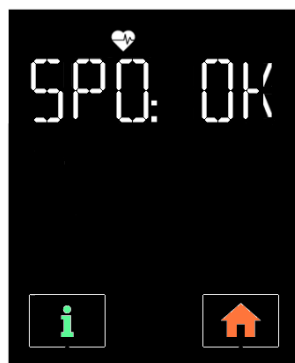


SD card status

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 pulse oximeter

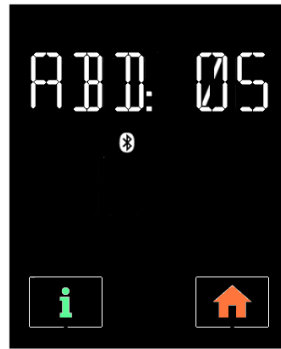
Possible displays: SPO: OK and SPO: _ _ _.

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



Views of the display:



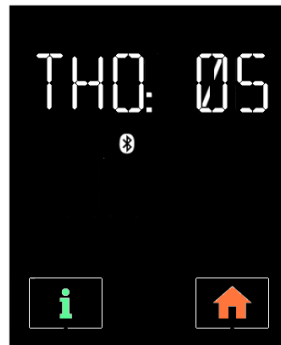
Status of the abdominal effort sensor

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

The information displayed will vary depending on the importance of the abdomen movements.

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

④
Tap the touch
button



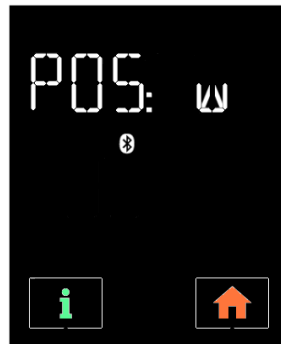
Status of the thorax effort sensor

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

The information displayed will vary depending on the importance of the thorax movements.

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

⑤
Tap the touch
button



Status of the body position sensor

Possible displays:

POS: (lying on back)

POS: (lying on stomach)

POS: (lying on right side)

POS: (lying on left side)

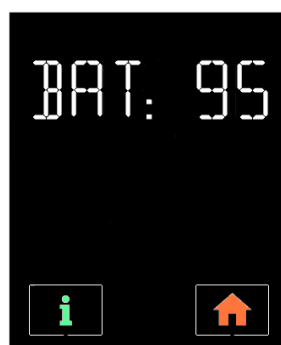
POS: (standing)

POS: (sensor inverted)

POS: _ _ _

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

⑥
Tap the touch
button




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

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

If the displayed value is low, recharge the internal battery using the USB charger.

Tap  to exit the status menu.


The adjustment of thorax and abdomen effort belts can be performed using SEFAM Access.

Select the icon  on your Smartphone or on your tablet to run the application "SEFAM Access" and follow the instructions on the screen.


If you are using a pulse oximeter WristOx2 in addition to the PolyLink kit, refer to the settings menu in the S.Box patient manual to pair the oximeter with the device.

Real-time acquisition

The PolyLink kit allows acquiring in real time the signals of respiratory efforts and of body position.

Hold down the start / standby button  to begin treatment. The compliance data stored in the machine is saved on the SD memory card. Then the acquisition of the signals from the PolyLink kit and from the pulse oximeter WristOx2 begins, if present.


CAUTION

- Make sure that the SD card is inserted in the S.Box device for the real-time acquisition.
- Check that the symbol  is present in the center of the display, showing that the BLE wireless communication is enabled.
- Do not unplug the S.Box device.

Once the S.Box comes back to standby, the polygraphic control is complete: the SD memory card can be removed from the S.Box device.

The data saved on the SD memory card can be retrieved by the Health Professional for later analysis with the SEFAM Analyze software.

Stopping treatment

1. With a thin tip like that of a pen, turn off the PolyLink effort/position kit by setting the switch to **OFF** (sliding door to left) and check that the LED is off.
2. Hold down the start / standby button  of the S.Box device to stop the treatment.

Transport of the PolyLink kit

Unplug the S.Box device and uninstall the PolyLink kit by following the instructions of paragraph "Removal of the PolyLink " page 13.

Pack the elements of the PolyLink kit in the transport bag.

Removal of the PolyLink kit

1. Unplug the S.Box device from the power supply or the electrical power grid.
2. Remove the side cover or the humidifier from the machine:
 - Press the button for unlocking the cover or the humidifier chamber and pull simultaneously the cover or the chamber towards you by using the corresponding integrated handle.
 - In addition, if the S.Box is equipped with a humidifier, unlock the heater plate by pushing the latch to the right and remove it.
3. Lift the lever of the PolyLink module and pull the module out of the accessory location of the device.
4. Re-place the side cover or the humidifier into the device:
 - Reinsert the cover on the rails in the side part of the device and push it against the device until you hear a "click".
 - If the S.Box is equipped with a humidifier, reinsert the heater plate on the rails in the side part of the device and push it against the device. Re-lock the heater plate by pushing the latch to the left. Place the base of the humidifier chamber on the heater plate and push the chamber against the device until you hear a "click".
5. Unplug the effort sensors from the PolyLink effort/position kit.
6. Refer to the user manuals to remove the effort sensors (thorax and abdomen) and their belts.

Cleaning and Caring

As the PolyLink module is an accessory designed to be installed inside the S.Box device, it does not require any special maintenance. However, if necessary, follow the procedure hereafter.

WARNING:

Unplug the S.Box device and remove the PolyLink module from the device before cleaning it (see paragraph "Removal of the PolyLink ").


CAUTION:

- To clean the PolyLink module, use only materials reserved for this purpose: do not use aggressive detergent, scratching sponge or hard bristle brush.
- Do not let any water enter the PolyLink module.
- Clean the outside of the PolyLink module with a damp cloth sprinkled with a little water and a drop of mild detergent.
- Let it dry completely before reinstalling the PolyLink module into the S.Box device.

The effort/position kit can be cleaned in the same way as the PolyLink module, after disconnection of the effort sensors.

For cleaning and caring the respiratory effort sensors and the belts, refer to their respective user manuals.

Trouble-shooting

Problem	Possible cause	Suggestion
No acquisition of the signals of effort / position.	The PolyLink module is not present or not correctly inserted in the S.Box device.	Check that the PolyLink module is properly inserted in the accessory location of the device. Otherwise, reinstall it (see "Insertion of the PolyLink module in the S.Box device" page 8).
	The PolyLink effort/position kit does not work.	With the tip of a pen, check that the switch of the effort/position kit is set to ON. Turn off, then turn on the effort/position kit and check that the LED lights in green. Check the charge of the internal battery. If the LED is lit in orange or in red, recharge the internal battery by using the USB charger (see "Implementation of the effort/position kit and " page 8).
	The thorax and abdomen effort sensors are not properly connected.	Check the connections between the effort/position kit, the thorax and abdomen effort sensors and the belts. Readjust them if necessary. If the problem persists, contact your Health Professional.
The LED of the effort/position kit is off.		The extinction of the LED is automatic when the effort/position kit has been working for 1 minute. If the LED never lights up, contact your Health Professional.
The symbol  is not present in the center of the display when the S.Box device is working.	The BLE (Bluetooth Low Energy) communication is not enabled.	Check that the BLE communication is enabled in the patient settings menu of the S.Box device. Otherwise, activate it (BLE:ON). See "Communication with the PolyLink kit" page 9. If the problem persists, contact your Health Professional.
Communication impossible with the PolyLink kit.	The PolyLink module is not paired with the PolyLink effort/position kit.	Check that the PolyLink module is paired in the settings menu of the S.Box device. See "Communication with the PolyLink kit" page 9. If the problem persists, contact your Health Professional.
The PolyLink kit seems to experience interference and does not work properly.	Too high electromagnetic disturbances.	Move the S.Box device and the PolyLink kit away from sources of interference, such as halogen lamps, cordless phones, etc.

Technical characteristics

Performance of the PolyLink kit

Expected lifetime:	5 years
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Radio specifications

RF emission type:	Bluetooth Smart (BLE 4.1)
Frequency band:	2402 to 2480 MHz (ISM band)
Maximum power:	5.3 dBm

Conditions of use

Pressure range:	700 hPa to 1060 hPa
Temperature:	+5°C to +40°C
Relative humidity:	between 15 % and 93 % without condensation
Altitude range:	Approximately 0 – 2 500 m

Transport and storing conditions

Pressure range:	700 hPa to 1060 hPa
Temperature:	-25°C to +70°C
Relative humidity:	between 5 % and 93 % without condensation

Electrical characteristics


PolyLink module for S.Box:

Input voltage:	5 Vdc \pm 5 % (powered by the electrical connector of the S.Box device)
Maximum power consumption:	45 mW / 9 mA

PolyLink effort/position kit:

Input voltage:	5 Vdc \pm 5 %
Maximum power consumption:	0,6 W / 120 mA

USB charger for effort/position kit:

Classe II device:	
Charger provided:	SMI 5 – 5 – V - I38 (different plug depending on country)
Input voltage:	100 – 240 V _{AC} , 50 – 60 Hz
Input current :	200 mA
Output voltage:	5 V \pm 5 %

Physical features

Dimensions of the PolyLink module (L x W x H) :	85 x 63 x 22 mm
Dimensions of the effort/position kit (L x W x H) :	37 x 67 x 22 mm (alone) 41 x 71 x 30 mm (fixing equipment to belt included)
Dimensions of the transport bag (L x W x H) :	200 x 150 x 60 mm
Weight of the PolyLink module:	60 g
Weight of the effort/position kit:	60 g

Radio certifications

Europe :

- EN 301489-1 V2.1.1 (2017-02) and EN 301489-17 V3.1.1 (2017-02) Electromagnetic Compatibility (art. 3.1b)
- EN 300328 V2.1.1 (2016-11) Effective use of spectrum allocated (art. 3.2)

Japan :

- Giteki : 209-J00169

CE marking

PolyLink kit: 2018.

Regulatory requirements

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

The PolyLink kit used with S.Box complies with the following directives and standards:

- Directive 93/42/EEC of the Council concerning medical devices, modified by the European Directive 2007/47/EC.
- Directive 2014/53/EU (RED) 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 2006/66/EC of the European Parliament and of the Council on batteries and accumulators.
- Directive 2011/65/EC 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/EC of the European Parliament and of the Council on waste electrical and electronic equipment (WEEE).
- CEI 60601-1:2005 + AC1:2006 + AC2:2007 + Amd1:2012: Medical electrical equipment. Part 1: General requirements for basic safety and essential performance.
- CEI 60601-1-2:2014: Medical electrical equipment. Part 1: General requirements for safety. Collateral standard: Electromagnetic compatibility – Requirements and tests.

Essential performances requirements for electromagnetic compatibility

The essential performance is defined as follows: the position of the PolyLink Efforts / Position kit and the two signals from the thoracic and abdominal belts are correctly and safely transmitted to the PolyLink Module for S.Box.

If the essential performances are lost or deteriorated, there is not risk for the patient. This can be acceptable as the signals displayed by the software SEFAM Analyze will be systematically checked and studied by a practitioner who will be able to identify signals resulting from an external perturbation.

Electromagnetic Compatibility

Electromagnetic emissions	Conformity	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1 Class B	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Equipment is tested in 'HOME HEALTHCARE ENVIRONMENT', more severe than the 'PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT'. It can be connected to PUBLIC MAINS NETWORKS due to its higher immunity test level.

Disposal of device no longer in use

In European Union, this accessory 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 7).

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

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

Contact your Health Professional.

Contact of your Health Professional



Manufacturer:

SEFAM
144 AV CHARLES DE GAULLE
92200 NEUILLY SUR SEINE
FRANCE

Manufacturing plant:

SEFAM
10 ALLEE PELLETIER DOISY
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