New Medical Inspiration

EO-70

Secretion Management Device

User Guide

Contents

Introduction

The EO-70 (ref EO70) Secretion Management Device (SMD) provides treatment for patients not able to manage their secretions on their own. It provides Insufflation – Exsufflation (INEX) and Intermittent Positive Pressure Breathing (IPPB) modes for adult and pediatric patients as prescribed by an attending doctor.

Indications for use

The EO-70 Secretion Management Device provides treatment support for pediatric and adult patients weighting at least 5 kg (11 lbs) who requires secretion management support. The EO-70 device is intended to be used in home, institution, hospital for both invasive and non-invasive interface. This device is transportable but not intended for use during transport.
The EO-70 device may be used either with a mask, mouthpiece or tracheostomy tube.

⚠	**WARNING**
•	**E0VE 70 is not for use with anaesthetic gases.**
•	**E0VE 70 is not for use in an oxygen enriched environment.**
•	**Do not use EO-70 device in an MRI equipment or in a barotherapy equipment**

Contraindications

- Barotrauma
- Pneumothorax
- Pneumomediastinum
- Bullous emphysema

Adverse Effects

- Dry nose or mouth
- Eye irritation
- Bloating
- Gastric distension
- Skin wound
- Sinus discomfort

Definitions

⚠	**WARNING**	**Indicates a condition that may endanger the patient or the device operator**
	CAUTION	Indicates a condition that may damage the device or equipment
	NOTE:	Advice that makes operation of the device more convenient or efficient

General warnings and cautions

	**WARNING**
•	**The user and/or the patient must inform its service provider of any serious incident occurred with the device. This information would be notified to EOVE and to competent local authorities if necessary.**
•	**Read and understand the entire manual before using the EO-70 device**
•	**The EO-70 device is a restricted medical device intended for use by qualified trained personnel, under the direction of a doctor.**
•	**Use the EO-70 device only as directed by a doctor or healthcare provider.**
•	**Information in this manual does not supersede instructions given by the prescribing doctor.**
•	**Install and configure the EO-70 device in accordance with the instructions given in this guide. Non-specialist operators or institutions encountering problems with set-up, operation or maintenance should immediately contact their EOVE representative.**
•	**Handle the EO-70 device and AC power supply with care during and after use especially if ambient temperatures are high as some surfaces may become hot. Do not leave the EO-70 device in direct contact with the patient for extended periods of time.**
•	**The EO-70 should be kept out of reach of children and domestic animals to ensure their safety and the safety of the patient and to avoid damage to the device and the accessories.**
•	**The battery and all machine parts of the device should be disposed of appropriately, following correct regulations for waste management in order to minimize the risk for the environment. They should not be disposed of in household waste.**
•	**Keep the device, and accessories away from water and all other liquids not specified in this document.**
	CAUTION
	The EO-70 device is transportable but not intended for use during transport.
	Do not expose the EO-70 device to excessive force, do not shake or drop.
	If the device or its power supply are dropped or mishandled, immediately discontinue use and contact your EOVE representative.
	Repairs and servicing should only be carried out by an authorized EOVE service representative or a qualified and certified Service representative.
	The airflow for breathing produced by the device can be higher than the temperature of the room by up to 6°C. It should not be used if the ambient air in the room exceeds 35ºC.
	The EO-70 SMD device is not a ventilator and should not be used for other purpose than punctual secretion management.

Chapter 1 – Description of the EO-70 device

Front Panel

1. Display screen	3. EO device housing unit
2. SMD module	4. Circuit Port
	5. Keyboard

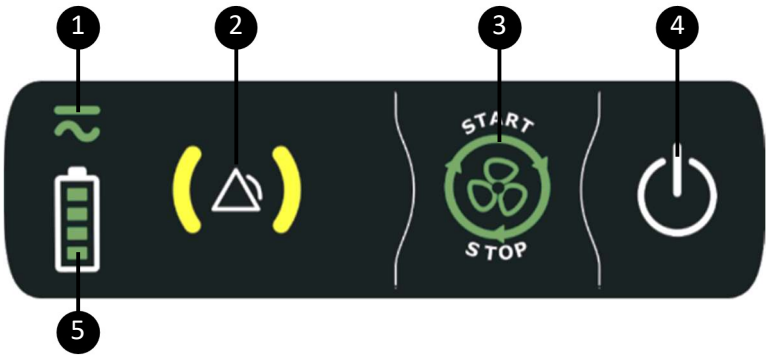
Rear Panel

1. Air inlet / outlet filters cover	5. USB-1 port
2. DC Power connector	6. SpO_2 connector
3. Power button	7. Remote Control connector
4. USB-2 port (Maintenance only)	

Rear view of device without housing

1.	USB port
2.	DC Power connector
3.	Connection to outer housing

Keyboard



1. Power source indicator
2. Alarm indicators
3. Treatment start / stop button
4. Power on/off button
5. Battery level indicator

Symbols Table

The following symbols may appear either on your product or its packaging.

Keypad indicators / buttons			
	Alarm indicator		
	Battery level indicator		AC/DC power indicator
	On/Off button		Treatment start / stop button
Touch interface symbols			
	Treatment start		Treatment stopping
	Menu access button		Settings menu access button
	Return to Home Screen		Battery charging
	Touch interface unlocked		Touch interface locked
	Battery charging but not enough charged to supply the device		Battery power indicator
	Power off button		Calibration screen access
	User manual access		Settings information
	Alarms screen access		Maintenance menu access
	Preferences screen access		Coaching screen access
	Export Data screen access		Skip the current serie
	Adds one breath to the current serie		Leak Indicator (inactive)
	Leak Indicator (excessive interface leaks)		Leak Indicator (acceptable interface leaks)
	Breath triggering on touch pad (IPPB)		INEX Manual mode actions: Slide Right = inspiration / Slide Left = Exhalation / Release = Pause
	Circuit without leak needed (INEX mode)		Circuit with leak needed (IPPB mode)
Device / packaging symbols			
	Inspiratory Port (to patient)		
	Connection port		Connection ports

	USB connector		Warning
	Remote control connector		Applied part BF type
	Consult operating instructions		Battery replacement warning: Only trained personnel can replace batteries
	DC power inlet	IP	International Protection Marking, IEC standard 60529. Protection against ingress of water and foreign objects.
	Date of manufacture		This side up
	Complies with European legal requirements		Manufacturer
	High and low temperature limitations	SN	Serial number
	Should not be disposed of in household waste	REF	Product reference number
	Keep dry		Recyclable
	Danger of fire if damaged	©	Copyright
	Fragile. Handle with care.		Class II device
	Storage and transport humidity range	MD	Medical device

Chapter 2 – Operating Instructions for the EO-70 device

⚠	**WARNING**
•	**Blocking the air inlet could lead to patient injury.**
•	**Keep machines clear of blankets, soft toys, and dust. Keep out of direct sunlight.**
	CAUTION
	To prevent possible damage to the device always place it on a flat, dry and stable surface. To protect the device during transportation, always ensure that the EO-70 device is transported using the EOVE Transport bag.
	Always protect the device from water if transported outdoors.

Set Up Test

Before using the EO-70 device, perform the following Set Up test.

⚠	**WARNING**
•	**If an alarm triggers during the Set Up test, do not use the device.**
	CAUTION
	Contact your healthcare provider or EOVE for assistance if any of the checks in the set-up test fail.
	If the EO-70 has been returned after servicing, ensure it is clearly labelled as disinfected before starting the set-up test or installing.

To perform a Set Up Test

During a first patient installation, it is recommended to check the correct operating status of the device:

1.	Connect the device to the AC power source and check the ACDC Symbol is active.
2.	Check the condition of the device and accessories, and the condition of the patient's circuit.
3.	Turn on the device (see next page). The device should sound, and the display screen should turn on correctly.
4.	Start treatment and verify air is coming in and out of the device outlet

⚠	**WARNING**
	If any of these steps fails, do not use the EO-70 device. Contact your healthcare provider or your Eove representative for a device checking.

Turning on the device

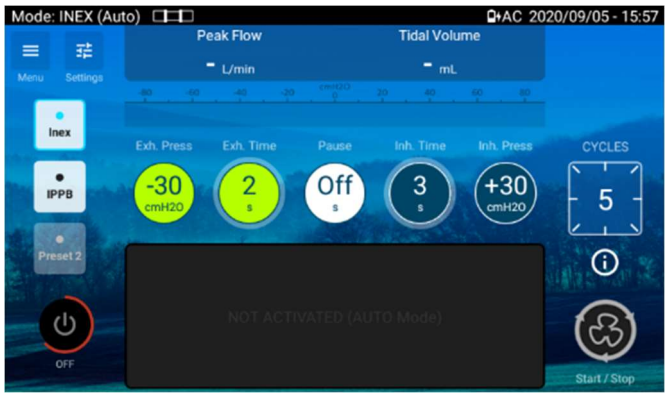
Ensure the device has been charged prior to use or connect to AC power or DC connector inlet.

1.	Insert AC connector into power inlet.
2.	Turn the screw lock clockwise to secure.
3.	Device will turn on automatically. If starting on battery, press on front panel keyboard to power on the device.

Turning off the device

From the touch interface - Main proceedings

1. From the Home screen or from the coaching screen of the touch interface, press and hold until the circle becomes red.



2.	A confirmation message is displayed. Validate.
3.	The device turns OFF.

	CAUTION
	The EO-70 device cannot be powered off during treatment
	Unplugging from mains power does not power off the device. It will continue to run on the internal battery.
	The device must be turned off manually before disconnecting from AC power for any extended period of time. Failure to do so may result in battery depletion.

From the SMD module - Secondary proceedings

1. Press and hold  for three seconds.
2. The SMD turns OFF.

Device Auto Power off on batteries

To keep the internal battery with the maximum autonomy, the device will automatically turn off after 15 min of inactivity.

After 14 minutes, the device will emit two beep sounds and a message will be displayed to user. It will allow the user to plug back the mains or Cancel this power off for the following minute.

End of batteries beeps

At 20% battery autonomy remaining the device will sound two beeps, then below 10%, the two beeps will sound every minute.

Starting and Stopping treatment

Treatment can be started and stopped from either the touch screen or from the keyboard. Various preset treatments may be installed on the device by your clinician to ensure the best therapy. Use these presets according to the instructions provided by the clinician.

To **START** treatment using the keyboard:

1. Press  on the Keyboard
2. Treatment starts.

To **START** treatment using the Touch Screen:

1. Press  on the touch screen
2. Treatment starts.

To **STOP** treatment using the Keyboard:

1. Press  on the keyboard
2. Treatment stops.

To **STOP** treatment using the Touch Screen:

1. Press  on the touch screen
2. Treatment stops.

	**CAUTION**

	The EO-70 device cannot be powered off during treatment
	Unplugging from mains power does not power off the device. It will continue to run on the internal battery.
	The device must be turned off manually before disconnecting from AC power for any extended period of time. Failure to do so may result in battery depletion.

Turning on and off the docking station

During a storage period or a long period of non-use without power supply, the docking station should be switched off.

To switch on and off the docking station and the touch screen when the SMD module is outside, press the **Power** button for a few seconds.

Using the SMD module outside of the docking station (click and go)

The SMD module can be used outside of the docking station.

To remove the module from the docking station:

1. Turn off the device and unplug from the mains
2. Remove the screw at the bottom of the station (see below).

3. Push on the back of the module while maintaining the docking station with the other hand

4. Pull the module while maintaining the docking station with the other hand

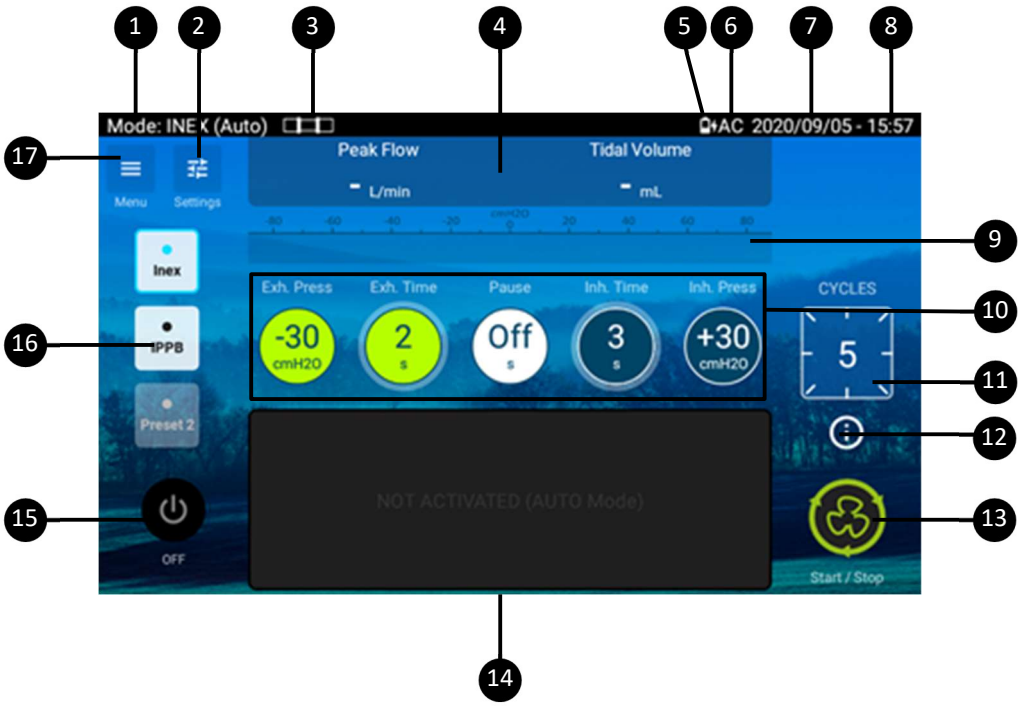
5. To use the SMD module on standalone configuration, turn on the module and press  on the keypad to start and stop treatment according to the previously set parameters.

6. To charge the module, plug it back in the docking station and restore the mains connection.

⚠	**WARNING**
•	**The SMD module extraction from the station must not be performed by the patient. Only trained persons are allowed to perform this operation.**
•	**To avoid contact with connectors, do not put the hands in the docking station while the module is out. Do not touch the inside of the station and the patient at the same time.**

The Home Screen

On the home screen, there is important information about the settings, the pressure of treatment, the preset modes set up by clinician. The Home Screen is accessible from all other screens by pressing 



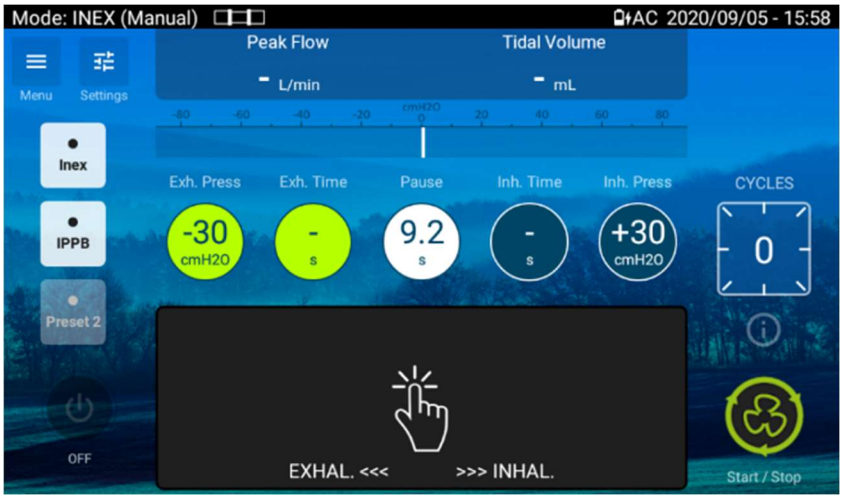
1. Treatment mode indicator: Choose from INEX, IPPB in the settings menu 2. Settings button: Allow access to settings menu. 3. Leak necessity indicator. 4. Treatment monitoring: display the live value for the displayed monitoring during treatment. 5. Battery life indicators: Indicates the level of charge left in the battery or whether the battery is charging. 6. Power source indicator: Indicates whether the device is operating on mains power (AC) or DC power and battery life. 7. Date: indicates the date on YYYY/MM/DD format. This can be set up and changed from Preferences menu. 8. Time: Indicates the time on 24hr clock. This can be set up and changed from the Preferences menu.	9. Airway pressure indicator: Indicates the pressure in the circuit. All inhalations are colored in blue, all exhalations are colored in green, all pause time are colored in white. 10. Main settings bar: Displays the main settings associated to the current mode. (can be adjusted when unlocked) 11. Start/Stop button: starts or stops treatment. 12. Settings information. 13. Treatment Start/Stop Button. 14. Touch pad: in INEX mode, permit to manually manage the treatment. All tactile actions with right movement trigger an inhalation, all actions with left movement trigger an exhalation. In IPPB mode, starts a breath, a click triggers an inspiration phase. 15. Power off button. 16. Preset mode menu (1-3): Presets installed by the clinician and accessible to the patient when needed. 17. Menu button: Allows access to patient screen and clinical menus.

Using the Touch Pad

The Touch Pad is activated in INEX mode when set to MANUAL or in IPPB mode.

INEX mode Manual operation

In INEX mode, the operation must start in the Touch Pad black area but then the full screen surface can be used if the finger keeps the contact with the screen.



1. Start the treatment. While the Touch Pad is not used, the device is in pause state controlling PEEP pressure.
2. Press the Touch Pad and slide to the right. The device is starting an inspiration phase.
3. Keep a finger on the pad to hold the inspiration
4. Without removing the finger from the Pad, slide to the left. The device is starting an exhalation.
5. Keep a finger on the pad to hold the exhalation
6. Release the Touch Pad. The device comes back to a pause phase.

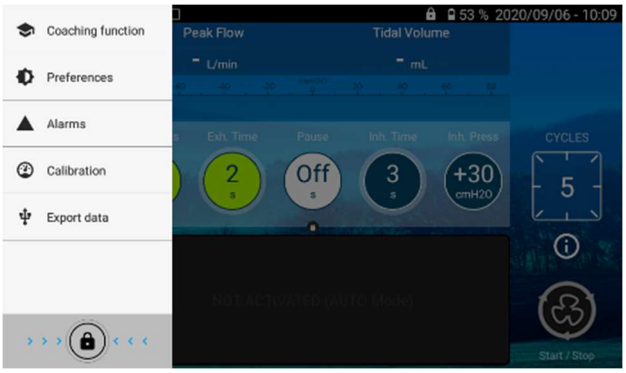
IPPB mode operation

In IPPB mode, a simple touch on the Touch Pad will trigger an inspiration.

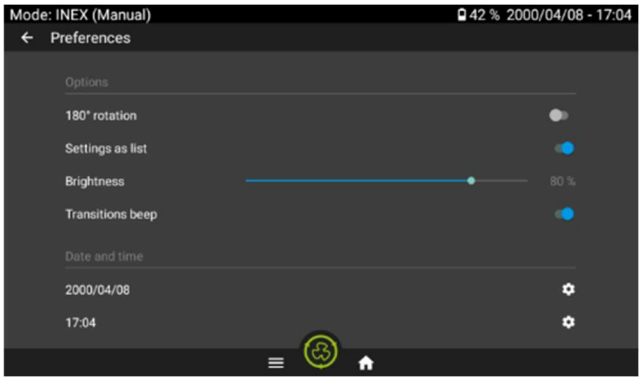
Navigating the Preferences Menu

From this screen the patient can change preferences.

From the Home Screen, choose to access the Preferences and Maintenance menus.



Press on Preferences to choose the Preferences Screen. (see below)



From this screen the patient can adjust the following settings for the device.

Rotation of screen	Allows the screen to be rotated 180°. Press the small circle to rotate the screen.
Settings as list	Select the display mode of the settings menu. To display the settings as list, press the small circle. The circle and the bar will become blue.
Luminosity	Adjusts screen luminosity.
Transition beep	Activates beeps at transitions from exhalation to inspiration (INEX and IPPB modes) and from inspiration to exhalation (INEX mode only).

Current Date	Sets the current day, month and year. To set the date, click on the wheel and choose the date from the calendar. Press ok when completed.
Current Time	Sets the current time on 24h clock. To set the time, click on the wheel at the end of the line and choose the time from the dial. Press ok when completed.

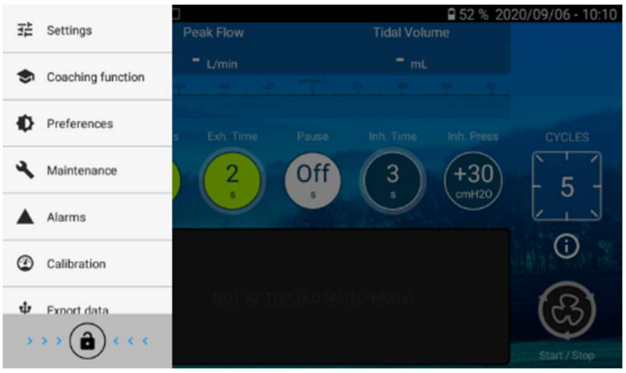
In the preferences menu, the user can also access traceability and connection information.

Accessing the settings menu

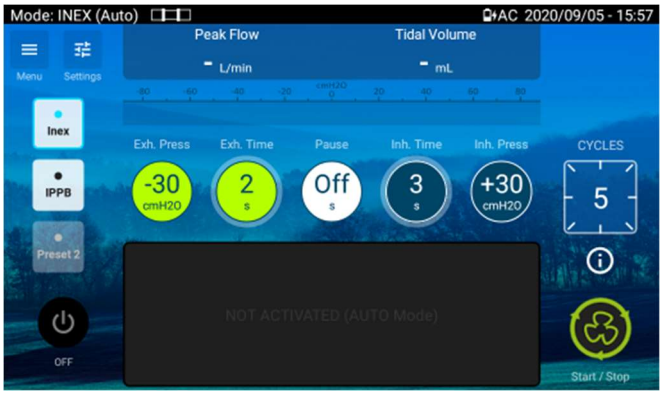
NOTE:	Do not access settings menu (unlocked mode 🔓) unless directed by a physician.

To access the settings Menu

1. Choose ☰ and hold down the lock button,  until it becomes red. A confirmation message is displayed. Validate.



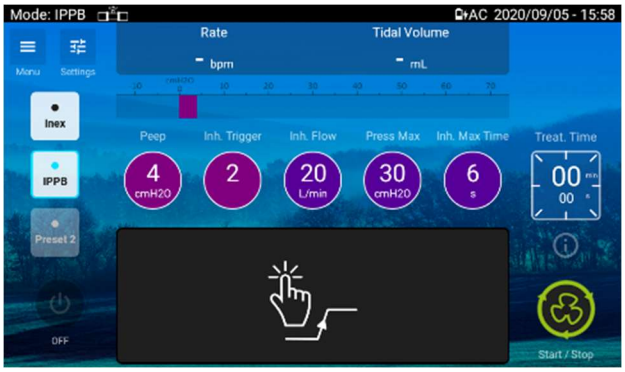
2. The settings button on the home screen is now available (no lock 🔓 on it)



3. Click on the home page settings for adjustment of the main settings or access the settings menu to adjust any setting.

Presets

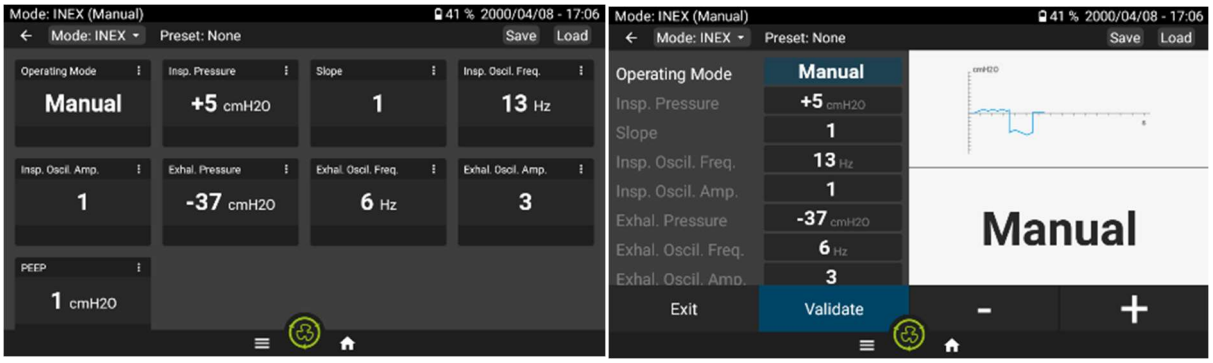
The EO-70 device can store up to three different treatment presets. Presets can be configured by clinicians to provide personalized alternative treatment options. These preset configurations allow for different treatments.

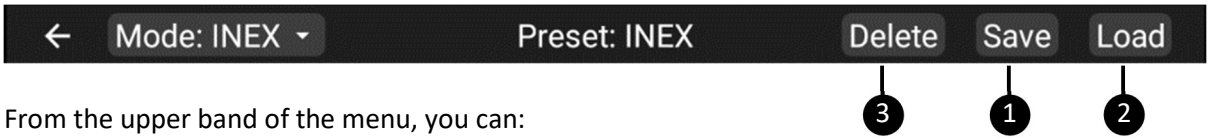


NOTE:	If more than one preset has been set up, follow the instructions of your clinician for when and how they should be used.

Presets Configuration Access

Access the settings screen (see instruction above).



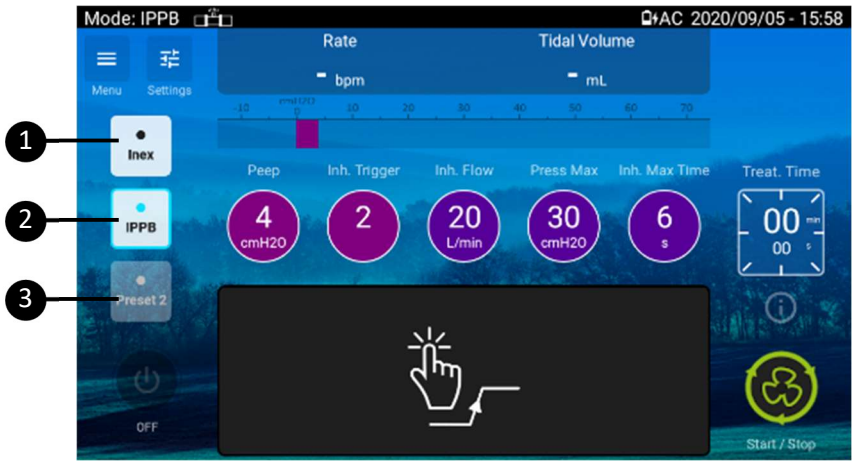


From the upper band of the menu, you can:

1. Save the active mode as preset and rename the saved preset,
2. Load a previously saved preset (to visualize the settings contained in the preset).
3. Suppress a preset (displayed only if a preset is loaded)

NOTE :	To change a setting from a preset, select the preset, change and validate the settings and confirm the save of the setting in the preset in the pop up which will appear.

Changing preset mode from Home screen

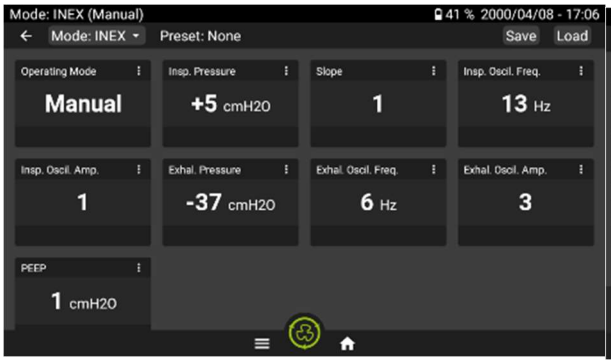


1. Available preset
2. Current preset / Activated preset
3. Empty preset

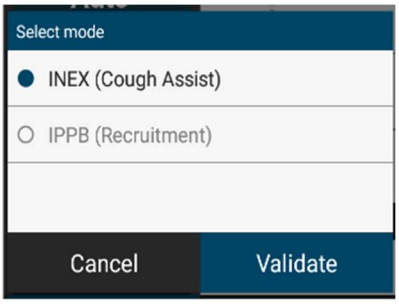
To change the preset, click on the preset you want to switch on.

Changing treatment mode

From the settings menu, click the mode bar on the upper left of the screen.



A pop up will be displayed to select the mode. Click on the desired mode and validate.



If the treatment is in progress, it is not possible to change the treatment mode.

Changing settings

In list setting display mode, several settings changes can be validated at the same time. In the boxes display mode, each setting must be adjusted individually.

List display mode

1. From the settings menu, click on one of the settings.
2. Adjust the settings with + and –
3. After all settings are adjusted, press Save to apply the changes.

Boxes display mode

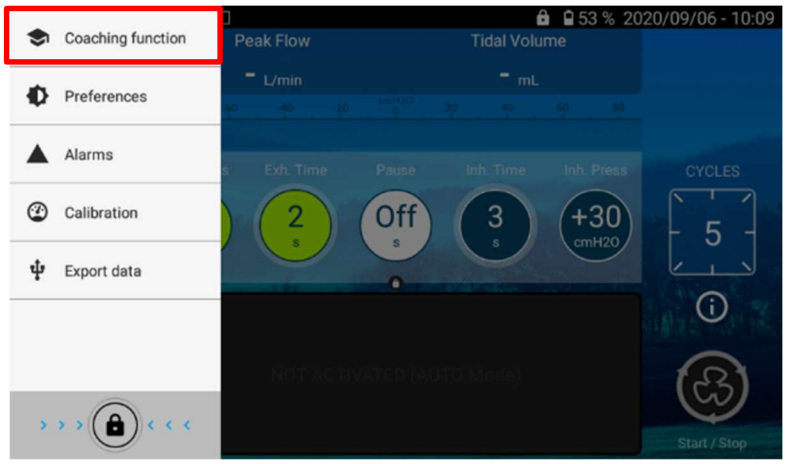
1. From the settings menu, click on one of the settings box.
2. Adjust the settings with + and – in the setting pop-up.
3. Validate the settings

Enabling the coaching function

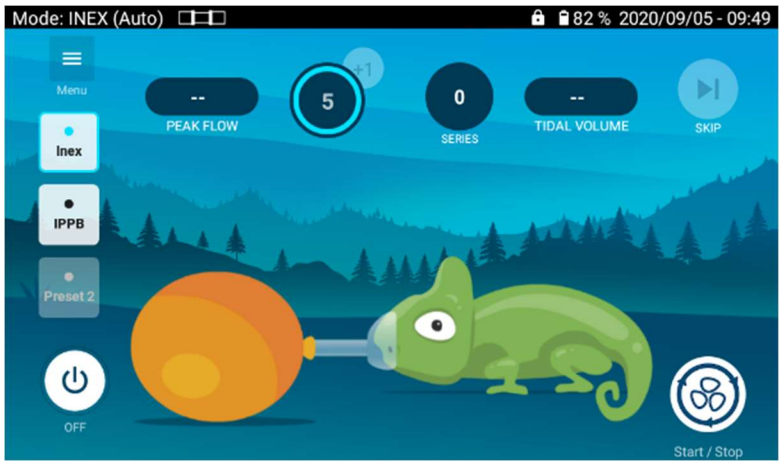
The user can switch to Coaching screen to perform a treatment previously saved as preset by the medical personal.

NOTE:	Coaching function is only available for preset with treatment in INEX-Auto mode or in IPPB mode.

From Home screen, click on to display the screens menu

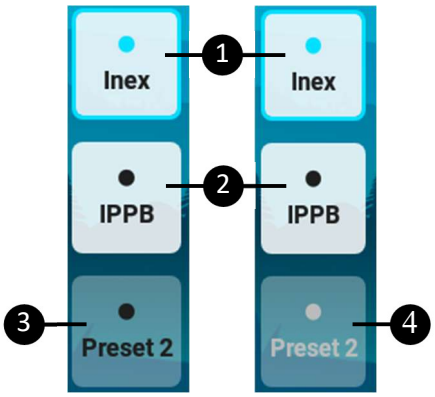


Choose the Coaching function screen.



NOTE:	The coaching function is not available for all treatment modes. A message will indicate if something is missing to start the function.
	If the screen indicates no compatible preset is available, contact your service provider.

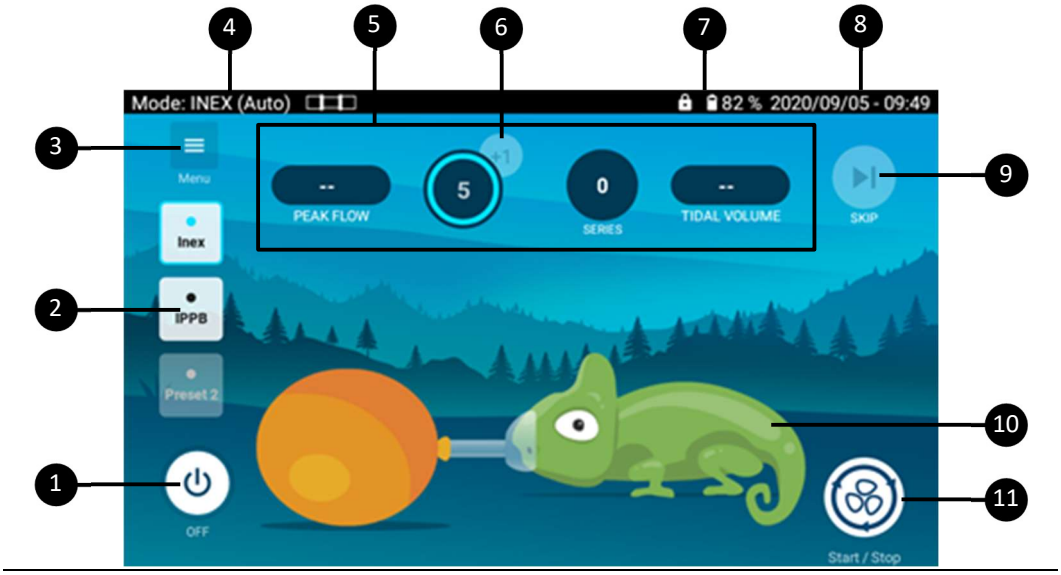
Changing preset mode from Coaching screen



1. Current preset / Activated preset
2.Available preset
3. Inactive preset (not available for Coaching)
4. Empty preset

To change the preset, click on the preset you want to switch on.
If the treatment is in progress, it is not possible to change the preset.

The INEX Coaching Screen

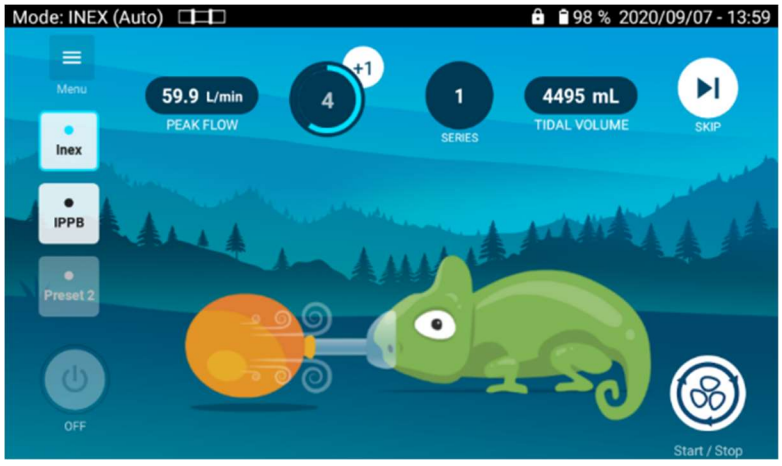


1. Power off button 2. Preset mode menu (1-3): Presets installed by the clinician and accessible to the patient when needed. 3. Menu button: Allows access to patient screen and clinical menus 4. Treatment mode indicator: INEX (manual/Auto) or IPPB 5. Treatment monitoring: display the live value for the displayed monitoring during treatment. 6. Cycle addition button: permit to add a cycle to the ongoing treatment if necessary	7. Battery life indicators: Indicates the level of charge left in the battery or whether the battery is charging. 8. Date: indicates the date on YYYY/MM/DD format. Time: Indicates the time on 24hr clock. This can be set up and changed from the Preferences menu. 9. Skip button: permit to stop the INEX serie on going. 10. Chameleon: Animation which will follow the treatment set up to help the patient 11. Start/Stop button: starts or stops treatment.

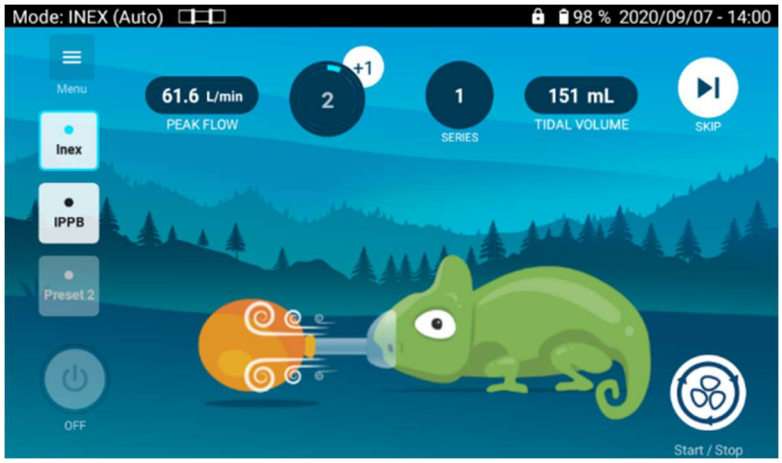
Performing an INEX treatment with Coaching function

Select a preset with an INEX Auto treatment and start the treatment. Chameleon and balloon animation will follow the treatment phases:

- During inhalation, chameleon inflates, and balloon deflates



- During exhalation, chameleon deflates, and balloon inflates

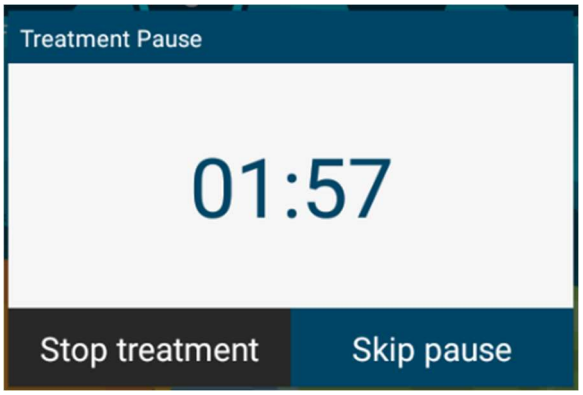


- During pause, chameleon and balloon do not move.

The monitorings:

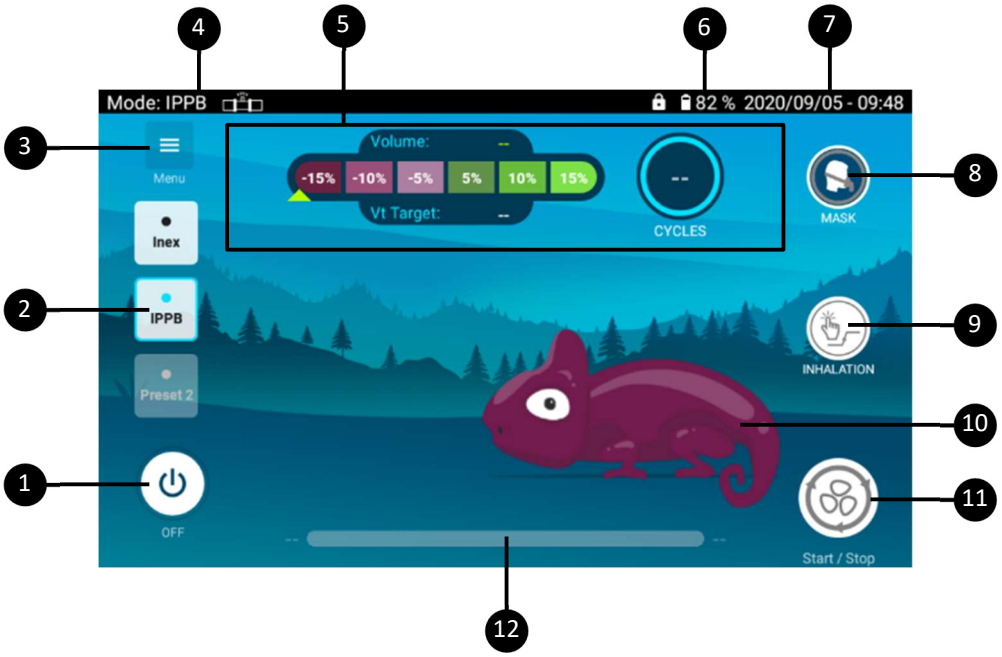
- The peak flow is updated after each exhalation
- The cycle decounter decreases after each exhalation. It can be increased with the «+1» button during the last cycle
- Series counter is incremented at each start of treatment. It is reset when changing preset or shutting down the devices
- Tidal volume is updated after each inhalation

At the end of the serie (or when stopping the treatment using the skip button), a pop up will appears to ask the patient if a new serie will be performed or not.



The timer is indicative. Click on «skip pause» to restart a serie or on «Stop treatment» to stop the treatment.

The IPPB Coaching Screen



1. Power off button 2. Preset mode menu (1-3): Presets installed by the clinician and accessible to the patient when needed. 3. Menu button: Allows access to patient screen and clinical menus 4. Treatment mode indicator: INEX (manual/Auto) or IPPB 5. Treatment monitoring: display the live value for the displayed monitoring during treatment. 6. Number of breaths.	7. Date and Time with format YYYY/MM/DD (can be changed in Preferences menu) 8. Leak indicator 9. Trigger button: permit to manually trigger an inhalation during a treatment 10. Chameleon: Animation which will follow the treatment set-up to help the patient 11. Start/Stop button: starts or stops treatment. 12. Treatment Time Bar: display the elapsed and the remaining treatment time during treatment when a treatment time is set by the clinician

Performing an IPPB treatment with Coaching function

Select a preset with IPPB treatment and start the treatment. Following the treatment set up, inhalation can either be triggered by the patient or by using the dedicated button.

Volume shows the volume live evolution during the inhalation. This monitoring stays to the final inhalation volume until the next inhalation. The breath counter is incremented at the beginning of each inhalation. At the end of each inhalation, the patient interface leaks are evaluated and the leak indicator  becomes green or orange. Orange will indicate that there is too much leak at the patient interface and that it should be better adjusted.

During inhalation, chameleon will inflates following the proportion of the target volume reached. It will progressively turn to green when reaching and exceeding the target volume.

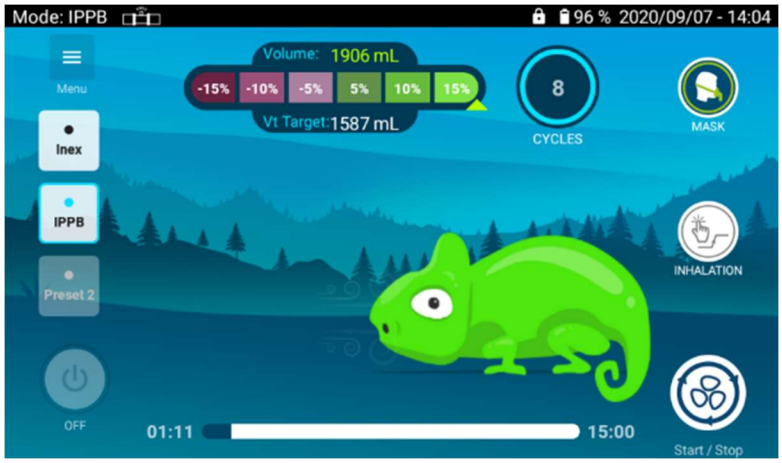
For the 3 first inhalations:

- Chameleon does not move
- V Target stays undefined

After 3 inhalations:

- V target is defined. It is the mean of the volume of the 3 first inhalations. It stays unchanged until end of the treatment.

During exhalation, chameleon will gradually deflate until reaching the initial position and colour. It stays like this until next inhalation. The volume bargraph arrow will move following the proportion of the target volume reached. It will stay to the maximum level reached until next inhalation.



Chapter 3 - Patient circuit, power supplies and accessories configurations

⚠	**WARNING**
•	**Use only CE marked circuit components approved for use with the EO-70.**
•	**Install patient circuit tubing carefully, to avoid risk of strangulation or tripping.**
•	**For usage in IPPB mode, a leak accessory must be added at the end of the circuit.**
•	**In IPPB mode, the leak orifice may not be enough to flush all patient CO2 depending on volume inspired and PEEP set. For prolongated usage, we strongly recommend setting a minimum PEEP of 4 cmH2O and exhal. Slope 1 minimum to allow minimum CO2 flush and checking that the patient is well tolerating the treatment.**

Patient Circuit installation

The EO-70 SMD device can be used with 22 mm diameter circuit only. It is recommended to use a bacterial filter at the outlet of the SMD device.

NOTE:	The applied part is located at the end of the patient circuit accessories.

INEX mode

1. Attach the antibacterial filter to the inspiratory port of the device.
2. Connect the breathing tube to the other side of the filter.
3. Perform a circuit calibration
4. Connect the patient interface to the other end of the breathing tube.

IPPB mode

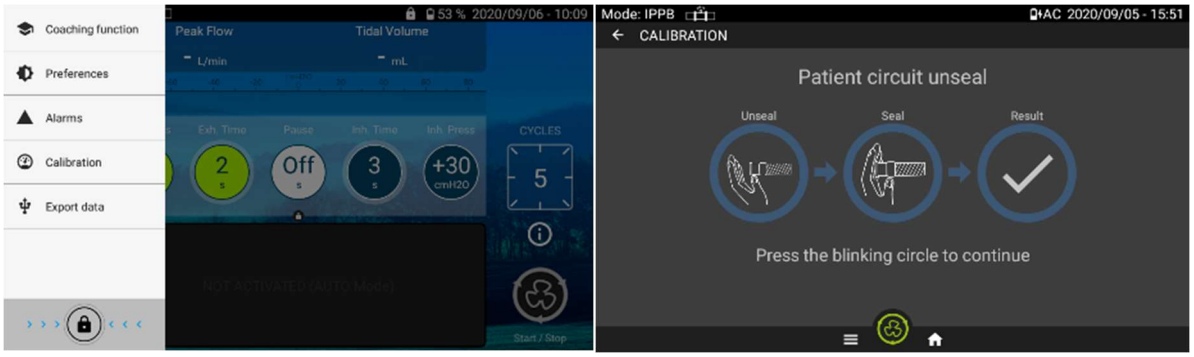
1. Attach the antibacterial filter to the inspiratory port of the device.
2. Connect the breathing tube to the other side of the filter.
3. Connect the leak accessory to the other side of the patient circuit.
4. Perform a circuit calibration
5. Connect the patient interface to the other end of the breathing tube.

Patient circuit calibration

For the EO-70 to provide expected performances, the patient circuit must be calibrated.
The procedure detailed below includes two steps and corresponds to the IPPB mode. In the INEX mode case, calibration will only include the first step.

1 – Select the desired mode and connect circuit and accessories (without patient interface)

2 – Access the calibration menu



3 – Unseal the patient circuit extremity and click on the blinking circle

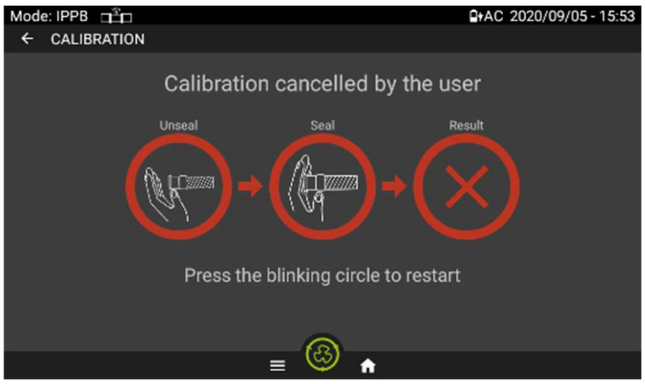
4 – Wait until the circle is completed

5 – Seal the patient circuit extremity and click on the blinking circle

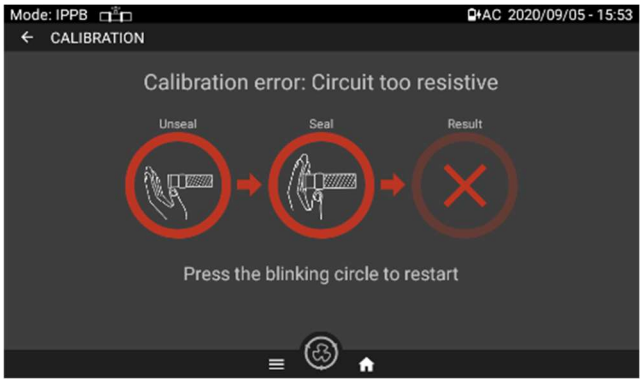
6 – Wait until the circle is completed

7 – Exit the calibration menu by clicking on “Validate”

At any time, calibration can be aborted if necessary (by pressing on “abort”, starting the treatment or selecting another menu), the data collected during the calibration in progress will not be recorded.



In case of error during the seal or unseal phases, the following message will be displayed:



Click then on “abort” to restart the process.

Accessories Compatible with EO-70

The EO-70 device is compatible with the following accessories:

- SPO2 Cable (EO-SPO2CBL)
- Remote control pedal (EO-70FSWITCH)

The EO-70 can be used with 22 mm diameter breathing circuits complying with CE regulations.

⚠	**WARNING**
	Before using any accessory, always carefully read the accompanying user Manual.
	The EO-70 device should only be used with accessories recommended by EOVE. Connection of other accessories could result in patient injury or damage to the device.

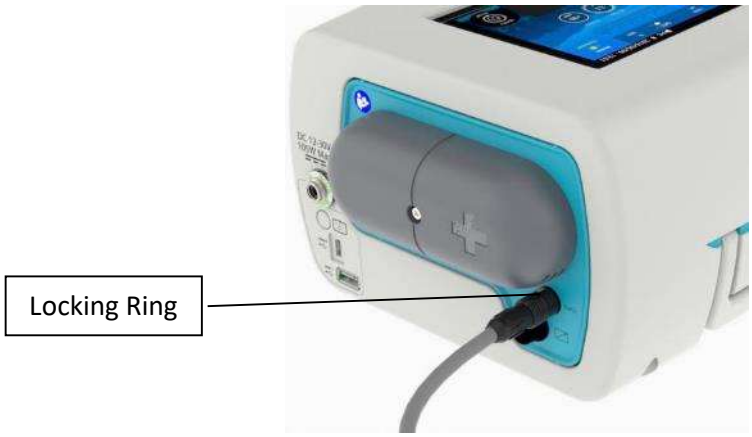
⚠	**WARNING**
	Do not use electrically conductive or anti-static air tubing.
	Due to their resistance to flow, accessories such as filters, many decrease patient pressure during inspiration and increase patient pressure during exhalation.

⚠	**WARNING**
	To prevent the risk of cross-contamination, an antibacterial filter is mandatory if the device is to be used on multiple patients.
	Regularly check the antibacterial filter for signs of moisture or other contaminants. **Failure to do so could result in increased system resistance and/or inaccuracies in pressures measurements.**
	Only use antibacterial filters that comply with the relevant safety standards, including ISO 23328-1 and ISO 23328-2.
	CAUTION
	The antibacterial filter must be used and replaced according to the manufacturer's specifications.

Attaching a pulse oximeter

⚠	**WARNING**
	Only use compatible NONIN finger pulse sensors
	CAUTION
	Some factors may degrade the performance of the pulse oximeter or affect the accuracy of the readings (e.g. blood flow restrictors (arterial catheters, blood pressure cuffs, infusing lines, etc.), excessive ambient light, excessive motion, electromagnetic interference, moisture in the sensor, improperly applied sensor, incorrect sensor type, a sensor not at heart level, poor pulse quality, venous pulsations, anemia or low hemoglobin concentrations, cardiogreen or other intravascular dyes, carboxyhemoglobin, methemoglobin, dysfunctional hemoglobin, artificial nails or fingernail polish.

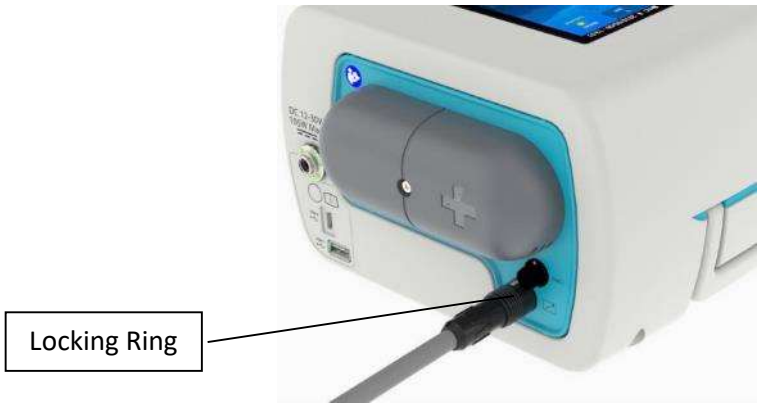
1. Connect the SpO2 adaptor (EO-SPO2CBL) connector at the rear of the device.
2. Connect the sensor to the adaptor and attach sensor to patient (according to NONIN instructions)



⚠	**CAUTION**
	To remove the cable, pull firmly on the locking ring. Do not twist.

Attaching a control pedal

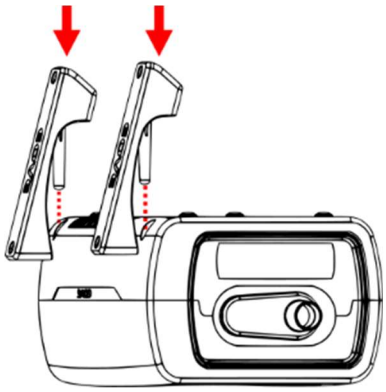
1. Connect the plug of the remote-control connector at the rear of the device.



⚠	**CAUTION**
	To remove the cable, pull firmly on the locking ring. Do not twist.

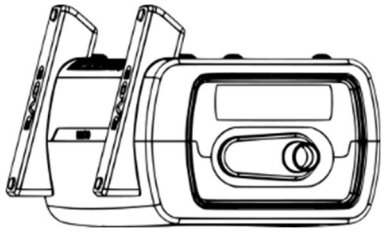
Upright Bracket installation for a vertical position of the device

1. Insert the upright brackets into the guides located on the lower housing of the device.

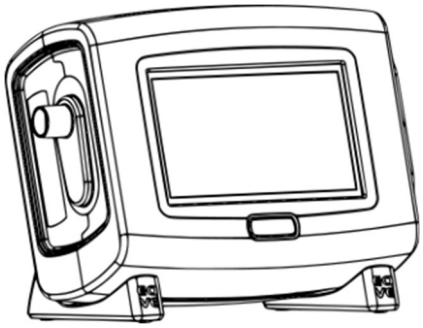


NOTE:	**Upright brackets are fully reversible and can be used on the right or left guide with the same feature**

2. Push the upright brackets until full contact with the lower housing.



3. Place the device on its upright brackets to use it on the vertical position



⚠	**CAUTION**
	Make sure to push the upright brackets until the contact with the lower housing to ensure good support for the device
	Be sure to check the positioning of the upright brackets after moving the device

Power Connections

⚠	**WARNING**
	Beware of electrocution. Do not immerse the device, power supply or power cord in water.
	Make sure the power cord and plug are not damaged and the equipment is in good condition.
	Keep the power cord and device away from hot surfaces.
	Explosion hazard—do not use in the vicinity of flammable anesthetics.

The EO-70 device can be used with two different power sources:

- Mains power
- Internal battery

For information on power supplies and sources see the technical specifications.

Connecting to mains power

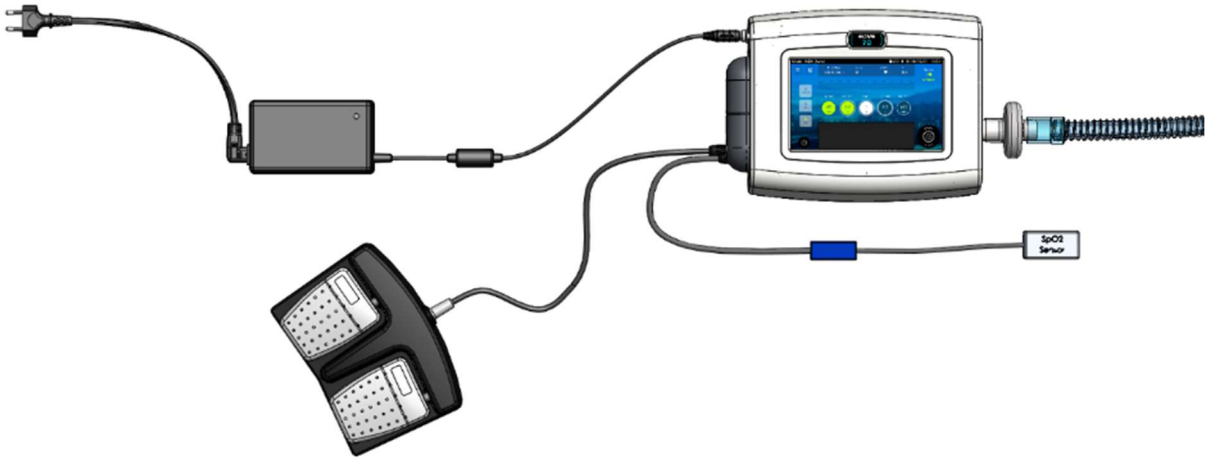
⚠	**WARNING**
	Ensure that the power cord does not pose a tripping or choking hazard.
	Ensure that the home AC mains supply and connections are safe and comply with the applicable regulations.
	Ensure that the device and its power charger are placed in a way that allows an easy disconnection from the mains.

To connect to mains power:

1. Connect the DC plug of the supplied external power supply unit to the rear of the EO 70 module or docking station. Ensure the connection is correctly aligned. Secure the connection by screwing the connector firmly in place.
2. Plug the other end of the power cord into the power outlet.

NOTE:	Do not twist or tug the power cord or the outer housing of the connector.

Complete assembly with accessories



Running the EO-70 on internal battery

⚠	**WARNING**
	The internal battery should be replaced every two years, or when a service notification is displayed.
	Replacement of lithium batteries or fuel cells by anyone other than trained personnel will result in dangerous risk (e.g., excessive temperatures, fire or explosion)
	The internal battery and any other device component should be disposed of following appropriate waste management regulations.
	The product owner must contact local authorities to identify the adapted way to dispose parts and accessories that could be dangerous for environment.
	CAUTION
	Plug device into AC mains power when the remaining capacity of the battery is low.
	The internal battery may stop charging when ambient temperatures of 35°C or more are reached.
	If the EO-70 device is left in storage for an extended period of time the internal battery will become depleted. If storing your device, recharge the internal battery once every four months. Never store a device with an empty battery.
	Storing the device at temperatures higher than 50°C for extended periods will accelerate battery ageing. This will not affect the safety of the battery or the device.

The internal battery of the EO-70 allows your SMD device to operate even when mains power is disrupted or when the device is not connected to the mains. When the EO-70 is operating on internal battery power, you are notified of the level of charge in the battery by the battery power source indicators both on the keyboard and touch screen.

NOTE:	The internal battery continues to charge when the device is connected to mains power, even when it is operating or on standby.
	The internal battery takes **6 hours** to fully charge from empty.

Battery run time

When the internal battery is being used to power the device, the amount of charge remaining in the battery is displayed as shown in the following table.

Touch Screen	Keyboard	Display Description
		When the internal battery is in use, the battery charge level is displayed by percentage on the touch screen and by 4 LEDs on the keyboard.
		When the internal battery is charging, the charge battery symbol is displayed on the touch screen and by scrolling LEDs on the keyboard.
		When the internal battery power is low, the charge battery symbol is displayed in red on the touch screen and the LEDs on the keyboard are red.

Internal battery run time is determined by:

- Environmental conditions (operating conditions See Technical Specifications)
- The condition and age of the battery
- The device settings
- The patient circuit used and the involuntary leaks

Storing and recharging

If the device is being stored with a 100% charged battery, its internal battery must be recharged every 4 months maximum during the storage period (recommended 2 months).
Never store a device with a depleted battery.

Prepare the battery for long-term storage

1. The battery charge level should be 100%.
2. Turn off the device.
3. Remove the power cord from the device.

Travelling with EO-70

The EO-70 must be transported in its transport bag.

⚠	**WARNING**
	The EO-70 device should not be operated while in the Transport.
	CAUTION
	Do not place any heavy or bulky objects in the zippered pocket on the inside front of the bag. This could result in damage to the touch screen.

Chapter 4 – Alarms indicator

The EO-70 is equipped with an alarm indicator to alert the user if the device is not functional for a technical reason. Those alarms are low priority (yellow indicator with no sound) and will all necessitate a technical support.

If the yellow alarm indicators are active, call your service provider or Eove customer support to have your device serviced.

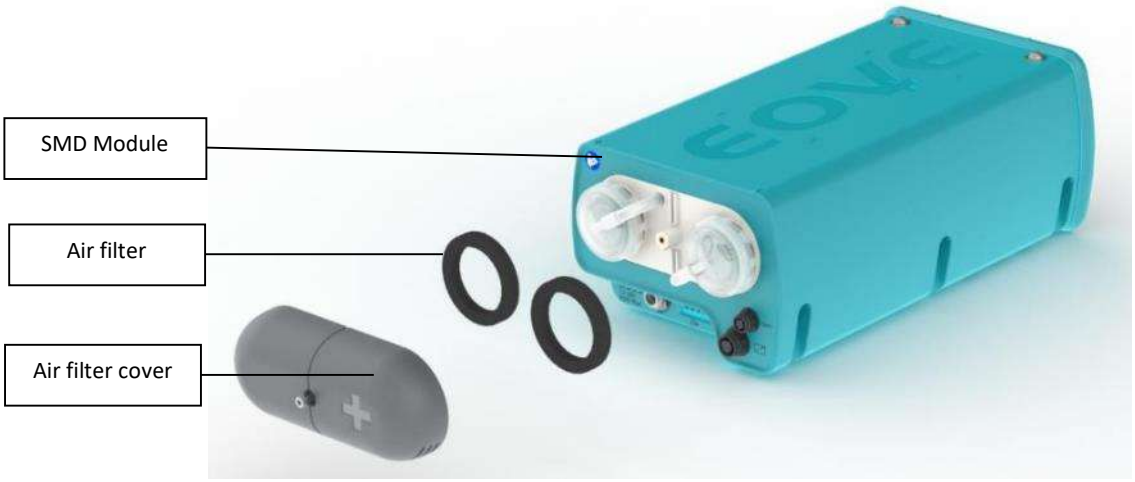
Chapter 5 - Routine Cleaning and Maintenance

⚠	**WARNING**
	Patients are vulnerable to infections. All equipment should be regularly cleaned and disinfected.
	Keep the device, and accessories away from water and all other liquids not specified in this document. Always turn off and unplug the device before cleaning and verify that it is dry before plugging it back in.
	CAUTION
	Clean only exterior surfaces of the EO-70 device.
	If necessary, wipe the exterior of the device with a damp cloth using a mild cleaning solution.
	For all circuit components and hoses, follow the manufacturer's recommendations for cleaning and maintenance.
	For disinfection, we recommend usage of products such as Microzid® sensitive liquid from Schülke or WILAsil® from WILAmed. For other product usage, please contact our customer service.

Proper cleaning and maintenance of your EOVE device is essential. Cleaning described in this section should be carried out regularly.
Refer to the user guides of any accessories in use for detailed instructions specific to those devices.

Maintenance	Method	Frequency
Inspect the condition of the connections and circuit adapters for any moisture or contaminants	Replace and clean as necessary using appropriate cleaning solutions	Weekly
Check the charge level of the internal battery	1.Unplug the device from external power and operate it for 10 minutes minimum. 2. Check the remaining battery level. 3. Restore the mains when the test is done.	Every six months (with normal daily use)

⚠	**CAUTION**
	The air filters cannot be washed or reused.



Instructions for hygienic reprocessing at patient change

The following process must be followed before change of patient:

- Wipe disinfection (of device housing exterior)
- Replacement of Bacterial filter or HME filter
- Replacement of patient circuit or sterilization of reusable circuit system
- Replace Air filter
- Function Check

Follow this procedure also for devices which have been previously been used by patients in whom MRSA infection, for example, has been verified. Please take all precautions for your own protection when reprocessing a device.

For disinfection, we recommend usage of products such as Mikrozid® sensitive liquid from Schülke or WILAsil® from WILAmed. The following basic products could be used:
- IPA (Iso Propyl Alcohol)
- Ethanol 70%
- Hydrogen peroxyde
- Chlore (1000 ppm)

For other product usage, please contact our customer service.

It is important to avoid the spilling of liquid on the electrical connector of the device. User must ensure that the disinfectant is dry before turning on the device. It is possible to use other equivalent disinfectants, however, the proof of compatibility of the product with the device is the responsibility of the manufacturer of this product.
The EO-70 device external surfaces in contact with the disinfectant products are made with the materials listed below:
- PC ASA UL94V0
- Terluran GP22 (ABS)
- FT Santoprene 8211-55B100
- Glass
- Polyester
- Polypropylene

Servicing

	**WARNING**
•	**Maintenance of the EO-70 device should be carried out by a trained technician. Attempting to repair the machine yourself could result in patient injury or damage to the machine.**
•	**It is forbidden to modify the EO-70 without manufacturer authorization.**
NOTE:	Retain the original packaging to use when shipping to/from service agent.

Maintenance Timetable

The EO-70 should be regularly serviced by an authorized EOVE technician according to the following schedule. The SMD device will provide safe and reliable functioning for 10 years provided that it is operated and maintained in accordance with the instructions given in this manual. As with all electrical devices, if any problem arises with your EO 70 device, you should exercise caution and have it inspected by an authorized EOVE technician.

Servicing schedule from the date of first use:

Recommended Service	Conducted by	Instructions
Every 1 year	Qualified EOVE technician	Replace the air filters
Every 2 years	Qualified EOVE technician	Replace internal battery or if service notification is displayed. Replace silicone membranes and micro-pump.
Every 20,000 hours of use	Qualified EOVE technician	Replace turbine

Essential performances

The EO-70 essential performances can be evaluated with this reference test :

Settings:
INEX Mode, Operating mode: AUTO, Inh. Pressure: 30 cmH2O, Slope: 3, Inh. Time: 3 s, Trigger : off, Pause : 1 s, Peep: 4 cmH2O, Exh. Pressure: - 30 cmH2O, Exh Time : 2 s, Insp. Oscillations I: on (Amp. 2, Freq. 10 Hz), Exp. Oscillations : OFF.

In these conditions, with a 22 mm tubing and a test lung (Compliance : 20 mL/mbar, Resistance : 20 mbar / L / s, Max volume 1000 mL), monitoring should be the following:
Tidal Volume: 700 ml +/- 140 ml
Peak Flow: 125 l/min +/- 25 l/min

Chapter 6 - Device information

Timing Operation

	WARNING
•	INEX mode of EO-70 is designed for an intermittent use (non-continuous). The device has to be in stand-by for a duration equal to the preceding usage time (typical use of 1 min 30 sec should be followed by a minimum stand-by period of 1 min 30 sec). For clinical reasons, it is not recommended to exceed 5 minutes of continuous usage. IPPB mode can be used continuously, within the limits of clinical indications.

Physical Specifications

Docking Specifications:	Weight: < 1.5 kg	Size: 250x210x131 mm
SMD Module Specifications	Weight: < 1.9 kg	Size: 300x140x105 mm

Functional Specifications

The EO-70 can be used in the following treatment modes:

- INEX: Insufflation - Exsufflation
- IPPB: Intermittent Positive Pressure Breathing

INEX

Auto operation

The Auto Mode delivers the therapy accordingly to the settings of: Inhalation Pressure, Exhalation Pressure, Inhalation Time, Exhalation Time, Pause Time, PEEP and Rise Time. The therapy delivered will follow the sequence below for the Number of Cycles set or until the user stops the therapy:

- PEEP (if set) during the Pause Time.
- Inhalation Pressure during the Inhalation Time.
- Exhalation Pressure during the Exhalation Time.

The therapy will end following the setting «Treatment end» (Inhalation or exhalation). The time that the device uses to reach the Inspiratory Pressure depends on the setting of the Rise Time.
In Auto Mode, it is possible to set a Trigger that allows the patient to start the cycle during the pause period.

Manual operation

The operator will determine the inspiration and exhalation time by switching the touch pad to the left (triggers an inspiration) and to the right (triggers an exhalation). When the touch pad is released, the device starts a pause phase and controls PEEP.

Setting	Range	Limitations
Operating mode	AUTO / MANUAL	In manual mode the insufflation and exsufflation are triggered by the user.
Inh. Pressure (cmH2O)	5 - 70	None
Slope	0 - 5	None
Inh Time (s)	0.5 - 5	Only applies in AUTO mode.
Insp. Oscillation Freq. (Hz)	4 - 20	None
Insp. Oscillation Amp.	1 - 3	None
Trigger	OFF/1 - 3	Only applies in AUTO mode. Not compatible with timed Pause.
Exh. Pressure (cmH2O)	0 to -70	None
Exh. Time (s)	0.5 - 5	Only applies in AUTO mode.
Exhal. Oscillation Freq. (Hz)	4 - 20	None
Exhal. Oscillation Amp.	1 - 3	None
Pause (s)	OFF / 0.5 - 5	Only applies in AUTO mode. Not compatible with Trigger. (Hidden when Trigger is set)
PEEP (cmH2O)	OFF / 1 to 20	None
Cycles Nb	1 to 20	Only applies in AUTO mode.
Treatment End	Inhalation/Exhalation	Only applies in AUTO mode

IPPB

The IPPB Mode delivers the therapy accordingly to the settings of: Inhalation Flow, Pressure Max, Inhalation Max Time, Inhalation Slope, PEEP, Exhalation Fall and Inhalation Trigger.
The therapy delivered will follow the sequence:

- Inhalation flow during inhalation
- Exhalation Fall and PEEP during exhalation

During the inhalation phase, the device delivers the Inhalation Flow until the device reaches one of the two limits: Pressure Max or Inhalation Max Time.
When Inhalation Slope is ON, the device will decrease the Inhalation Flow as pressure is increasing in order to reach the Pressure Max when the flow decreased at half of the Inhalation Flow.
During the exhalation phase, the device switch to the set PEEP decreasing the pressure accordingly with the Exhalation Fall.
The Trigger function allows the patient to start the therapy during the exhalation. The touch pad can be used to trigger the inhalation.
The treatment time, if activated, will automatically stop the treatment at the end of the set time.

Setting	Range	Limitations
Inh. Flow (l/min)	5 - 100	None
Inh. Slope	ON/OFF	None
Pressure Max. (cmH2O)	10 - 50	None
Inh. Trig.	OFF / 1 - 5	None
PEEP (cmH2O)	OFF / 1 - 20	None
Exh Slope	0 - 5	None
Inh. Max Time (s)	0.5 - 20	None
Treatment time (min)	OFF/ 5-30	None

Accuracy of settings

- Pressure (plateau) : ± (1 cmH2O + 10%)
- Pressure peaks : ± (2 cmH2O + 20%)
- Time : ± 0.2 s
- Flow : ± (5 l/min + 10%)

Monitored Parameter Specifications

(Rounded values for readings)

Inspiratory Tidal Volume (VTI)	0 to 4000 ml
Inspiratory Time (I Time)	0 to 9.9 s
Exhalation Time (E Time)	0 to 9.9 s
Pause Time (P Time)	0 to 99.9 s
SpO2	0 to 100 %
Heart Rate	0 to 300 bpm
Peak Exhalation Flow	0 to 300 l/min
Rate	0 to 99.9 bpm

A monitored value displayed as "-" means that the measurement is not available or invalid.

Accuracy of monitoring data

- Inspired volume: ± (10 ml + 10%)
- Time : ± 0.2 s
- Peak Flow : ± (5 l/min + 15%)
- SPO2 : according to manufacturer specifications
- Heart Rate : according to manufacturer specifications
- Rate : ± 1 c/min

Power specifications

	**WARNING**
	This device is intended to function with external power supply 2440 from Mascot, never use any other power supply unless recommended by Eove.
	To disconnect the device from the mains, unplug power supply.

AC Inlet Voltage	100-240V
AC Inlet Power	1.6-0.7A
AC Inlet Power	50-60 Hz
DC Inlet voltage	12 to 30 V
Power	115w maximum
Internal battery capacity voltage discharge current	2,8 Ah 21,6 V nominal 7 A max.

Environmental Specifications

Storage and transport conditions:

Ambient temperature	From -20°C to +60°C.
Relative humidity	From 10% to 95%, (non-condensing)
Waiting time before usage after storage at extreme temperatures (min or max).	2 hours

Operating conditions:

Ambient temperature	From +5°C to +35°C (after conditioning at 23° for 20 minutes)
Relative humidity	From 10% à 95%, (non-condensing).
Atmospheric pressure	From 700 hPa à 1060 hPa. (by default, EO-70 compensates for atmospheric pressure variations e.g. related to altitude up to 3000 m).
Start-up time	< 1 min

Software versions

Main: C070 0006XX	Power: P150 0004XX	Interface: V2.3.X_APIXX_TRXX

Guidance and Manufacturer's Declaration Electromagnetic Emissions & Immunity

⚠	**WARNING**
	The EO-70 should not be used in close proximity to other equipment or stacked on top of other devices. If this kind of use is unavoidable, the device should be checked carefully and observed to ensure correct functioning of the device.
	Only accessories recommended for the EO-70 should be used. Using any other accessories could result in risk to the device or the patient.
	Any additional equipment connected to medical electrical devices must comply with the respective IEC or ISO standards (eg, IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Adding additional equipment configures a medical system and this system must comply with the requirements for medical electrical systems. Any person undertaking this kind of addition shall be responsible to ensure that all requirements are complied with. It is important to note that local laws take priority over the above mentioned requirements. If in doubt, consult an EOVE representative or the technical service department.
	Interference may occur in the vicinity of equipment marked with the following symbol: 
	EO-70 is designed for use in the electromagnetic environment described below. Those using the device should ensure that the EO-70 is used in such an environment.
	No RF communication equipment (including antenna's cables or antennas) should be closer than 30 cm (12 inch) of any part of EO-70, including cables. Otherwise the functioning of these devices could be altered.

Electromagnetic emissions

Emissions test	Level of compliance	Guidance for EM environment
RF emissions CISPR 11	Class B	EO-70 is suitable for home health care environment and a professional health care establishment
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complying	

Electromagnetic immunity

Immunity Test	IEC 60601 level	Level of compliance	Guidance for EM environment
Electrostatic discharge (ESD) IEC 61000-4-2	8 kV contact 15 kV air	8 kV contact 15 kV air	For home health care environment and a professional health care establishment
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	2 kV for power supply lines 2 kV for input/output lines	For home health care environment and a professional health care establishment
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	1 kV differential mode 2 kV common mode	For home health care environment and a professional health care establishment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% Ut for 0.5 cycle With 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0% Ut for 1 cycles 70% Ut for 25 cycles at 50 Hz 0% Ut For 30 cycles at 60 Hz Monophased at 0°	0% Ut for 0.5 cycle With 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0% Ut for 1 cycles 70% Ut for 25 cycles at 50 Hz 0% Ut For 250 cycles at 60 Hz Monophased at 0°	Mains power quality should be as home health care environment and a professional health care establishment If operating during power cuts, it is recommended to use other power sources.

Immunity Test	IEC 60601 level	Level of compliance	Guidance for EM environment
Voltage Interruption IEC 61000-4-11	0 % UT for 250 cycles at 50 Hz for 300 cycles at 60 Hz	0 % UT for 250 cycles at 50 Hz for 300 cycles at 60 Hz	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	For home health care environment and a professional health care establishment
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 V in ISM band and from 0.15 MHZ to 80 MHZ, amateur radio band included 80% MA at 1 KHz	6 Vrms 150 kHz to 80 MHz 6 V in ISM band and from 0.15 MHZ to 80 MHZ, amateur radio band included 80% MA at 1 KHz	For home health care environment and a professional health care establishment
Electromagnetic fields Radiated RF* IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.7 GHz	For home health care environment and a professional health care establishment

Immunity Test	IEC 60601 level	Level of compliance	Guidance for EM environment
Proximity fields emitted by RF wireless communication devices IEC 61000-4-3 (provisional method)	9 V/m : 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m : 385 MHz 28 V/m: 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m : 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5500 MHz, 5785 MHz 27 V/m : 385 MHz 28 V/m: 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	For home health care environment and a professional health care establishment

Recommended separation distance

EO70 device must be used in an electromagnetic environment in which the perturbations due to RF are controlled.

The user or installer of the device can help to prevent any electromagnetic interference by maintaining a minimum distance depending on RF emitter maximum power. Portable RF devices (included cables and antennas) must not be used closer than 30 cm (12 inches) from any part of the EO 70, including specified cables. Not respecting this recommendation could lead to performance alteration.

NOTE:	Additional technical description (pneumatical description, theory of operation, measurement uncertainty, functional tests) can be found in the technical manual

Standards compliance

The EO-70 meets the following standards:

EN ISO 14971: Medical Device Risk Management
IEC 60601-1 Ed3 (&CSA22.2): Medical Electrical Equipment –Part 1: General Requirements for Safety 1: Collateral Standard: Safety Requirements for Medical Electrical Systems
The device is classified according to Chapter 5 of the norm CEI 60601-1, as follows:

Class II Equipment
Internally Powered Equipment
Type BF Applied Parts
IP22 with respect to access to hazardous parts and ingress of moisture
Not suitable for use in the presence of flammable anaesthetic mixtures
Not suitable for sterilisation
Non continuous operation (50%)
Detachable power supply cable

IEC 60601-1-2: 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: Medical Electrical Equipment – Part 1-6 General requirements for basic safety and essential performance – Collateral Standard – Usability
CEI 60601-1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Cybersecurity contact

If you believe you have discovered a vulnerability or have a security incident to report, please contact us at **security@eove.fr** .

Use this email for all information security incidents to ensure they are correctly captured and handled in a timely manner. If you have discovered a security concern, we will work with you to make sure that we understand the scope of the issue and that we address the exposure.

Training and support

Training and support are available on the EOVE website, www.eove.fr or by calling our helpline at +33 05 59 21 86 84

Limited warranty

The seller guarantees that the Product delivered complies with the use for which it is intended, and guarantees the Purchaser in this respect from defects in materials and workmanship.

Subject to the extended warranty that the Seller may offer to the Purchaser, depending on the Product, the Seller offers to the Purchaser a TWELVE (12) month warranty period, covering the costs of defective parts. Such warranty shall be effective from the expiration of a FIFTEEN (15) day period following the invoice date.

This warranty is only applicable when Products are installed and operated in accordance with factory recommendations and user manual instructions. This warranty specifically excludes damage or wear to Products caused by misuse, abrasion, corrosion, negligence, accidents, faulty installation or by using material incompatible with the Product. Also, this warranty does not cover associated consumables or disposables relative to the use of the Product.

Whatever the claim on the quality of the Product made by the Purchaser, the latter remains liable for paying the corresponding amounts, on their due date.

The condition of the supplied Products must be verified by the Purchaser upon receipt. As such, any claim from the Purchaser based on the quality of the Product must be made by written notice within THREE (3) days from the discovery of the relevant defect. The Purchaser shall be responsible for providing all necessary proofs showing evidence of defects or non-conformity.

Once defects or non-conformity are duly recorded by the Seller, the Purchaser may return the relevant Product if the Seller believes that it can be repaired in whole or in part. Otherwise, the Seller shall substitute the non-repairable dysfunctional equipment with equivalent new equipment.

In any case, any return of Products requested by the Purchaser must be agreed in writing by the Seller. In particular, no returns will be accepted if:

- Products have not been installed and operated in accordance with factory recommendations and user manual instructions;

- Products are no longer in their original packaging;

- Products are not accompanied by their instruction manuals and accessories;

- Products have been repaired by a non-Seller-accredited provider.

CE 0459

EOVE
4 bd Lucien Favre
Bâtiment Poincaré
64000 Pau France

www.eove.fr

T +33 05 59 21 86 84