AC-70

Secretion Management Device

User Guide (patient)

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Introduction

The AC-70 (ref AC-70) Secretion Management Device (SMD) provides assistance 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.

Intended use

The **AC-70 Secretion Management Device** is an element of airway secretion management therapy, which seeks to assist patients unable to autonomously remove airway secretions and improve their pulmonary volume capacities. Within airway secretion management therapy, the AC-70 **Secretion Management Device** provides INEX and IPPB modes for paediatric and adult patients weighing at least 10 kg (22 lbs).

To do so, the device is equipped with two complementary modes:

- An insufflation-exsufflation mode (INEX), which delivers a positive pressure followed by negative pressure to promoting a rapid breathing outflow;
- An intermittent Positive Pressure Breathing mode (IPPB), which delivers a constant airflow to promote deep inspiration.

The AC-70 device may be used either with a mask, mouthpiece or tracheostomy tube.

Medical indication

Indications for mechanical cough (INEX) assistance therapy and IPPB therapy are the following:

Physiological characteristics :

- A vital capacity (VC) of <50% of the predicated value*;
- Incapacity to generate cough flow peaks of >4.2 L/s (or 250 L/min) (only for INEX therapy);
- Abnormal lung growth or chest wall development in paediatric patients (only for IPPB therapy);

** predicated value: value for an equivalent healthy patient*

Clinical characteristics :

- Neuromuscular disease;
- Polyneuromyopathy;
- Paralytic disease.

Environment of use

The AC-70 device is intended to be used in home, institution, hospital. This device is transportable but not intended for use during transport.

Users

AC-70 Secretion Management Device is designed to be used by the following users:

The non-specialist operators, as defined by the IEC 60601-1:

- The patient,

- The patient's family,
- The patient's caregivers

The clinician operators:
- Doctors,
- Nurse,
- Physiotherapist

The responsible organization operators:
- Installation technician
- Maintenance technician

Following appropriate mandatory training from the responsible organization operators, patients, and/or caregivers should be able to safely perform the following operation:
- Start and stop the device
- Start and stop therapy;
- Switch presets
- Change preference settings (e.g.interface display related setting such as date or luminosity)
- Perform circuit replacement and circuit calibration

Furthermore, patient and /or caregivers are not intended to:
- Change clinical settings;
- Perform any maintenance operation.

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

Contraindications
- A history or current symptoms of respiratory disease (i.e. pneumothorax and pneumomediastin) ;
- Tracheoesophageal fistula;
- Epistaxis;
- Severe gastroesophageal reflux with risk of aspiration;
- Severe oesophageal and gastric varices

Adverse Effects
The **AC-70 Secretion Management Device** may cause the following undesirable side-effects for adults and children:

- Nausea;
- Bradycardia;
- Tachycardia;
- Pneumothorax;
- Dry nose or mouth;
- Eye irritation;
- Abdominal and gastric distension, bloating;
- Skin wound;
- Sinus discomfort;

For children only:

- Crying;
- Agitation;
- Thoracic wall discomfort;
- Exacerbation of preexisting chronic abdominal pain;
- Oesophageal reflux.

Clinical benefits

The direct benefit to the patient is provided by the ventilation therapy, the AC-70 Secretion Management Device itself only has indirect benefit.

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**
•	**Do not add intermediate pieces or accessories to the AC-70 device that are not listed in the operating instructions, otherwise the device may not work properly**
•	**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 AC-70 device**
•	**The AC-70 device is a restricted medical device intended for use by qualified trained personnel, under the direction of a doctor. User lack of training or lack of knowledge about the device could lead to patient risks such as Barotrauma.** Note: a barotrauma can be characterized by sudden, violent chest pain (stabbing like), bloody pulmonary secretion and/or breathing difficulties and sudden shortness of breath during the therapy.
•	**Use the AC-70 device only as directed by a doctor or healthcare provider.**
•	**Information in this manual does not supersede instructions given by the prescribing doctor.**
•	**Follow doctor prescription for the use of the AC-70 device. Lack of therapy can lead to health degradation of the patient, e.g. moderate desaturation.**

•	**Install and configure the AC-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 AC-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 AC-70 device in direct contact with the patient for extended periods of time.**
•	**The AC-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.**
•	**In case of open wounds or skin lacerations, avoid touching the AC-70 device**
	CAUTION
	The AC-70 device is transportable but not intended for use during transport.
	Do not expose the AC-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 AC-70 device is not a ventilator and should not be used for other purpose than occasional secretion management.

Chapter 1 – Description of the AC-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

References of the Secretion Management Device module, docking station and accessories included in the first shipment

AC-70 device, ref AC-70SMD includes:

- A secretion management module: **AC-70 SMD module**, ref **AC-70SM**
- A docking station: **EO-1X0 Docking station**, ref **EO-DCK70**
- A power supply (AC/DC): **EO Charger module**, ref **EO-PWRCHRG**
- A pair of upright brackets, ref **EO-UPRIGHT**
- A bag for transport: **Transport Bag,** ref **EO-CARBAG70**
- A user manual

Serial Number explanation

The serial number of AC-70 can be found on the label just after the SN symbol. It appears also after the application identifier (21) encoded in the barcode. The format is EO070YYMMiiiX. It includes the manufacturing date at the format YYMM.

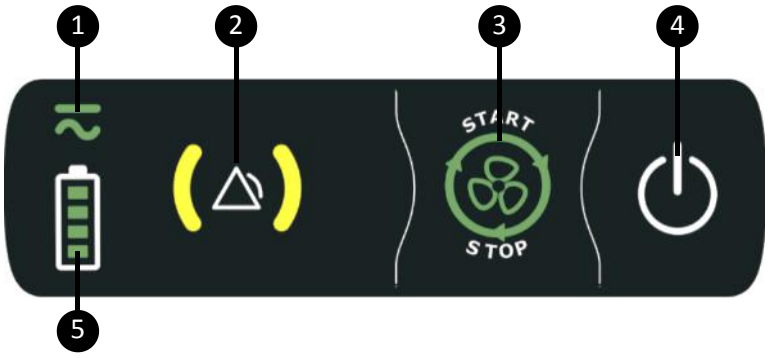
The format was updated since serial number SN EO070021xxxxxx. Before that, the format was EO070MMYYiiiX.

Example: The AC-70 secretion management device below was built in January 2024.

Three different stickers can be found on EOVE devices and packaging:

- One sticker with a C extension after the Serial Number placed on the main device box
- One sticker with a B extension at the end placed on the device module
- One sticker with an S extension at the end placed on the docking station

Keyboard



1. Power source indicator
2. alert indicators
3. Therapy 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			
	alert indicator		
	Battery level indicator		AC/DC power indicator
	On/Off button		therapy start / stop button
Touch interface symbols			
	therapy start		therapy 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
	alerts 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 (INEX)		Leak Indicator (inactive)
	Leak Indicator (excessive interface leaks)		Leak Indicator (acceptable interface leaks)
	Breath triggering on touch pad (IPPB and INEX Auto)		INEX Manual mode actions: Slide Right = inspiration / Slide Left = Exhalation / Release = Pause
	Circuit without leak needed (INEX mode)		Circuit with leak needed (IPPB mode)
	Reset of the target volume (IPPB)		

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
CE 0459	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
95 % 10	Storage and transport humidity range	MD	Medical device
	Importer		Atmospheric Pressure Limitation range
https://eove.fr	Consult electronic instructions for use		Do not push (symbol for trolley accessory)
	Do not step (symbol for trolley accessory)	: 20kg	Maximum weight for trolley (including SM Device and accessories)
AC power supply additionnal symbols			
	Consult instruction for use	c US	UL certification for US and Canada
	For indoor use only	EAC	Complies with UEEA legal requirements

Chapter 2 – Operating Instructions for the AC-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 AC-70 device is transported using the EOVE Transport bag.
	Always protect the device from water if transported outdoors.

Set Up Test

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

⚠	**WARNING**
•	**If an alert 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 AC-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 therapy and verify air is coming in and out of the device outlet

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

Turning on the device

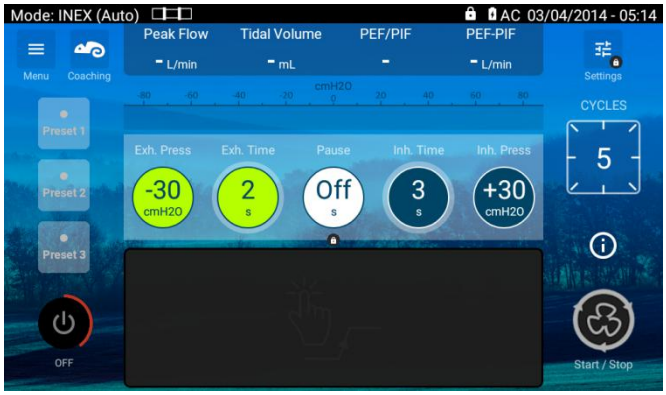
Ensure the device has been charged prior to use or connect to AC power or DC connector inlet.

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 AC-70 device cannot be powered off during therapy
	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

In order 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. Below 10% of battery, it will not be possible to start a therapy anymore.

Starting and Stopping therapy

Therapy can be started and stopped from either the touch screen or from the keyboard. Various preset therapies 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** therapy using the keyboard:

1.	Press on the Keyboard
2.	therapy starts.

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

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

To **STOP** therapy using the Keyboard:

1.	Press on the keyboard
2.	therapy stops.

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

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

	CAUTION
	The AC-70 device cannot be powered off during therapy
	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 therapy according to the previously set parameters.

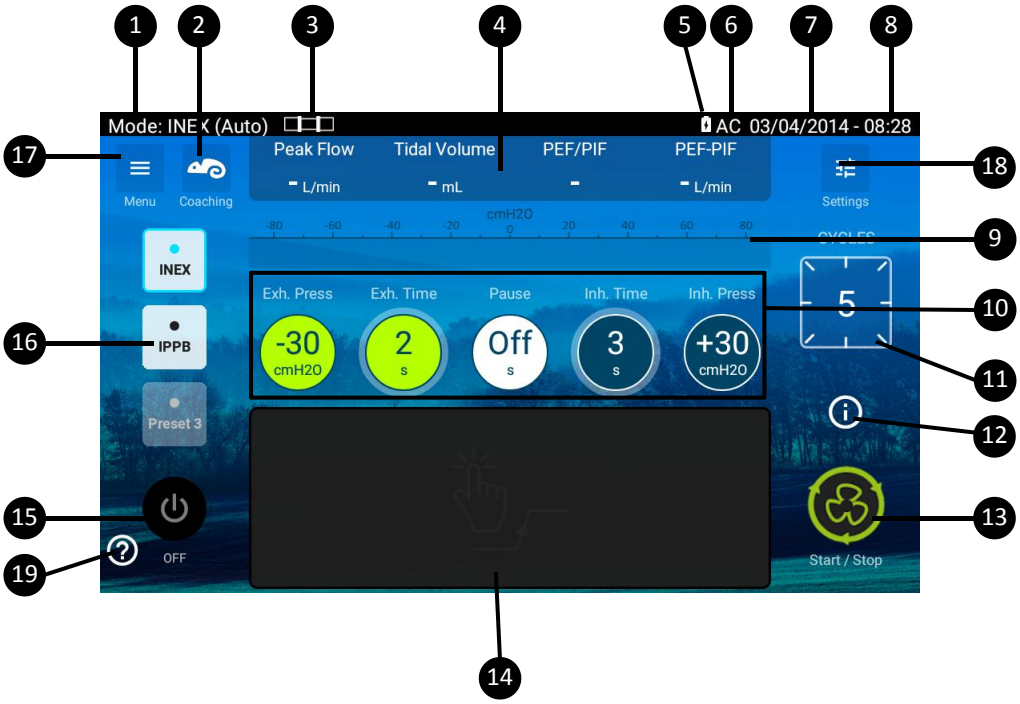
6. To charge the module, plug it back in the docking station and restore the mains connection.

	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.**

NOTE: When module is outside the station, the waveforms and monitorings will not be recorded and could not be visualized on the clinical software

The Home Screen

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



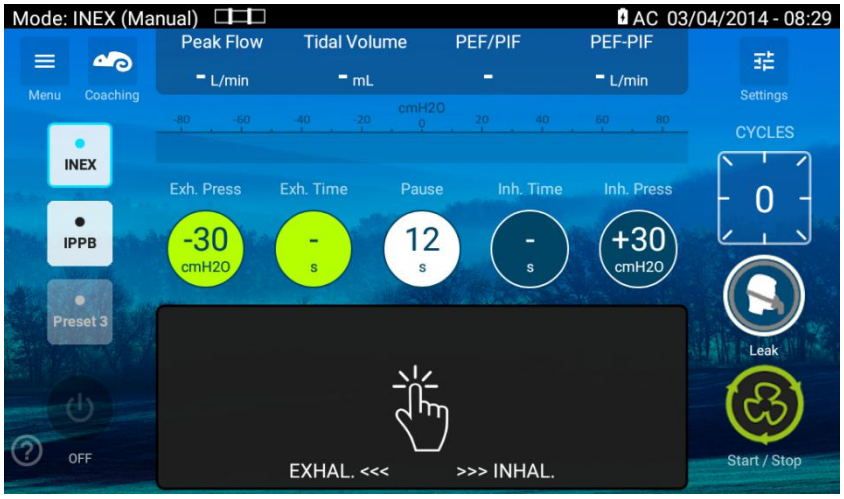
1. Therapy mode indicator: Choose from INEX, IPPB in the settings menu 2. Coaching button: Allow access to coaching function. 3. Leak necessity indicator. 4. Therapy monitoring: display the live value for the displayed monitoring during therapy. 5. Battery life indicators: Indicates the level of charge 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 inspirations 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. Therapy cycles remaining. 12. Settings information when therapy is OFF or Leak indicator when therapy is ON 13. Therapy Start/Stop Button. 14. Touch pad: in INEX mode, permit to manually manage the therapy. All tactile actions with right movement trigger an inspiration, all actions with left movement trigger an exhalation. In IPPB and INEX Auto modes, 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. 18. Settings button: Allow access to settings menu. 19. Help button: Allow to display the patient or clinican manual.

Using the Touch Pad

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

INEX mode Manual operation

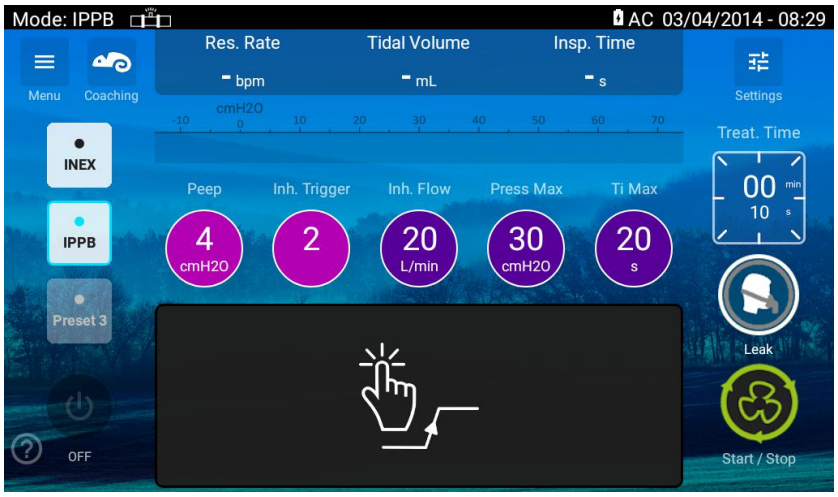
In INEX mode, the operation must start in the Touch Pad black area but then the full screen surface can be used if the finger keeps the contact with the screen.



1. Start the therapy. 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 and INEX Auto mode operation

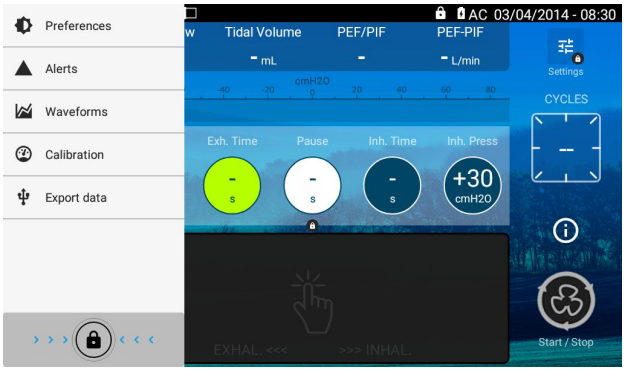
In IPPB and INEX Auto mode, a simple touch on the Touch Pad will trigger an inspiration.



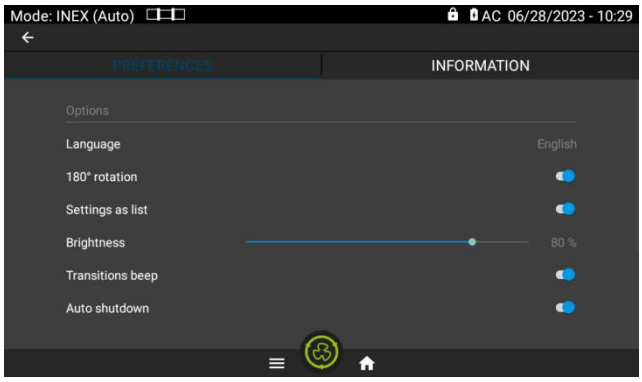
Navigating the Preferences Menu

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.

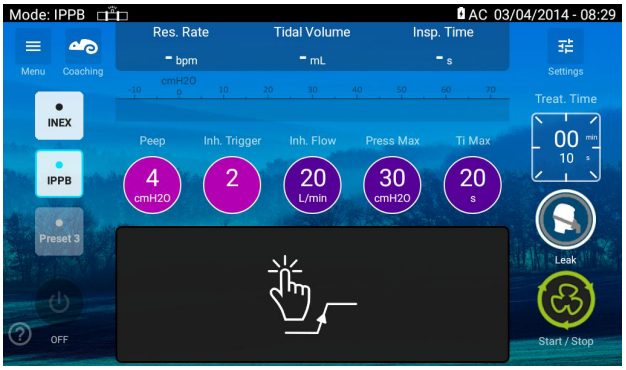
Language	Give the actual interface language and allows to select the interface language.
Rotation of screen	Allows the screen to be rotated 180°. Press the small circle to rotate the screen.
Settings as list	Select the display mode of the settings menu. To display the settings as list, press the small 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).
Auto shutdown	Allows to deactivate the automatic shutdown of the device (which occurs after 15 minutes of inactivity, when on battery mode).
Chart controls position	Allows to set up the side for the buttons of control in the Waveform screen (left or right)

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.

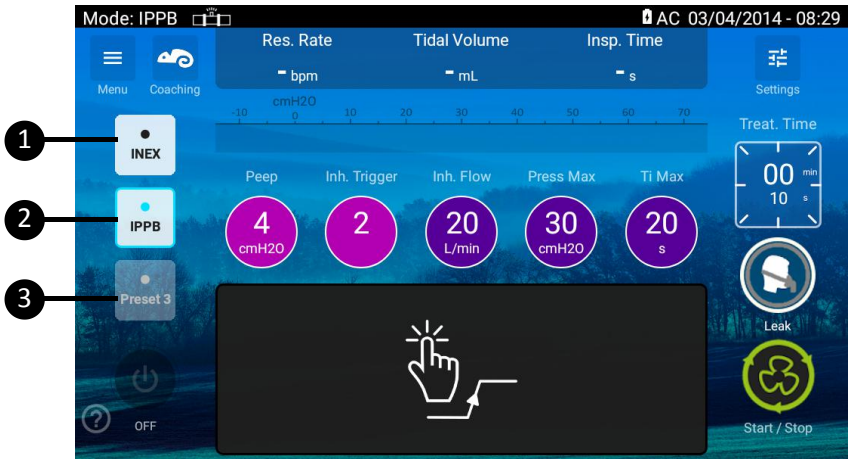
Presets

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



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

Changing preset mode from Home screen



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

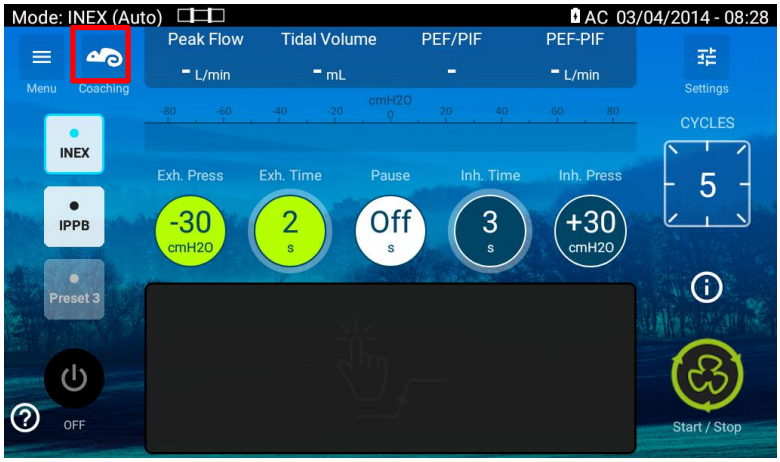
To change the preset, click on the preset you want to switch on.

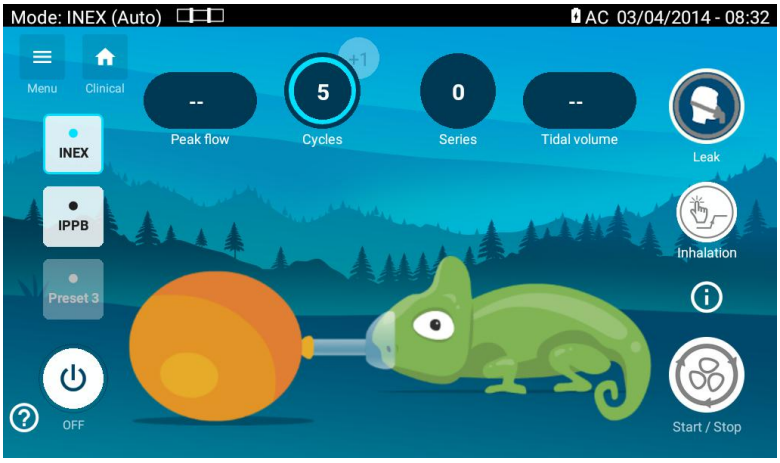
Enabling the coaching function

The user can switch to Coaching screen to perform a therapy.

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

From Home screen, click on to display the Coaching function screen.

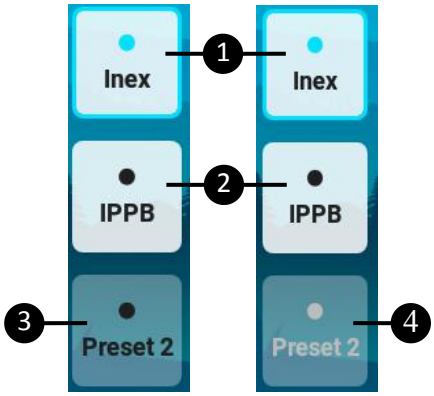




NOTE:	The coaching function is not available for all therapy modes. A message will indicate if something is missing to start the function.

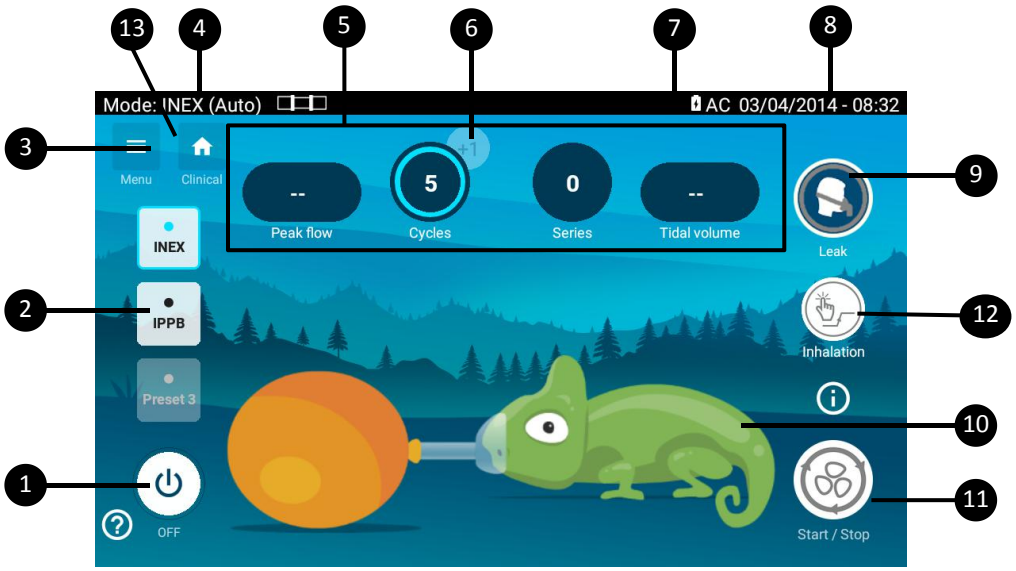
Changing preset mode from Coaching screen

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



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

The INEX Coaching Screen

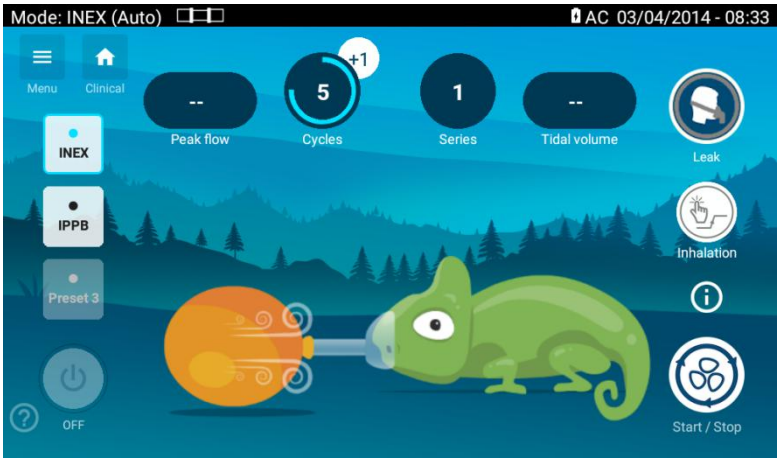


1. Power off button 2. Preset mode menu (1-3): Presets installed by the clinician and accessible to the patient when needed. 3. Menu button: Allows access to patient screen and clinical menus 4. therapy mode indicator: INEX (manual/Auto) or IPPB 5. therapy monitoring: display the live value for the displayed monitoring during therapy. 6. Cycle addition button: permit to add a cycle to the ongoing therapy 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. Leak indicator 10. Chameleon: Animation which will follow the therapy set up to help the patient 11. Start/Stop button: starts or stops therapy. 12. Trigger an inspiration during the therapy 13. Clinical screen shortcut

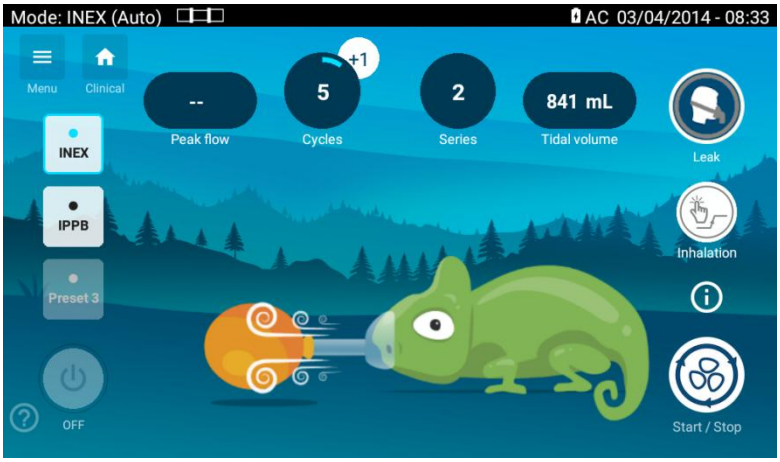
Performing an INEX therapy with Coaching function

Configure an INEX Auto therapy and start the therapy. Chameleon and balloon animation will follow the therapy phases:

- During inspiration, chameleon inflates, and balloon deflates



- During exhalation, chameleon deflates, and balloon inflates

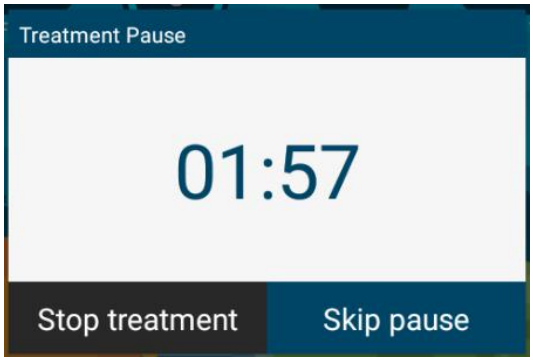


- During pause, chameleon and balloon do not move.

The monitorings:

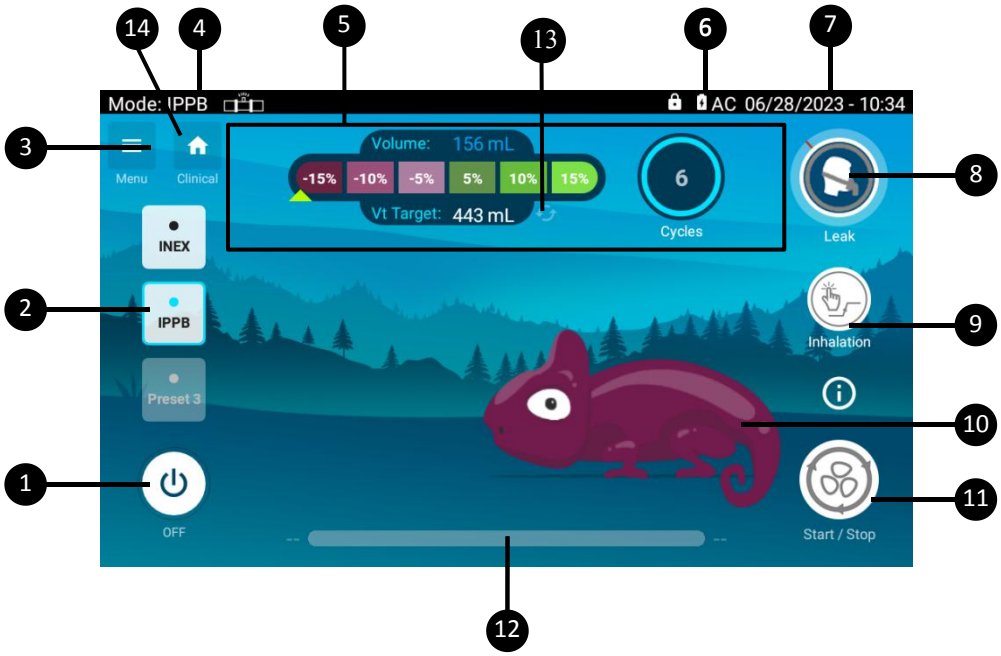
- The peak flow is updated after each exhalation
- The cycle decounter decreases after each exhalation. It can be increased with the «+1» button during the last cycle
- Series counter is incremented at each start of therapy. It is reset when changing preset or shutting down the devices
- Tidal volume is updated after each inspiration
- The leak indicator will turn orange at the end of the inspiration if the end inspiration pressure does not reach 80% of the set pressure. The first cause would be the presence of important leaks at the patient interface. Another cause could also be that the inspiratory time is too short for the lung pressure to reach the set inspiratory pressure.

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



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

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. Therapy mode indicator: INEX (manual/Auto) or IPPB 5. Therapy monitoring: display the live value for the displayed monitoring during therapy. 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 inspiration during a therapy 10. Chameleon: Animation which will follow the therapy set up to help the patient 11. Start/Stop button: starts or stops therapy. 12. Therapy Time Bar: display the elapsed and the remaining therapy time during therapy when a therapy time is set by the clinician 13. Reset of the target volume previously defined 14. Clinical screen shortcut

Performing an IPPB therapy with Coaching function

Configure an IPPB therapy and start the therapy. Following the therapy set up, inspiration can either be triggered by the patient or by using the dedicated button.

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

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

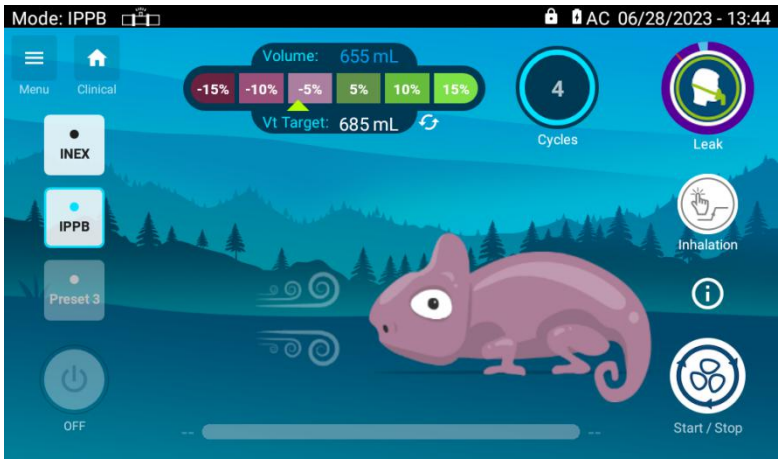
If initial volume setting is OFF, for the 3 first inspirations:

- Chameleon does not move
- Initial Volume stays undefined

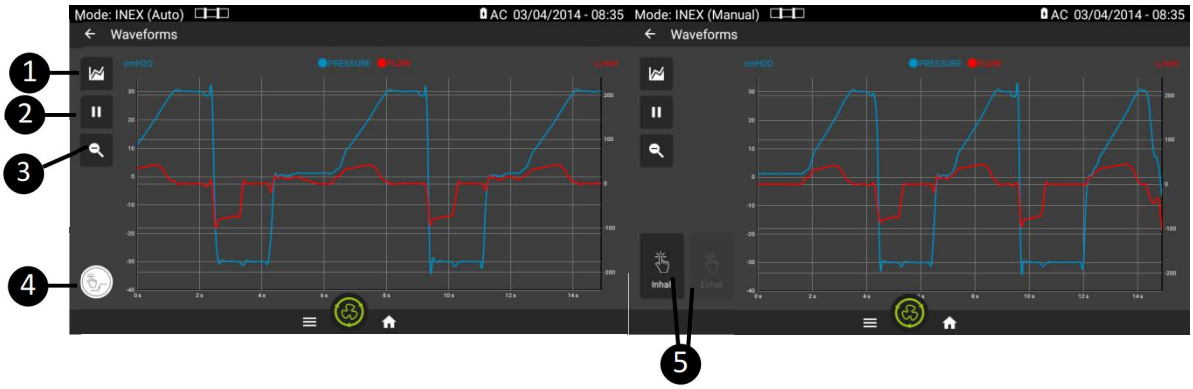
From the first inspiration if Initial Volume setting is ON or after 3 inspirations If initial volume setting is OFF:

- Initial Volume is defined. It is the mean of the volume of the 3 first inspirations. It stays unchanged until end of the therapy.

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



The Waveform Screen



1. Curve selection: pressure, flow	4. Inhalation manual trigger (INEX Auto or IPPB mode)
2. Pause/Play	5.Treatment management button (INEX manual mode)
3. Zoom reset	

This screen reports the patient data (flow in red and pressure in blue) and is updated with every breath.

Chapter 3 - Patient circuit, power supplies and accessories configurations

	WARNING
•	**Use only CE marked circuit components approved for use with the AC-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. We recommend to keep Peep activated.**
•	**The responsible organization must guarantee compatibility of the device with all accessories intended to be used for patient connection before usage**

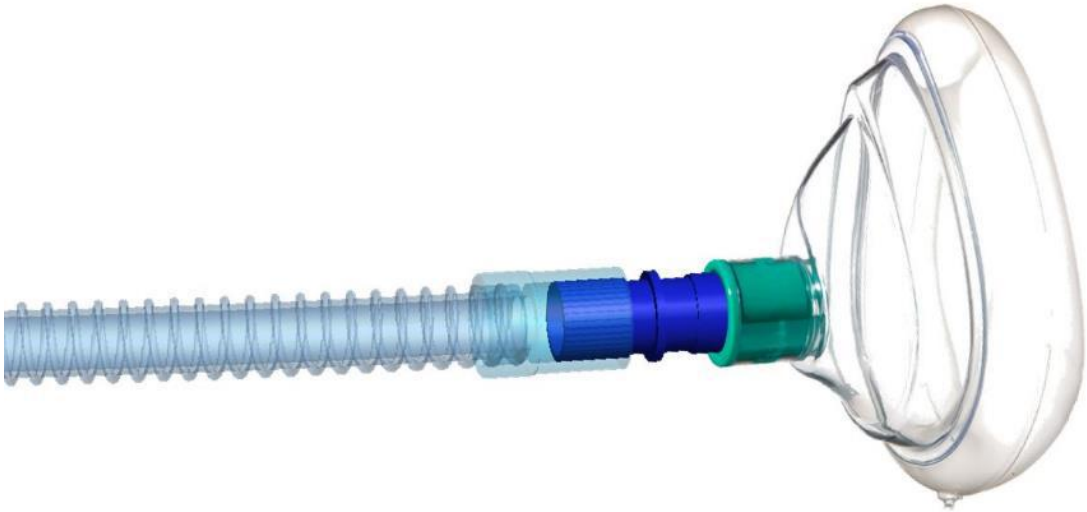
Patient Circuit installation

The AC-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 parts are located : - at the end of the patient circuit accessories, - at the end of the SPO2 sensor

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.



NOTE:	If a leak is present in the circuit it will lead to non accurate monitoring value

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.

NOTE:	If no leak is present in the circuit or if it is not correctly calibrated, an alert will be triggered during the IPPB therapy.

Patient circuit calibration

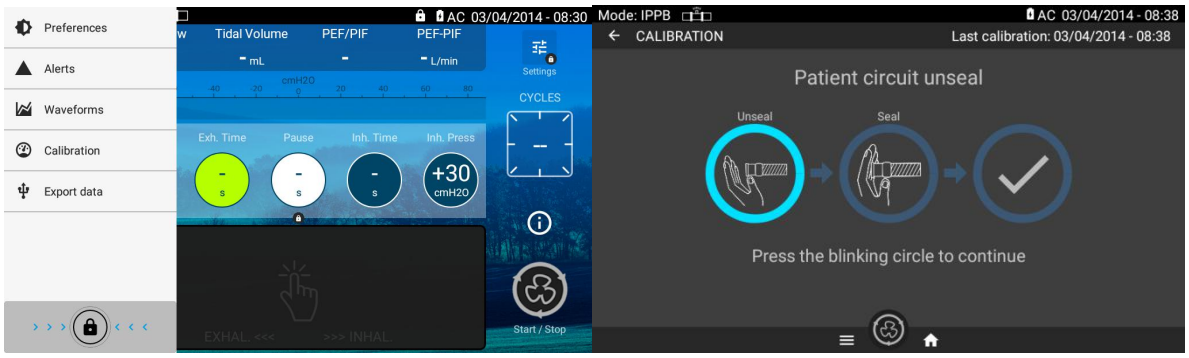
For the AC-70 to provide expected performances, the patient circuit must be calibrated.
The procedure detailed below includes two steps and corresponds to the IPPB mode. In the INEX mode case, calibration will only include the first step.

When the circuit use for the IPPB mode is the same as the one used in INEX mode with the addition of a leak accessory, the calibration can be performed only in IPPB mode, with the circuit with leak and it is not necessary to perform the calibration again in INEX mode.

The last calibration date is indicated directly on the calibration screen. It corresponds to the last calibration applicable to the mode selected.

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

2 – Access the calibration menu



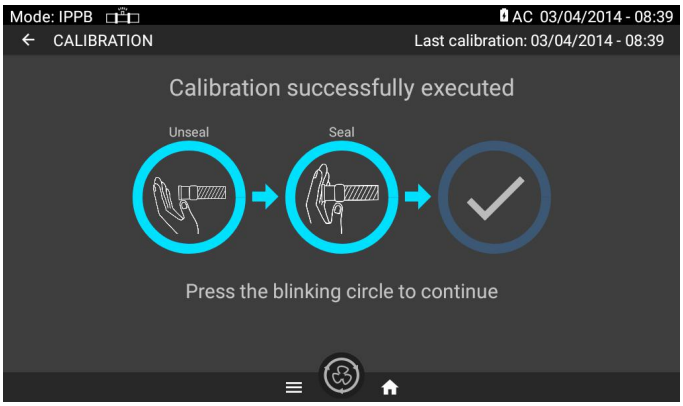
3 – Unseal the patient circuit extremity and click on the blinking circle

4 – Wait until the circle is completed

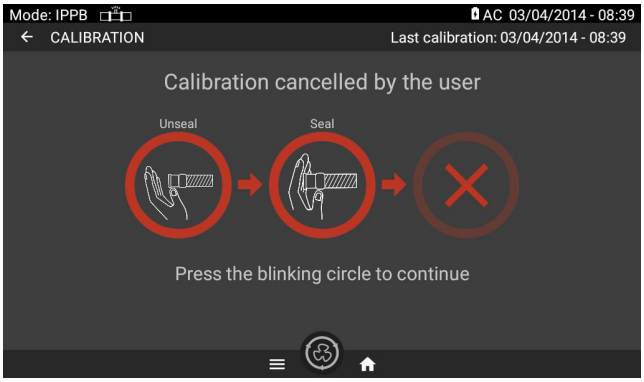
5 – Seal the patient circuit extremity and click on the blinking circle

6 – Wait until the circle is completed

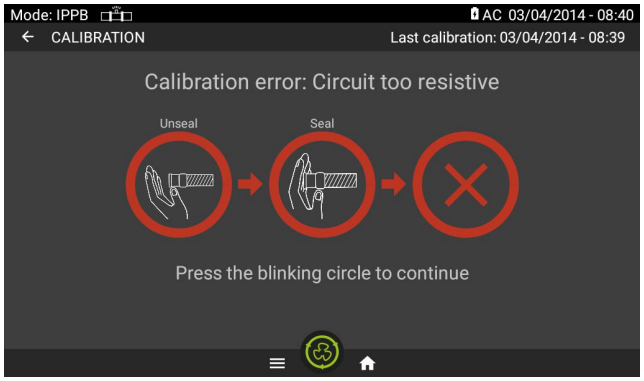
7 – Exit the calibration menu by clicking on “Validate”



At any time, calibration can be aborted if necessary (by pressing on “abort”, starting the therapy 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 AC-70

The AC-70 device is compatible with the following accessories.

- SPO2 Cable (EO-SPO2CBL) to connect an SPO2 sensor from Nonin (sensor not provided by EOVE)

- Remote control pedal (EO-70FSWITCH)
- Trolley (EO-TROLLEY and EO-TROARM)
- Up-right brakets (EO-UPRIGHT)

The AC-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 AC-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.
	The SPO2 sensor to be connected to the SPO2 cable must be a class II 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.

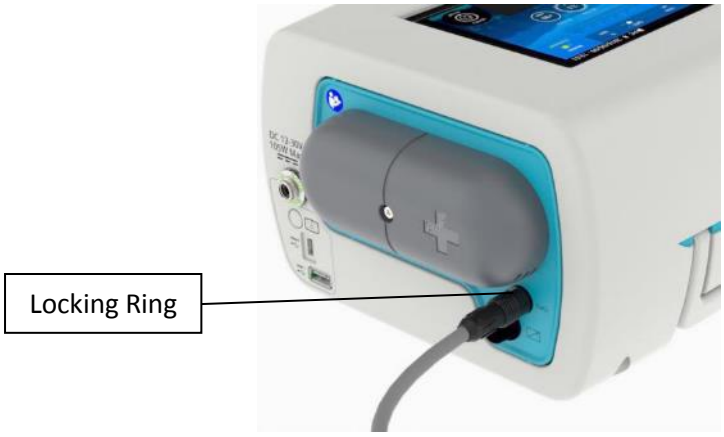
⚠	**WARNING**
	To prevent the risk of cross-contamination, an antibacterial filter is mandatory if the device is to be used on multiple patients.
	Regularly check the antibacterial filter for signs of moisture or other contaminants. **Failure to do so could result in increased system resistance and/or 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.

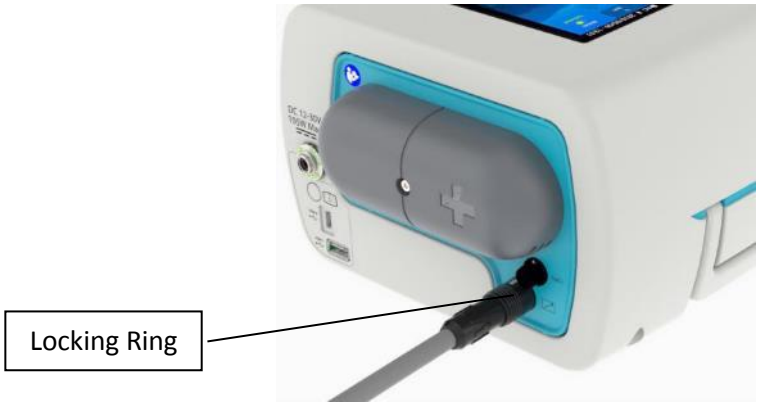
1. Connect the SpO2 adaptor (EO-SPO2CBL) connector at the rear of the device.
2. Connect the sensor to the adaptor and attach sensor to patient (according to NONIN instructions)



⚠	**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.



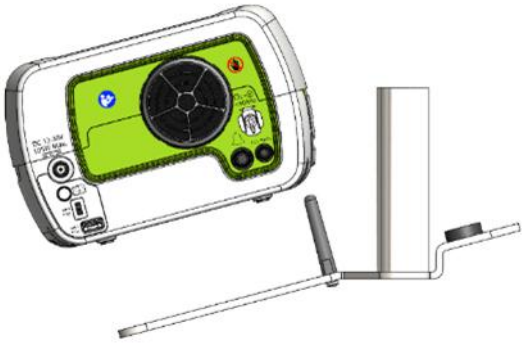
⚠	**CAUTION**
	To remove the cable, pull firmly on the locking ring. Do not twist.

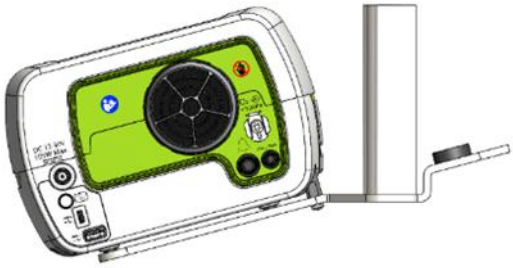
Mounting AC-70 on trolley (EO-TROLLEY)

⚠ **WARNING**
• **When using the trolley in combination with AC-70 and other accessories, always verify a maximum weight of 20 kg is not exceeded. Always use the handle to move the trolley (always pull, do not push). Not respecting this could result in damaging the device or causing patient injury.**

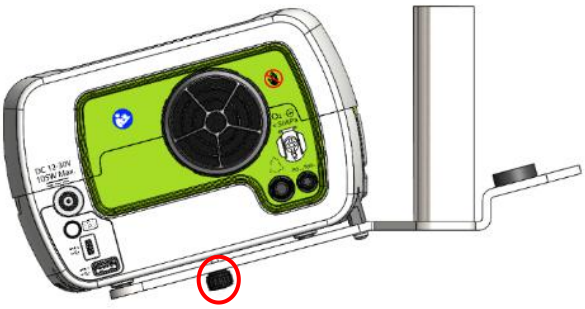
The AC-70 device must be mounted on the trolley according to the following instructions:

1. Insert the device on the trolley columns.





2. Fix the device on the trolley with bottom screw.



3. Insertion of the arm. Insert the arm inside the dedicated trolley port and secure with screw.

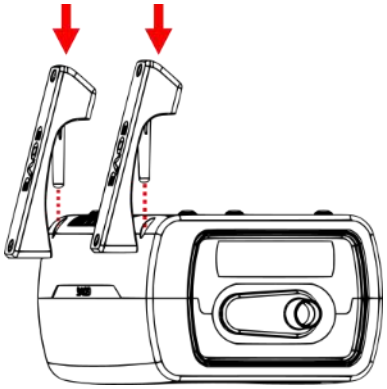
4. Insertion of humidifier. Insert the humidifier inside the dedicated trolley port.

⚠ **WARNING**
• **Use only screws delivered by Eove. Otherwise, there is a risk to damage the ventilator or its**

accessories.

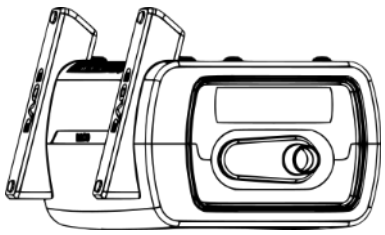
Upright Bracket installation for a vertical position of the device

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

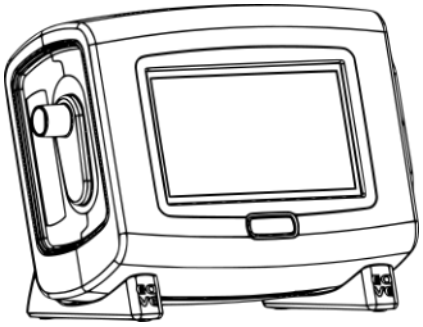


NOTE:	Upright brackets are fully reversible and can be used on the right or left guide with the same feature

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 AC-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 AC-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 AC-70 on internal battery

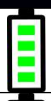
⚠	**WARNING**
	The internal battery should be replaced every two years, or when a service notification is displayed.
	Replacement of lithium batteries or fuel cells by anyone other than trained personnel will result in dangerous risk of burning of the user (e.g., excessive temperatures, fire or explosion)
	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 AC-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 AC-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 AC-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

The device internal battery will operate for at least 2h when the device is used according to the following configuration for an adult patient (Resistance : 20 cmH2O/l/s, Compliance : 25 ml/cmH2O) : inhalation pressure + 40 cmH2O, inhalation time : 2s, exhalation pressure - 40 cmH2O, exhalation time : 2s, pause time 2s.

Storing and recharging

If the device is being stored with a 100% charged battery, its internal battery must be recharged every 6 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 AC-70

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

⚠	**WARNING**
	The AC-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.

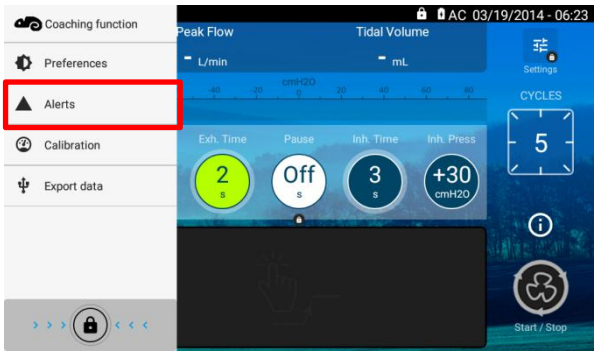
Chapter 4 – Alerts indicator

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

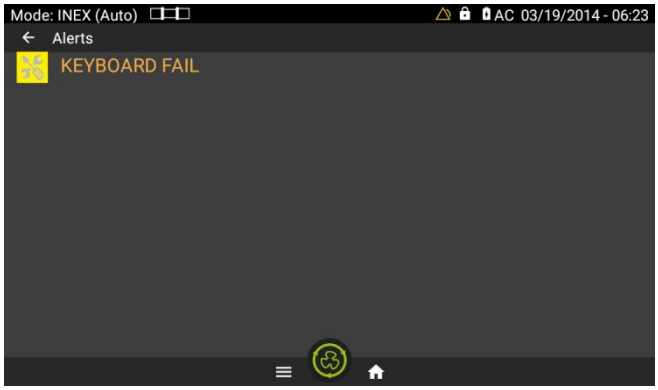
If the yellow alert indicators are active, call your service provider or Eove customer support to have your device serviced.

Access to Alert menu

From home screen, click on to display the screens menu



Choose the Alerts screen



Alert	Cause/Ventilator response	Type of alert
Speed Fault	Speed < 1000 rpm during ventilation	
Supply Fail	Communication lost with power system	
Battery Fail	Battery doesn't charge properly or battery out of order	
Battery under 20%	Battery < 20%	
Battery under 10%	Battery < 10%	
CPU Fail	CPU fail/Internal failure	
Check Settings	Discount all values by default (voluntarily)	
Saved Parameter Lost	Memory Fail -Lost setting value	
Saved Parameters Lost Non Critical	Memory Fail – Loss of memorized value (other than settings)	
Proximal Fail	Sensor out of service	
Keyboard fail	Button pressed longer than 20 seconds	
Bat. Temp. High	Battery temperature out of range during discharge	
Bat. Charge Pause	Battery temperature >45°C or <0°C during charge	
Blower Overheat	Blower temperature >80°C	
Blower Fail	Blower temperature out of range or temperature not in accordance with speed measure	
Insp. Flow Fail	Sensor out of service (3 attempts to reinit sensor unsuccessful)	
Pressure Abs Fail	Sensor out of service	
High Pressure	Pressure >80 mbar	
Pressure fault	Difference between pressure measured and pressure expected	
Gauge com Fail	Battery Gauge not functionnal	
Turbine Maintenance	Turbine counter > 20 000 hours	
Battery Maintenance	Battery ageing < 70%	
Valve Maintenance	Valve A or B counter > 100 000 000	

Pump Maintenance	Pump timer > 1000	
No Leak	No leak detected on the circuit (flow detected during peep is less than 50% of the estimated peep flow)	

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 AC-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
- 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 AC-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 AC-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 AC-70 without manufacturer authorization.**
NOTE:	Retain the original packaging to use when shipping to/from service agent.

Maintenance Timetable

The AC-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 AC-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	Person trained in the use of the AC-70	Replace the air filters
Every 2 years	Qualified EOVE technician	Replace silicone membranes
Every 20,000 hours of use	Qualified EOVE technician	Replace turbine
When battery ageing reach 70% or lower	Qualified EOVE technician	Replace the battery
Every 1000 hours of use	Qualified EOVE technician	Replace micro pump

Essential performances

The AC-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 AC-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

Treatment sound level for a treatment at +40/-40 mbar	< 60 dB

Functional Specifications

The AC-70 can be used in the following therapy modes:

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

INEX

Auto operation

The Auto Mode delivers the therapy accordingly to the settings of: inspiration Pressure, Exhalation Pressure, inspiration 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.
- inspiration Pressure during the inspiration Time.
- Exhalation Pressure during the Exhalation Time.

The therapy will end following the setting «treatment end» (inspiration 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.

Leak indicator:

The leak indicator will turn orange at the end of the inspiration if the end inspiration pressure does not reach 80% of the set pressure. The first cause would be the presence of important leaks at the patient interface. Another cause could also be that the inspiratory time is too short for the lung pressure to reach the set inspiratory pressure.

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	inspiration/Exhalation	Only applies in Auto mode

IPPB

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

- inspiration flow during inspiration
- Exhalation Fall and PEEP during exhalation

During the inspiration phase, the device delivers the inspiration Flow until the device reaches one of the two limits: Pressure Max or inspiration Max Time.
When inspiration Slope is ON, the device will decrease the inspiration Flow as pressure is increasing in order to reach the Pressure Max when the flow decreased at half of the inspiration 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 inspiration.
The therapy time, if activated, will automatically stop the therapy at the end of the set time.

The Initial Volume setting have not impact on the therapy but is used by the interface for the coaching function (see chapter 2).

Leak indicator:

The leak indicator will turn orange at the end of the inspiration if the end inspiration pressure does not reach 90% of the set pressure. The first cause would be the presence of important leaks at the patient interface.Another cause could also be that the inspiratory time is too short for the lung pressure to reach the set inspiratory pressure.

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 - 8	None
PEEP (cmH2O)	OFF / 4 - 20	Deactivation to avoid, deactivate only for short time therapy
Exh Slope	0 - 5	None
Inh. Max Time (s)	0.5 - 20	None
Treatment time (min)	OFF/ 5-30	None
Initial Volume (ml)	OFF / 50-5000	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	18 to 256 bpm
Peak Exhalation Flow	0 to 300 l/min
Rate	0 to 99.9 bpm
PEF/PIF	0 to 655
PEF-PIF	0 to 300 l/min

PEF = Peak Expiratory Flow, PIF = Peak Inspiratory Flow
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, AC-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.X.X_APIXX_TRXX

Guidance and Manufacturer's Declaration Electromagnetic Emissions & Immunity

⚠	**WARNING**
	The AC-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 AC-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:
	AC-70 is designed for use in the electromagnetic environment described below. Those using the device should ensure that the AC-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 AC-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	AC-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.
Voltage Interruption IEC 61000-4-11	0 % UT for 250 cycles at 50 Hz for 300 cycles at	0 % UT for 250 cycles at 50 Hz for 300 cycles at 60	

Immunity Test	IEC 60601 level	Level of compliance	Guidance for EM environment
	60 Hz	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 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	For home health care environment and a professional health care establishment
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

Immunity Test	IEC 60601 level	Level of compliance	Guidance for EM environment
Proximity magnetic field IEC 61000-4-39	8 A/m (30 kHz, CW) 65 A/m (134.2 kHz, PM 2.1 kHz) 7.5 A/m (7.5 kHz, PM, 50 kHz)	8 A/m (30 kHz, CW) 65 A/m (134.2 kHz, PM 2.1 kHz) 7.5 A/m (7.5 kHz, PM, 50 kHz)	Power frequency magnetic fields should be at levels characteristic of a location in a typical domestic, commercial or hospital environment.

Recommended separation distance

AC-70 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 AC-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 AC-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 anesthetic mixtures
Not suitable for sterilization
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;

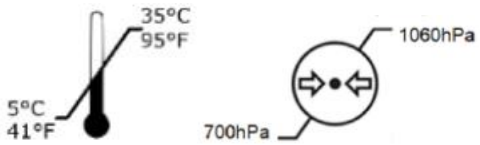
- Products have been repaired by a non-Seller-accredited provider.

Revision history

Date	Revision	Change details from previous version
October 2022	**DD** Documentary update, no effective change on the product	● Introduction: intended use clarifications, update of the adverse effects, clinical benefit addition, additionnal warning ● Chapter 1: addition of serial number explanation ● Chapter 3: additionnal warning
March 2023	**DE** Documentary update, no effective change on the product	● Introduction: update of the clinical benefit, addition of a warning about skin contact ● Chapter 5: Align servicing schedule with technical manual
June 2023	**DF** Interface navigation enhancement, setting limit update	● Chapter 1 : update of the Coaching function screen shortcut ● Chapter 2: therapy limitation if low battery, describing the new shortcuts, language selection on the Preferences Screen ● Chapter 3: Addition of information of the consequence of a leak presence during an INEX therapy. Addition of information on the calibration data shared between the INEX and IPPB mode. Adaptation of a warning fololwing the modification of the Peep min in IPPB. ● Chapter 5: Deletion of the air inlet filter change for each patient change ● Chapter 6: update of IPPB Peep limit, add information about Peep deactivation in IPPB
December 2023	**DG** Documentary update, addition on the EO-TROLLEY as accessory	● All document: change «alarm» into «alert», addition of the temperature and pressue range logo ● Introduction: Completion of the information on the indication of use, adding precisions for some warnings. Complete contraindication and Adverse effect following clinical data ● Chapter 1: update of the device label image, adding the logos of the power supply, of atmospheric range logo and of the electronical IFU

		● Chapter 3: adding precision on a warning, add EO-TROLLLEY installation instructions, adding information on battery autonomy ● Chapter 4 detailing the alert menu access and the list of alerts. ● Chapter 6: addition of the sound level indication
June 2025	DH	● Chapter 2: Addition of leak indicator on the clinical screen for INEX and IPPB. Addition of charts control in Preferences menu. Change saving logic for settings in mode list. Coaching function available without preset. Addition of the possibility to set manually the initial Volume for IPPB coaching screen. Addition of waveforms screen description ● Chapter 3: Addition of last calibration date on calibration screen . ● Chapter 6: Addition of the Initial volume setting in IPPB. Addition of the PEF/PIF and PEF -PIF monitoring. Adjustement of heart rate range. Addition of the results for the immunity tests for proximity magnetic field

CE 0459



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