EO-300

IPPB Device

User Guide (clinician)

105_3001 revF 03/2026

Contents

Introduction

The EO-300 (ref EO300) device provides Intermittent Positive Pressure Breathing (IPPB) modes for adult and pediatric patients as prescribed by an attending doctor.

Indications for use

The EO-300 IPPB device is part of the whole therapy process that assists patients in the management of airway secretion removal. It is intended for adult and paediatric patients weighting at least 10 kg (22 lbs); that are unable to autonomously remove airway secretions and require improvement of their pulmonary volume capacities.
To do so, the device is equipped with an intermittent Positive pressure Breathing mode (IPPB), which delivers a constant airflow to promote deep inspiration.

The EO-300 IPPB device may be used either with a mask, mouthpiece or tracheostomy tube.

Medical indication

Indications for IPPB therapy are the following:

Physiological characteristics :

- A vital capacity (VC) of <50% of the predicated value*;
- 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 EO-300 IPPB device is intended to be used in home, institution, hospital. This device is transportable but not intended for use during transport.

Users

EO-300 IPPB 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:

- The installation technician
- The maintenance technician

Following appropriate mandatory training from the responsible organization operators, patients, and/or caregivers should be able to safely perform the folowing operation:

- Start and stop device
- Start and stop therapy
- Switch pressets
- Change preference settings (e.g.interface display related setting such as date or luminosity)

Furthermore, patient and /or caregivers are not intended to:

- Change clinical settings
- Perform any maintenance operation

	**WARNING**
•	**E0VE 300 is not for use with anaesthetic gases.**
•	**E0VE 300 is not for use in an oxygen enriched environment.**
•	**Do not use EO-300 IPPB device in an MRI equipment or in a barotherapy equipment**

Contraindications

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

Adverse Effects

- 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 EO-300 IPPB 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

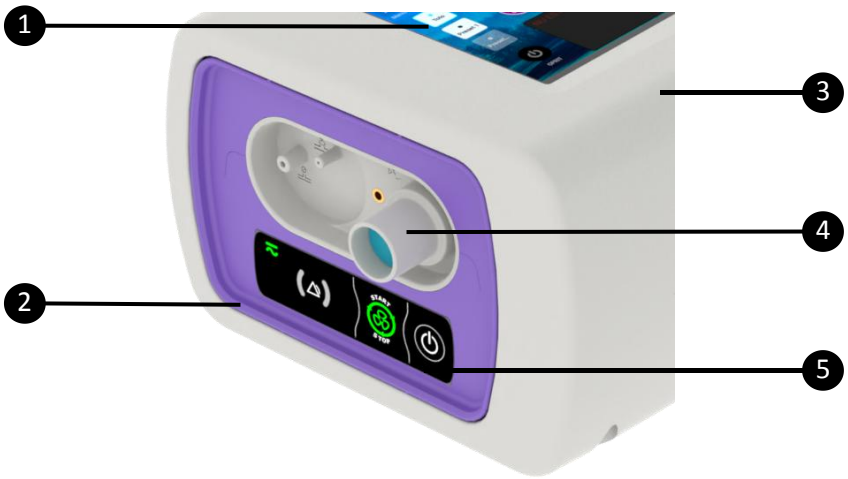
General warnings and cautions

⚠	**WARNING**
•	**Do not add intermediate pieces or accessories to the EO-300 IPPB 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 EO-300 IPPB device**
•	**The EO-300 IPPB 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 EO-300 IPPB 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 EO-300 IPPB device. Lack of therapy can lead to health degradation of the patient, e.g. moderate desaturation.**
•	**Install and configure the EO-300 IPPB 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-300 IPPB 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-300 IPPB device in direct contact with the patient for extended periods of time.**
•	**The EO-300 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.**
•	**All 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.**
•	**It is advise to be sure that the device and its AC power supply are installed so that the disconnection form the main can be easily done.**

•	**Keep the device, and accessories away from water and all other liquids not specified in this document.**
•	**Never touch the device with an injured skin**
	CAUTION
	The EO-300 IPPB device is transportable but not intended for use during transport.
	Do not expose the EO-300 IPPB 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-300 SMD device is not a ventilator and should not be used for other purpose than punctual therapy.

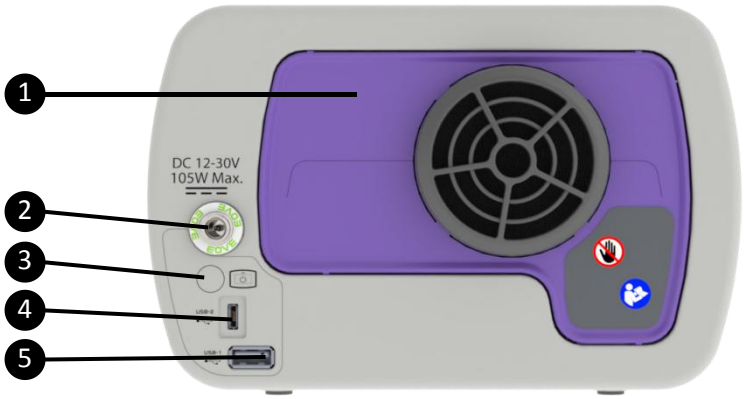
Chapter 1 – Description of the EO-300 IPPB device

Front Panel



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

Rear Panel



1. Air inlet / outlet filters cover	4. USB-2 port (Maintenance only)
2. DC Power connector	5. USB-1 port
3. Interface Power button (Maintenance only)	

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

EO-300 device, ref EO-300VNT includes:

- A secretion management module: **EO-300 IPPB module**, ref **EO-VM300**
- A docking station: **EO-1X0 Docking station**, ref **EO-DCK300**
- A power supply (AC/DC): **EO Charger module**, ref **EO-PWRCHR-002**
- A pair of upright brackets, ref **EO-UPRIGHT**
- A bag for transport: **Transport Bag,** ref **EO-CARBAG300**
- A user manual

Serial Number explanation

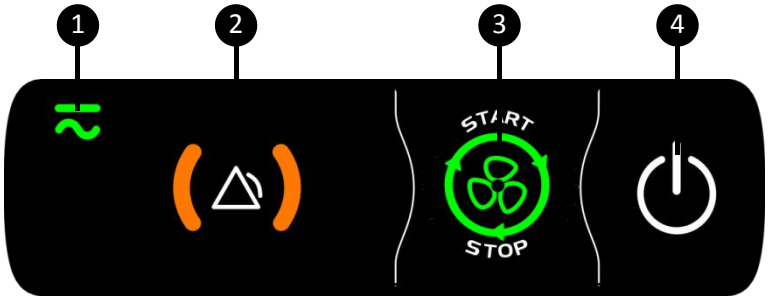
The serial number of EO-300 can be found on the label just after the SN symbol. It appears also after the application identifier (21) encoded in the barcode. The format is EO300YYMMiiiX. It includes the manufacturing date at the format YYMM.

Example: The EO-300 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

Symbols Table

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

Keypad indicators / buttons			
	Alert 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
	Coaching function access button		Clinical screen access button
	Return to Home Screen		Touch interface locked
	Touch interface unlocked		Settings information
	Power off button		Maintenance menu access
	User manual access		Export Data screen access
	alerts screen access		Coaching screen access
	Preferences screen access		Leak Indicator (inactive)
	Leak Indicator (excessive interface leaks)		Leak Indicator (acceptable interface leaks)

	Breath triggering on touch pad		Reset of the target volume (IPPB)
Device / Power supply / packaging / manual symbols			
	Inspiratory Port (to patient)		Proximal Pressure Port
	Connection port		Connection ports
	USB connector		Warning
	Consult operating instructions		Applied part BF type
	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
	Do not obstruct		Do not push (symbol for trolley accessory)
	Consult electronic instructions for use		Do not step (symbol for trolley accessory)
	Maximum weight for trolley (including SM Device and accessories)		Atmospheric Pressure Limitation range
	Importer		
AC power supply additionnal symbols			
	For indoor use only		Consult instructions for use
EAC	Complies with UEEA legal requirements	c US	UL certification for US and Canada

Chapter 2 – Operating Instructions for the EO-300 IPPB 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-300 IPPB device is transported using the EOVE Transport bag.
	Always protect the device from water if transported outdoors.

Set Up Test

Before using the EO-300 IPPB 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 EO-300 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 EO-300 IPPB device. Contact your healthcare provider or your Eove representative for a device checking.

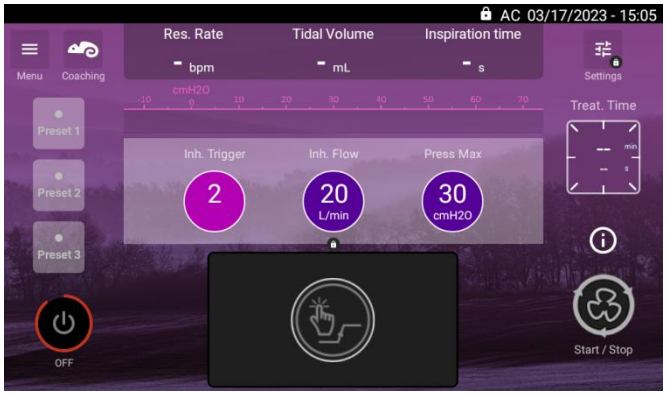
Turning on the device

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 device is already connected to AC, 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-300 IPPB device cannot be powered off during therapy

From the keyboard - Secondary proceedings

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

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.

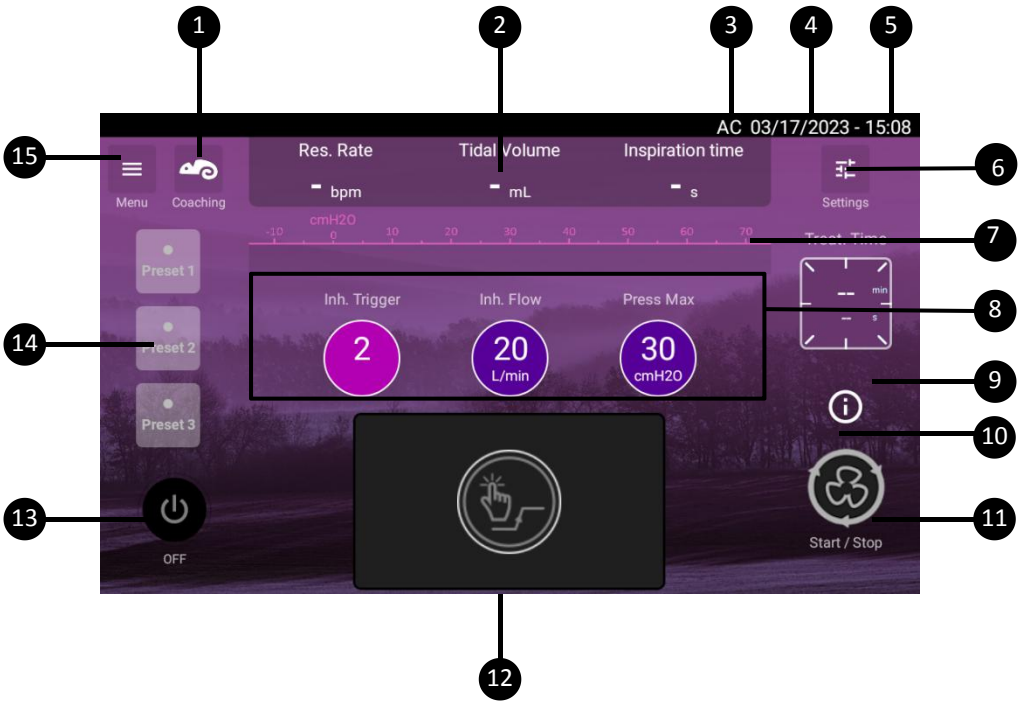
To **STOP** therapy using the Touch Screen:

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

	**CAUTION**
	The EO-300 IPPB device cannot be powered off during therapy

The Home Screen

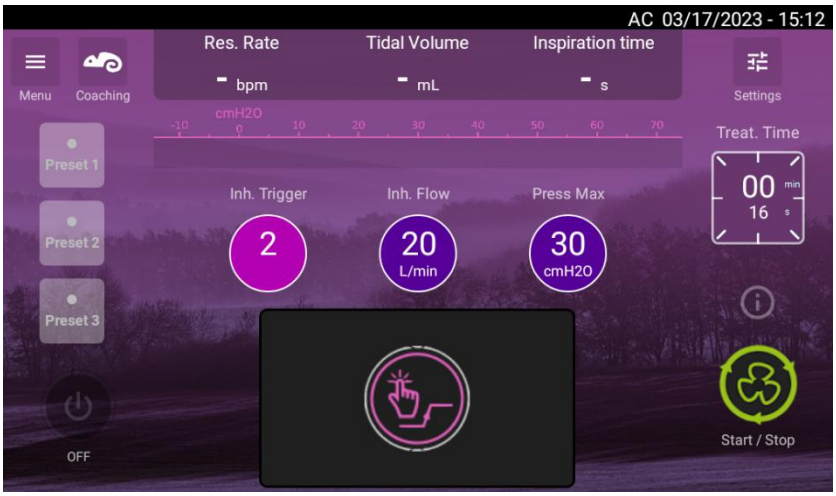
On the home screen, there is important information about the settings, the pressure of therapy, the preset modes set up by clinician. The Home Screen is accessible from all other screens by pressing 



1. Coaching button: Allow access the coaching screen. 2. Therapy monitoring: display the live value for the displayed monitoring during therapy. 3. Power source indicator: Indicates whether the device is operating on mains power (AC) or DC power. 4. Date: indicates the date on YYYY/MM/DD format. This can be set up and changed from Preferences menu. 5. Time: Indicates the time on 24hr clock. This can be set up and changed from the Preferences menu. 6. Settings button: Allow access to the settings screen 7. Airway pressure indicator: Indicates the pressure in the circuit. All inspirations are colored in light purple, all exhalations are colored in deep purple.	8. Main settings bar: Displays the main settings associated to the current mode. (can be adjusted when unlocked) 9. Therapy time elapse or remaining. 10. Settings information. 11. Therapy Start/Stop Button. 12. Touch pad: to start a breath, a click triggers an inspiration phase. 13. Power off button. 14. Preset mode menu (1-3): Presets installed by the clinician and accessible to the patient when needed. 15. Menu button: Allows access to patient screen and clinical menus. 16. Help button: display the clinician or patient manual

Using the Touch Pad

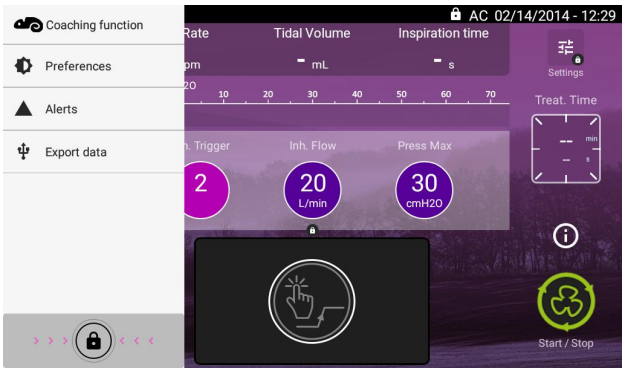
A simple touch on the Touch Pad will trigger an inspiration.



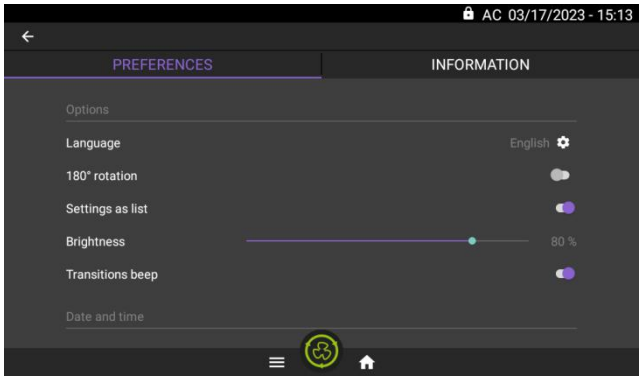
Navigating the Preferences Menu

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	Allows to select the language of the interface
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.
Brightness	Adjusts screen luminosity.
Transition beep	Activates beeps at transitions from exhalation to inspiration and from inspiration to exhalation.

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.

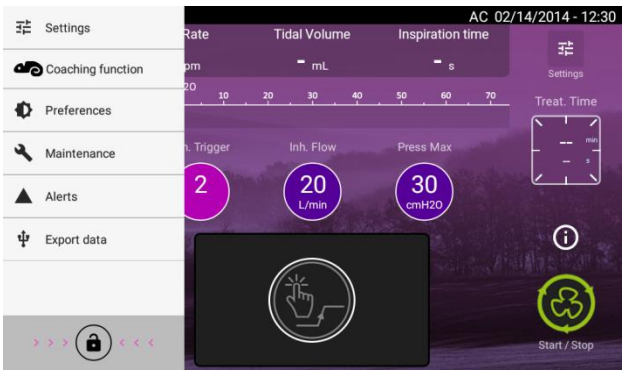
In the preferences menu, the user can also access traceability and connection information.

Accessing the settings menu

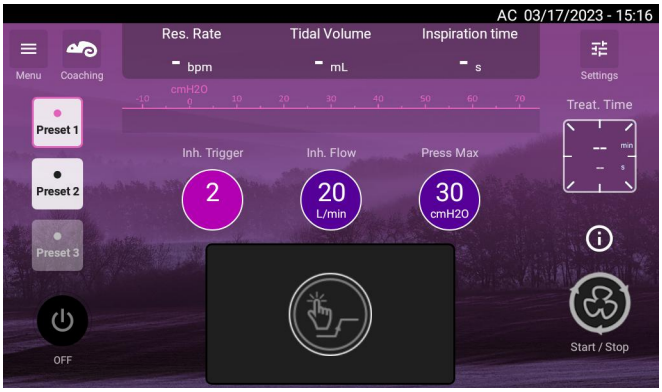
NOTE:	Do not access settings menu (unlocked mode) unless directed by a physician.

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)

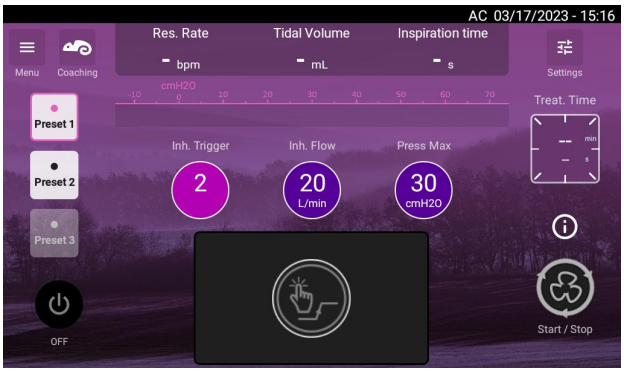


3. Click on the home page settings for adjustment of the main settings or access the settings menu to adjust any setting.

NOTE :	Unlock the application will permit to change the language in the Preferences menu.

Presets

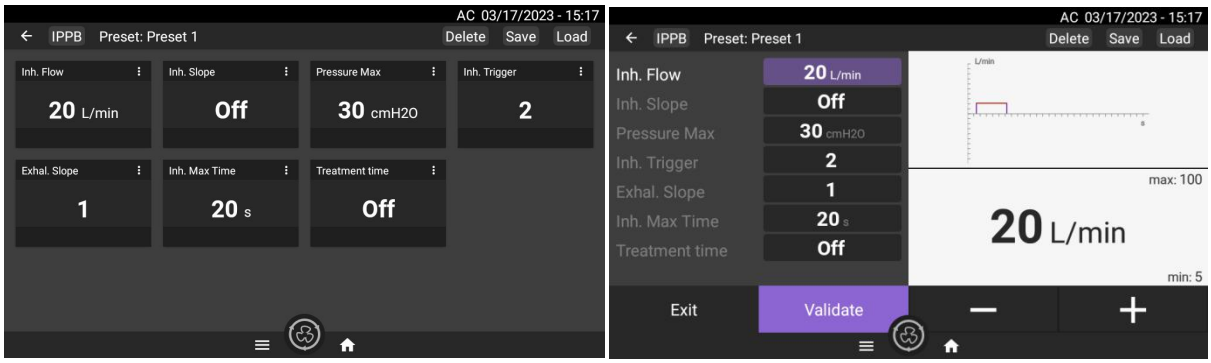
The EO-300 IPPB device can store up to three different therapy presets. Presets can be configured by clinicians to provide personalized alternative therapy options.



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).

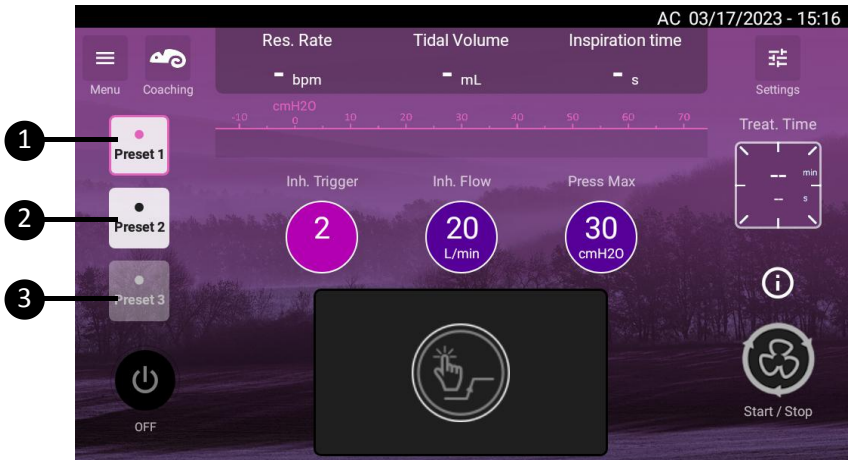


From the upper band of the menu, you can:

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

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 therapy 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

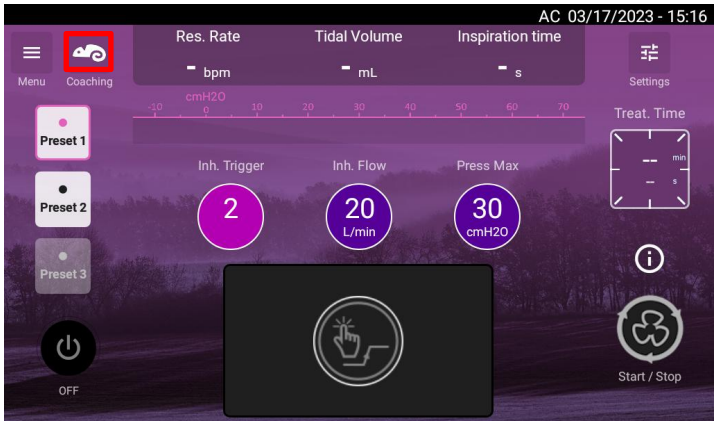
1. From the settings menu, click on one of the settings box.
2. Adjust the settings with + and – in the setting pop-up.
3. Validate the settings

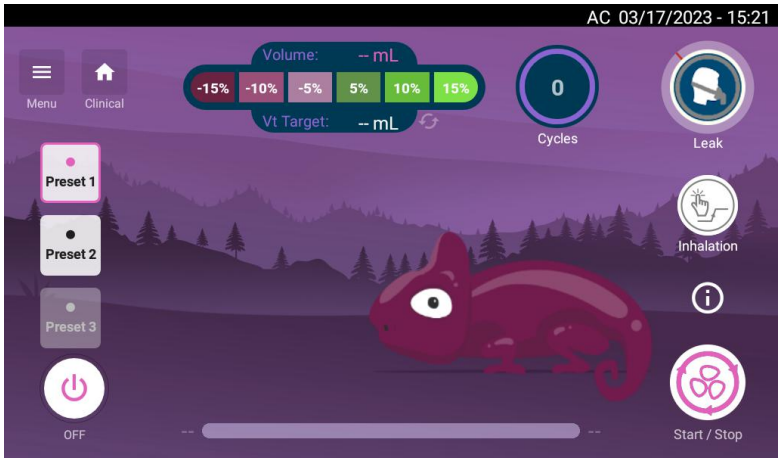
Enabling the coaching function

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

NOTE:	Coaching function is only available when a preset is selected.

From Home screen, click on  to display the coaching screen

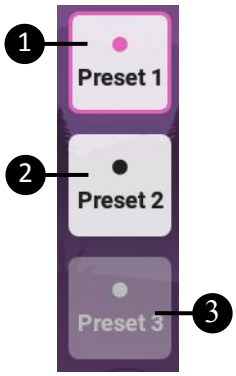




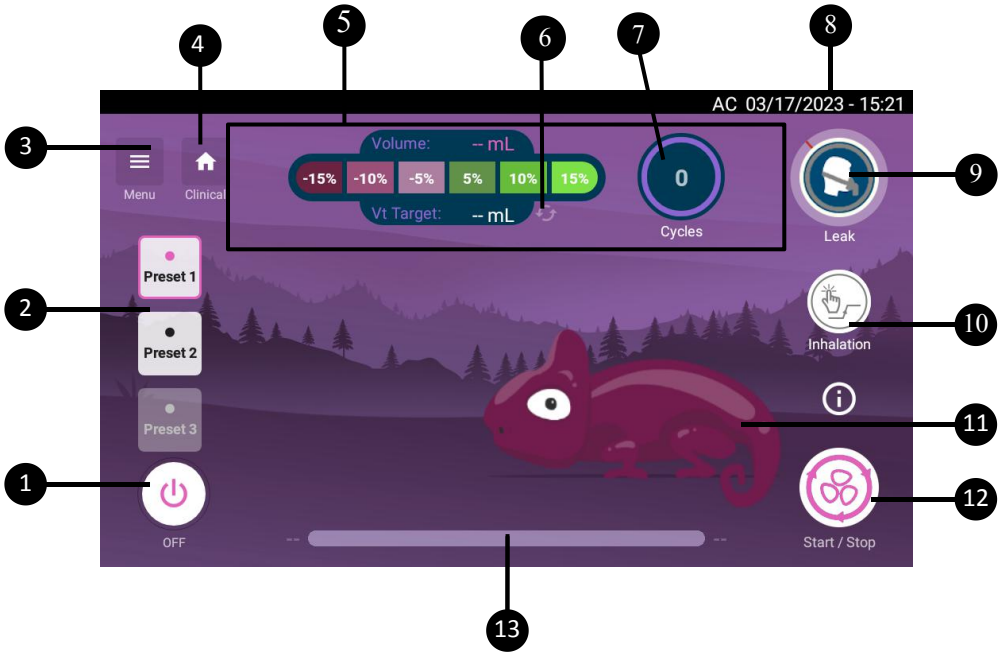
NOTE:	The coaching function is Only available when a preset is selected
	If the screen indicates no compatible preset is available, contact your service provider.

Changing preset mode from Coaching screen

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



The IPPB Coaching Screen



1. Power off button 2. Preset mode menu (1-3): Presets accessible to the patient when needed. 3. Menu button: Allows access to clinical home screen and clinical menus 4. Clinical screen button: Allow access to the clinical home screen 5. therapy monitoring: display the live value for the displayed monitoring during therapy. 6. Reset of the target volume previously defined 7. Number of breaths.	8. Date and Time with format YYYY/MM/DD (can be changed in Preferences menu) 9. Leak indicator 10. Trigger button: permit to manually trigger an inspiration during a therapy 11. Chameleon: Animation which will follow the therapy set up to help the patient 12. Start/Stop button: starts or stops therapy. 13. therapy Time Bar: display the elapsed and the remaining therapy time during therapy when a therapy time is set by the clinician

Performing a therapy with Coaching function

Select a preset 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 green or orange. Orange will indicate that 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 target volume reached. It will progressively turn to green when reaching and exceeding the target volume.

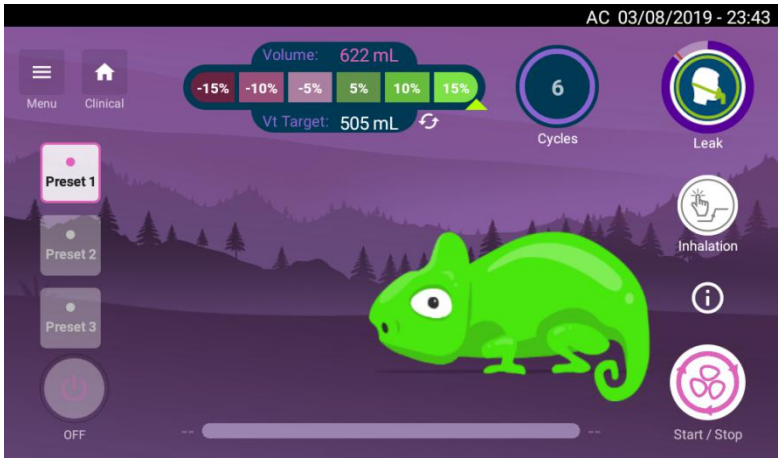
For the 3 first inspirations:

- Chameleon does not move
- V Target stays undefined

After 3 inspirations:

- V target 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 colour. It stays like this until next inspiration. The volume bargraph arrow will move following the proportion of the target volume reached. It will stay to the maximum level reached until next inspiration.



Chapter 3 - Patient circuit, power supplies and accessories configurations

⚠	**WARNING**
•	**Use only CE marked circuit components approved for use with the EO-300.**
•	**Install patient circuit tubing carefully, to avoid risk of strangulation or tripping.**
•	**The responsible organization must guarantee compatibility of the device with all accessories intended to be used for patient connection before usage**

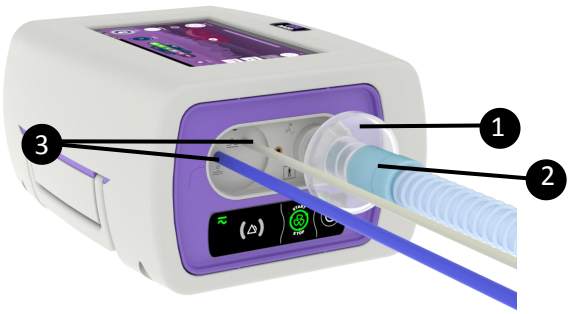
Patient Circuit installation

The EO-300 IPPB device can be used with 22 mm diameter circuit only, including an exhalation valve and a proximal pressure line and complying with CE regulations. It is recommended to use a bacterial filter at the outlet of the device.

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

Connecting circuit configuration

1. Attach any accessories that may be required (eg. Filter)
2. Connect the tubing to the inspiratory/circuit port on the front of the device (see image)
3. Attach the proximal pressure line and the valve to the proximal pressure and valve ports.(see image)
4. Attach the patient mask or other interface to the patient circuit.



⚠	**WARNING**
	Before using any accessory, always carefully read the accompanying user Manual.
	The EO-300 IPPB 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, may 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.

Oxygen can be added in the ventilation circuit after the EO300 device.

NOTE:	The addition of oxygen through an external medical device (not provided by EOVE) is permitted ; and it can be done for example with a T link placed in the patient circuit. This oxygen addition stay however under the responsiblity of the healthcare professional which performs it ; considering the impact it may have on the treatment (for example, for the ventilatory performances or the biocompatibility matters). Given its conception, the EO-300 device has a check valve placed at the level of the connection of the patient circuit. It ensures that there will be no return of oxygen, nor management of this oxygen by the EO-300 device. The oxygen is not taken into account in the flow measured and delivered by the EO-300 device. Therefore the oxygen flow added through an external device, will be added to the flow set up on the EO-300 device. The volume measured by the EO-300 does not take into account this addition, which constitute an additionnal volume for the patient.

	**WARNING**
	Use only medical grade oxygen
	Ensure that the device is ventilating before the oxygen supply is turned on.
	The oxygen flow must be turned off when the device is not ventilating so that oxygen does not accumulate within the circuit. The accumulation of oxygen presents a fire risk
	Oxygen supports combustion, Only use oxygen in well-ventilated rooms. Using oxygen while smoking or in presence of an open flame creates a fire hazard.
	Always turn off the oxygen supply when ventilation is stopped for any reason.

Accessories Compatible with EO300

The EO300 device is compatible with the following accessories.

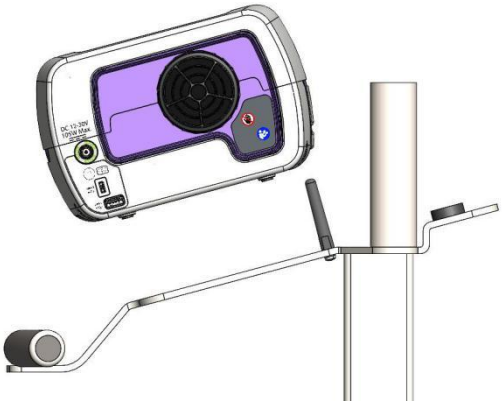
- Trolley (reference EO-TROLLEY)
- Up-right brakets (reference EO-UPRIGHT)

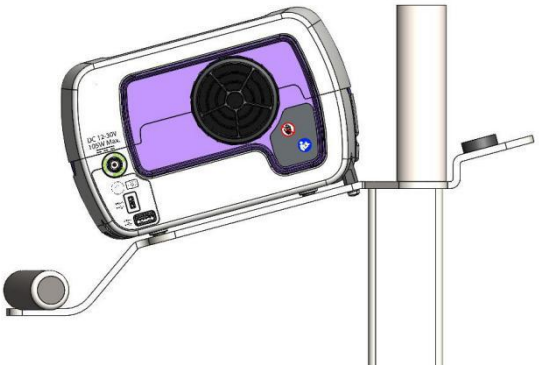
Mounting EO300 on trolley (EO-TROLLEY)

 **WARNING**
• **When using the trolley in combination with EO300 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.**

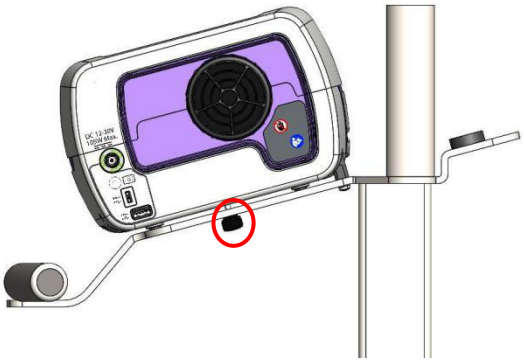
The EO-300 IPPB device must be mounted on the trolley according to the following instructions:

1. Insert the device on the trolley columns.





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

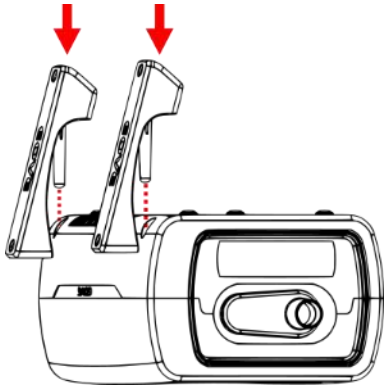


3. Insertion of the articulated arm:
Insert the articulated arm inside the dedicated trolley port and secure with screw.
The reference KB029900 provided by ALMS is recomanded.

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

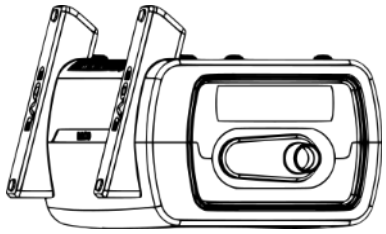
Upright Bracket installation for a vertical position of the device

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

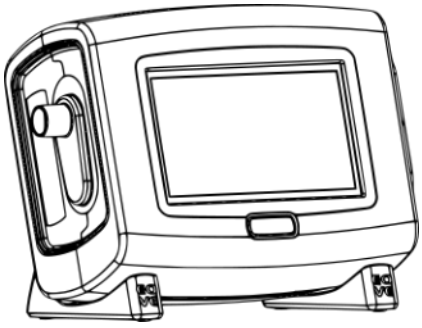


NOTE:	**Upright brackets are fully reversible and can be used on the right or left guide with the same feature**

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 EO-300 IPPB device can only be used with mains power
For information on power supplies and sources see the technical specifications.

Connecting to mains power

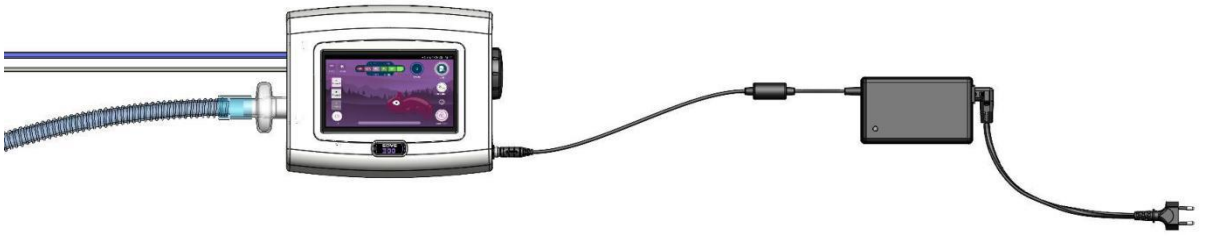
⚠	**WARNING**
	Ensure that the power cord does not pose a tripping or choking hazard.
	Ensure that the home AC mains supply and connections are safe and comply with the applicable regulations.
	Ensure that the device and its power charger are placed in a way that allows an easy disconnection from the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

To connect to mains power:

1. Connect the DC plug of the supplied external power supply unit to the rear of the EO-300 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



Travelling with EO-300

The EO-300 must be transported in its transport bag.

⚠	**WARNING**
	The EO-300 IPPB 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.

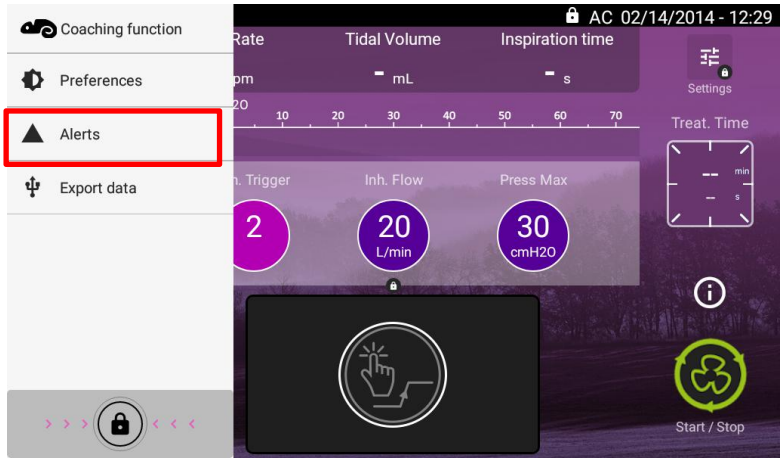
Chapter 4 – Alerts indicator

The EO-300 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 (orange indicator with no sound) and will all necessitate a technical support.

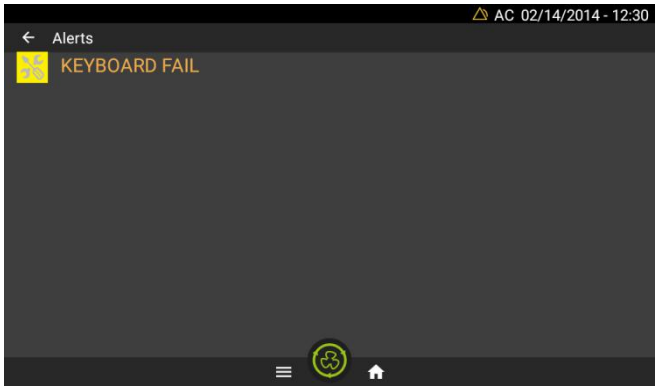
If the orange alert indicators are active, call your service provider or Eove customer support to have your device serviced.

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	
Technical Problem	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	
Blower Overheat	Blower temperature >75°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	
Turbine Maintenance	Turbine counter > 20 000 hours	
Turbine Init Fail	Turbine speed is still 0 after initiation sequence	
Check valve missing	An expiration flow is detected at the flow sensor during expiration	

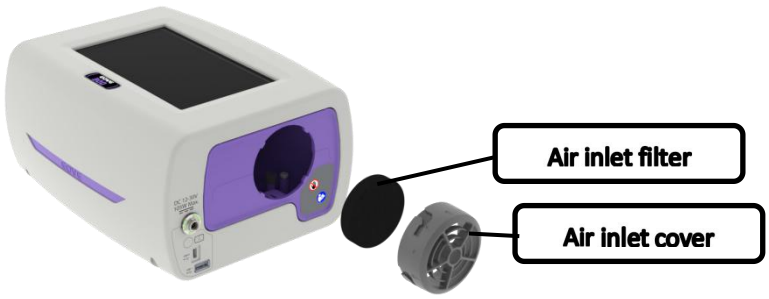
Chapter 5 - Routine Cleaning and Maintenance

⚠	**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-300 IPPB 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

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



Instructions for product cleaning and disinfection at patient change

The following process must be followed before change of patient:

- Disconnection of the device from the power supply
- Cleaning the exterior of the device with a damp cloth and mild detergent, then wipe dry
- Verification of the cleaning completeness (no dust, no fingerprints, no stain or residue of food, human, animal or domectics product origin)
- Surface disinfection of device exterior shells with a wipe or a soft, lint-free cloth using one of the recommended disinfectant solution, with emphasis on the areas near the patient output, the fresh air inlet, the keyboard and the station handle. Follow the product manufacturer recommandation. Let dry the product completely before next use

Area to be covered by the cleaning and disinfection

- Replacement of Bacterial filter or HME filter
- Replacement of patient circuit or sterilization of reusable circuit system
- Function Check, as per set up test described in chapter 2

Follow this procedure also for devices which have been previously been used by patients in whom MRSA infection, for example, has been verified.

CAUTION	Follow the use precautions of the disinfectant (Protective glass, gloves and / or mask as indicated on the product)
	Do not apply the liquid cleaning solution directly on the device
	Be careful to not wet the electrical connection
	When using a liquid solution on a wipe, the wipe should be saturated but not dripping

For disinfection, we recommend usage of the following products:

- Mikrozid® sensitive liquid from Schülke
- Mikrozid® sensitive wipes from Schülke
- Mikrozid® AF liquid from Schülke
- WILAsil® from WILAmed.

Servicing

	**WARNING**
•	**Maintenance of the EO-300 IPPB 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-300 without manufacturer authorization.**
NOTE:	Retain the original packaging to use when shipping to/from service agent.

Maintenance Timetable

The EO-300 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-300 IPPB 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 EO-300	Replace the air filters
Every 20,000 hours of use	Qualified EOVE technician	Replace turbine

Essential performances

The EO-300 essential performances can be evaluated with this reference test (every 2 years or after a spare part replacement):

Settings:
Inh. Flow 20 L/min, Inh. Slope OFF, Pressure Max. 30 cmH2O, Inh. Trigger 2, Exh. Slope 1, Inh. Max Time 20 s, therapy Time 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: 600 ml +/- 120 ml

With a 22 mm tubing and a test lung (Compliance 25 ml/mbar, Resistance 20 mbar /L/s, Max volume 1000 mL), monitoring should be the following:

Tidal Volume: 760 +/- 120 ml

Chapter 6 - Device information

Physical Specifications

Weight: < 3.3 kg

Size: 274x207x132 mm

Functional Specifications

The EO-300 can be used for the following therapy : IPPB: Intermittent Positive Pressure Breathing

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

- inspiration flow during inspiration
- Exhalation Fall 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. This pressure may be maintained during the Inhalation plate.
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 stop the flow delivered and decrease 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.

Setting	Range	Limitations
Inh. Flow (l/min)	5 - 100	None
Inh. Slope	ON/OFF	None
Inh. Plate time (s)	0,5 - 5 / OFF	None
Pressure Max. (cmH2O)	10 - 50	None
Inh. Trig.	1 - 8	None
Exh Slope	0 - 5	None
Inh. Max Time (s)	1 - 20	None
Therapy 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
Peak Exhalation Flow	0 to 300 l/min
Rate	0 to 99.9 bpm
Treatment time display	0 to 99 min

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

Accuracy of monitoring data

- Inspired volume: ± (10 ml + 10%)
- Time, except treatment time display : ± 0.2 s
- Treatment time display: ± 1 s
- Peak Flow : ± (5 l/min + 15%)
- Rate : ± 1 c/min

Power specifications

	**WARNING**
	This device is intended to function with external power supply 2420 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	105w maximum

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-300 compensates for atmospheric pressure variations e.g. related to altitude up to 3000 m).
Start-up time	< 1 min

Software versions

Main: C300 0001XX	Power: P150 0004XX	Interface: V1.X.X_APIXX_TRXX

Guidance and Manufacturer's Declaration Electromagnetic Emissions & Immunity

	**WARNING**
	The EO-300 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-300 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-300 is designed for use in the electromagnetic environment described below. Those using the device should ensure that the EO-300 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-300, 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-300 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	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	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

Immunity Test	IEC 60601 level	Level of compliance	Guidance for EM environment
	cycles 70% Ut for 25 cycles at 50 Hz 0% Ut For 30 cycles at 60 Hz Monophased at 0°	at 50 Hz 0% Ut For 250 cycles at 60 Hz Monophased at 0°	other power sources.
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
Radiated fields in close proximity IEC 61000-4-39	30kHz 8A/m CW 134.2kHz 65A/m PM 2.1kHz 13.56MHz 7.5A/m PM 50kHz	30kHz 8A/m CW 134.2kHz 65A/m PM 2.1kHz 13.56MHz 7.5A/m PM 50kHz	for home health care environment and a professional health care establishment

Recommended separation distance

EO-300 IPPB 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-300, including specified cables. Not respecting this recommendation could lead to performance alteration.

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

Standards compliance

The EO-300 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
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;

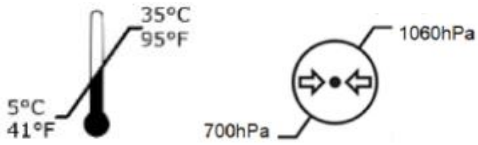
- Products are not accompanied by their instruction manuals and accessories;

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

Revision history

Date	Revision	Change details from previous version
March 2023	**A**	Creation
June 2023	B	Introduction: Update of the intended use, adverse effect and contra indication Chapter 1: Addition of missing logo for trolley Chapter 3 : Add information about Oxygen addition and accessories list Chapter 6 : Add a therapy setting
June 2024	C	Chapter 5 : update of the cleaning and disinfection instruction. Chapter 6: Modify a setting minimum
January 2025	D	Chapter 2: Remove unrelevant INEX mention, correct some legends error Chapter 6: Correction of an error in the setting table
August 2025	E	Chapter 3: Addition of a note detailing the conditions for oxygen addition
March 2026	F	Chapter 3: Replacement of an obsolete accesssory reference. Chapter 5: addition of reference values for the performance verification using the EOVE lung. Chapter 6: addition of the precision for the treatment time display. Addition of last CEM norm for electromagnetic immunity

CE 0459



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