



**This is not a complete guide for the Clearo.**

**Before using this device, see your manual for complete warnings, cautions and instructions.**



### General Warnings and Precautions

- Training is required to operate this device.
- The Clearo, must only be used as prescribed by a qualified clinician, such as a physician.
- If the patient is using the Clearo outside the hospital environment, there should always be a trained caregiver administering the therapy and to monitor the patient during and after therapy is carried out.
- When using the Clearo, suction and emergency resuscitation equipment shall be readily available.
- Monitor the device while in use and stop providing treatment if the device malfunctions. Do not use the Clearo in the event of suspected damage to the device, unexplainable or sudden pressure, performance or sound changes during operation, or if the delivered air from the Clearo is abnormally hot or emits an odour. In these cases, contact the patient's responsible care provider or Breas Medical for an inspection.
- The Clearo and its accessories must not be opened or modified other than by authorised service personnel.



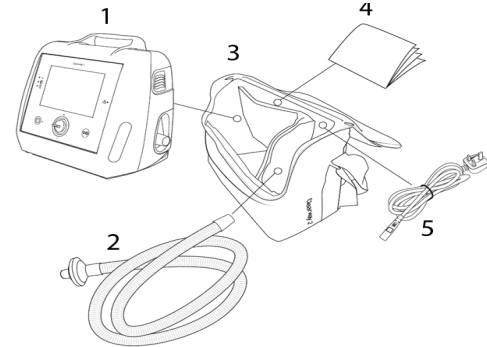
### Preparing the Clearo for Use

- Before operating the Clearo, inspect all parts, including the power cord and accessories for any signs of damage. Do not use the device or accessories if damage is suspected.
- Do not use the Clearo while in a warm place, such as in direct sunlight or close to a radiator as this may lead to a temperature outside of specifications.
- Check that both white and grey air filters are installed within the air inlet.
- Ensure all cables for the device and accessories are away from the patient to avoid risk of accidental strangulation.

### Positioning the Clearo

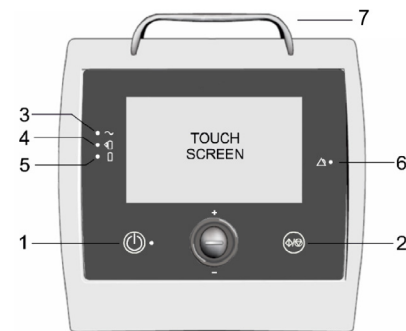
Before use, ensure that the Clearo is placed on a solid flat surface. It should be positioned lower than the patient but not on the floor. Make sure that nothing can block the patient air inlet. Make sure that nothing can block the cooling air inlet or outlet.







### Main Components



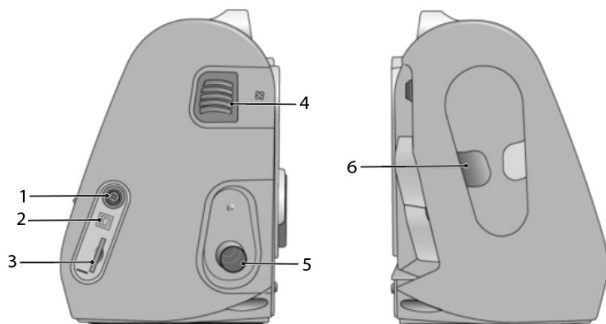
No.	Description	Product Code
1	Clearo device	232000
2	Patient MI-E Circuit	008276
3	Clearo Carry Bag	009067
4	User Manual	010076
5	AC Mains Power Cord	010080

### Front Panel



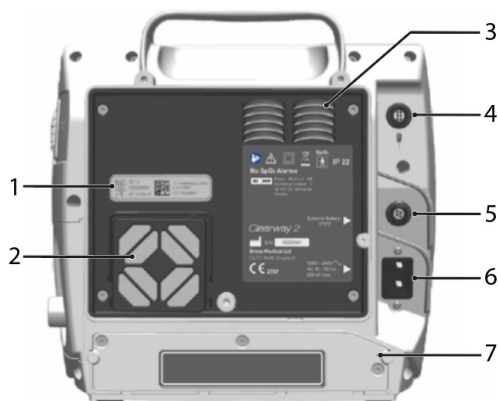
No.	Symbol	Description	LED
1		Standby ON/OFF	Green
2		Start/Stop Treatment	(None)
3		AC Power Source	Green
4		Not used	-
5		Internal Battery	Green
6		Alarm	Amber
7	-	Carry handle	(None)

## Side Panels



No.	Description
1	SpO <sub>2</sub> Connection. See also "Handling Alarms" on page 4
2	USB Connection. Restricted to use by Breas Medical Service only.
3	SD memory card slot. Restricted to be used to save patient compliance data to a memory card, only.
4	Cooling air outlet
5	Patient air outlet
6	Hand remote dock (optional)

## Rear View



No.	Description
1	Serial number and identification code
2	Air inlet, with filter
3	Negative air outlet
4	Connector for hand remote
5	Not used
6	AC power (Mains) inlet
7	Internal battery cover

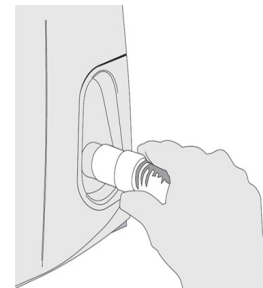
## Connecting the Clearo to Mains (AC Power Outlet)

1. Plug the mains cable into the Clearo's power inlet.
2. Make sure a clicking sound is heard to ensure the cable is completely inserted.
3. Connect the cable to the mains supply.

## Connecting Patient Circuit

1. Always inspect the circuit prior to use.
2. Connect the circuit to the device by pushing the cuff onto the air outlet.

**⚠** Fit a bacterial filter close to patient mask, to minimise the risk of contamination of the Clearo device and circuit.



## Turning the Clearo On/Off

With the Clearo plugged in to the mains (AC power), press the Standby On/Off button.

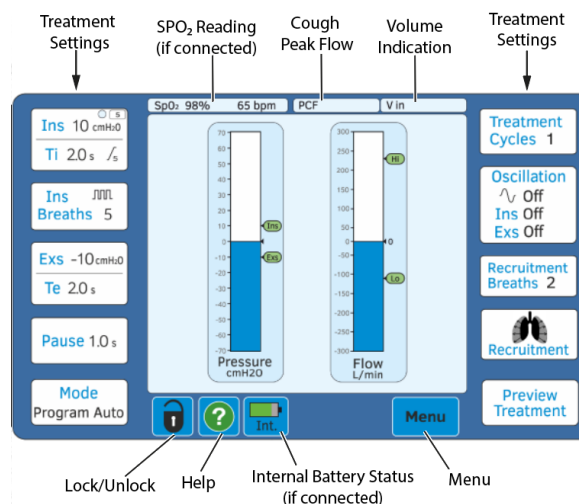


The device will be in standby mode. When the device has been switched on, a message appears asking the user to "ensure bacterial filter is fitted before use". This message must be acknowledged before continuing with any treatment.

To turn off (shutdown), press the 'standby' button. A shutdown icon will appear in the centre of the LCD touch screen. Press the power icon on the touchscreen to shut down the device. Alternatively press the 'standby' button for twenty seconds.

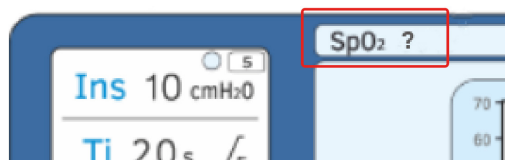
## General Functionality and Display

The Clearo is a touch screen device, and all settings and parameters are changed onscreen. Treatment is controlled only using the 'hard' buttons on the device (i.e. start/stop, manual switch, hand controller).



The treatment settings INS and EXS are displayed on the bar-graph to indicate the Insufflation and Exsufflation pressure, respectively, set by the user.

**NOTE** If the data collected from the sensor is corrupted or unreadable, the SpO<sub>2</sub> reading will display a "?" next to the reading.



## Locking and Unlocking

### To Lock the Clearo

1. Close all screens.
2. Press and hold the padlock button for 4 seconds.
3. Press the padlock icon on the popup 'screen lock' screen.



The padlock icon will change to 'locked' to confirm the device is now locked.

### To Unlock the Clearo

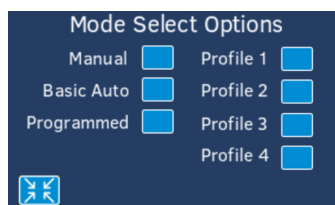
1. Close all screens.
2. Press and hold the padlock button for 4 seconds.
3. Press the padlock icon on the popup 'screen lock' screen.



The padlock icon will change to 'unlocked' to confirm the device is now unlocked.

## Selecting a Mode

On the Menu, select Mode Select. The Mode Select Options screen is now displayed. Here you can select each mode that is available to the user from the Mode Select screen.



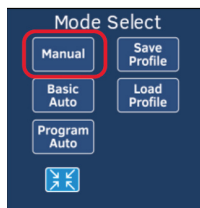
The example screen shown here, displays all modes available, except for Profiles 3 and 4, because no MI-E treatments or TreatRepeats have been saved to these profiles. See section 5.13 in the Clinician's manual for more information on TreatRepeat and Saved Profiles.

## Manual Mode

Manual mode is one of the modes for MI-E treatment. It allows the clinician to deliver the required sequence of insufflations and/or exsufflations and timings manually via the remote hand control or the front insufflation/exsufflation switch.

For information about setting parameters for manual mode, see section 5.12 in the Clinician's manual.

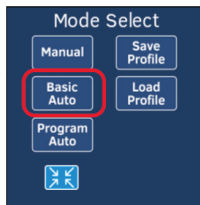
Note that a treatment carried out in manual mode can be recorded and saved to a profile, using the TreatRepeat function. See section 5.13 in the Clinician's manual.



## Basic Auto Mode

Basic Auto is one of the modes for MI-E treatment modes. It delivers one insufflation, followed by one exsufflation followed by a pause, not shorter than 0.5s.

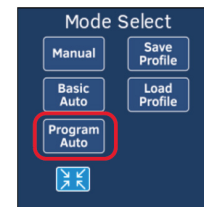
This is one cycle. The number of cycles delivered is determined by pressing the start/stop button on the hand control or on the front of the Clearo. The maximum number of cycles delivered in one sequence is 20. If you wish to set a specific number of cycles, without relying upon stopping the device manually, you can set this in the Program Auto Mode.



For information about setting parameters for Basic Auto Mode, see section 5.12 in the Clinician's manual.

## Program Auto Mode

Program Auto mode allows the clinician to set a number of repeated insufflations prior to the exsufflation. You can also repeat the cycle. This enables a specific programme to be set for the individual patient. This will enable consistent therapy for the patient in the community or sub-acute setting, allowing the therapist or carer to carry out manual techniques if required. You can also set a limited number of Auto Mode cycles by setting one insufflation, the exsufflation and the number of cyclerepeats you require. The Clearo can be programmed to deliver insufflations in a timed format, or they can be triggered by the patient.

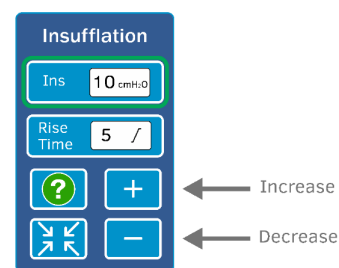


## Changing Treatment Settings

All patient prescription settings are displayed and accessed on the home screen. No treatment related settings are altered in the Menu.

**NOTE** The Device must be unlocked to be able to change any Patient Prescription Settings.

To change a setting, touch the relevant setting and select the parameter that is to be altered. Then use the **plus** and **minus** buttons to change the value or setting. The value is automatically saved and applied as it is changed.



For information on the highlighted setting, press the help symbol. Hide the screen again using the 'Hide' button.

Some settings and parameters are only available in certain modes. Settings that are not required in the current mode will be shown as an empty button (blank box).

## Starting and Stopping Treatment

**NOTE** If required, you can terminate a treatment while it is being delivered.

- In manual mode: Stop the treatment by releasing the front switch or the switch on the hand controller, whichever has been used for starting the treatment.
- In auto or programmed modes, press the Start/Stop Treatment button.

### Starting a Manual Mode Treatment

1. On either the front panel or the hand control, use the treatment switch to start the treatment. Move the switch up for insufflation, hold to maintain pressure until the switch is released and move down to activate exsufflation. Release the switch for a pause.
2. To end the treatment, release the switch.



### Starting an Automatic Treatment

To start a treatment saved to a profile, or defined in the Mode settings:

1. On either the front panel or the hand control, press the Treatment Start/Stop button.
2. To end the treatment, press the button again.



## Using the Hand Control

The hand control is an optional accessory for the Clearo which allows users to deliver manually insufflations and exsufflations using the switch. Also, it allows users to start and stop automatic treatment prescriptions.

The hand control must be connected to the Clearo to use it. It is connected on the rear of the device at the point labelled with the hand control icon, see “Rear View” on page 2.

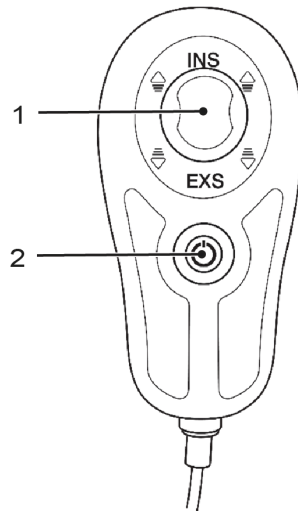
1. The Manual switch is used to deliver insufflations and or exsufflations.

To deliver insufflations, press the manual switch to the up position. To deliver exsufflations, press the manual switch to the down position.

Insufflations and exsufflations are delivered if the switch position is held up to a maximum of five seconds.

2. The Standby button is used to change the state of the Clearo between standby and active treatment (start/stop automatic treatment).

To deliver automatic treatment, press the standby button. To stop an automatic treatment, press either the standby button or manual switch.



## Handling Alarms

**NOTE** SpO<sub>2</sub> sensor alarm: The user will be notified with an alarm if the SpO<sub>2</sub> sensor becomes disconnected.

The alarm function consists of a yellow LED on the front panel, an audible alarm and a message box on the front LCD screen. See “Front Panel” on page 1 for the position of the LED.

The visual alarm indicators are visible within a distance of 4 metres and to within an angle of 30° facing the front panel. The operator must be within audible range to receive the audible alarm.

## Alarm Indication

**CAUTION** The power fail alarm will only be indicated by a yellow flashing LED and constant audible alarm

### Medium Priority Alarm

LED	Yellow - one flash every 2 seconds
Audible	3 signals repeated after a 3 second pause
Message	Yellow box on screen with information in black text

### Low Priority Alarm

LED	Solid yellow
Audible	2 signals
Message	Yellow box on screen with information in black text

### Message

LED	None
Audible	None
Message	Blue box on screen with description of the message.

## Alarm Reset

An alarm condition will be automatically reset when the cause of the alarm has been corrected or the alarm condition no longer exists.

**!** If an alarm cannot be resolved, stop using the Clearo and request technical support.

When an alarm has been acknowledged on screen, the alarm message will disappear unless the fault is reoccurring or still exists. If the fault still exists after acknowledgment, the alarm symbol will remain on screen and enables the user to view the current list of live alarms.

## Cleaning the Clearo

**!** To avoid electrical shock, disconnect the mains supply to the Clearo before cleaning. Do not immerse the device into any fluids.

### CAUTION!

- Disassembly by opening of the device main unit is not to be performed by unauthorized personnel as this should only be done by Breas Medical.
- Always be careful when cleaning to ensure that you do not damage any equipment.
- Fluid must not be allowed to enter the Clearo.
- Never apply any liquids directly on the Clearo by spraying, splashing, or pouring. Use a moistened lint-free cloth when cleaning.
- Do not use an excessive amount of liquid when cleaning the Clearo.
- Do not autoclave the Clearo.

**NOTE** General cleaning may be carried out by the lay operator in the homecare environment.

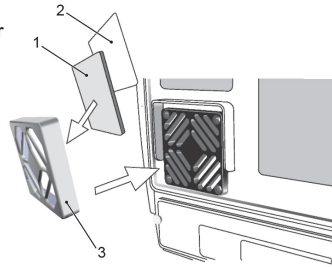
### Cleaning the Exterior of the Clearo

Inspect the device, power cord and patient circuit for damage whilst cleaning. If there is any damage noticed, do not continue to use the device, and contact your care provider, hospital or referring clinician immediately.

1. Turn off the Clearo and disconnect the mains supply.
2. Remove the patient circuit.
3. Disconnect all electric cables.
4. Clean the outside of the Clearo using disinfection wipes containing ethanol 70%.
5. Perform a visual inspection of the exterior to ensure that it is clean and that there are no visual contaminants. Repeat if there are visual contaminants.
6. Reconnect the patient circuit or replace with a new patient circuit if preparing the device for a new patient.
7. Make sure all parts are dry before the Clearo is put into operation.

## Air Inlet Filter Maintenance

The air inlet filters are located on the rear of the device and accessed by simply removing the filter housing.



1. Cleanable coarse filter.
2. Disposable fine filter.
3. Filter housing.

The filters should be inspected weekly, and changed if discoloured, or more frequently if advised by your referring clinician.

**CAUTION!** Be careful when fitting the filter housing to avoid pinching skin.

### Replacing the Fine Filter (White)

Replace the white filter at least every 4th week, or more frequently when used in high pollution or pollen-rich environments.

**CAUTION!** Do not wash or reuse the disposable filter, this must always be replaced with a new filter.

1. Pull out the filter housing.
2. Remove and separate the two filters.
3. Replace the fine filter. Insert the filters to the filter housing with the coarse filter before the fine filter and mount the filter housing onto the Clearo.

### Cleaning or Replacing the Course Filter (Grey)

Clean the coarse filter at least once a week and replace it at least once a year.

1. Pull out the filter housing.
2. Remove and separate the two filters.
3. Carefully vacuum the grey coarse filter to remove any build up of dust. Check that the filter is visibly clean and undamaged after cleaning, if not, replace the filter.
4. Insert the filters to the filter housing with the coarse filter before the fine filter and mount the filter housing onto the Clearo.

## Change of Patient

- If the Clearo is used in a clinic by several patients, the use of a low resistant bacterial filter between the air outlet and the patient circuit is essential to prevent patient cross-contamination.

- The Clearo is not suitable for sterilization.

1. Clean the Clearo as described in “Cleaning the Clearo” on page 4.
2. Replace the air inlet filters according to “Air Inlet Filter Maintenance” on page 5.
3. If a low resistant bacterial filter is used, it shall be replaced regularly.
4. Use a cleaned or a new patient circuit and a new bacterial filter when the Clearo is used by a new patient.

## Transferring Data

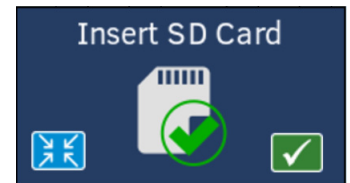
**NOTE** Do not connect an SD card to the Clearo during treatment. Downloading of data is prohibited by the software during treatment.

### Compliance Data

**NOTE** The Clearo must be unlocked to be able to transfer Compliance Data to an SD card. See “Locking and Unlocking” on page 3.

Patient compliance data may be downloaded to a PC via an SD card, by selecting Compliance Summary from the Main Menu.

1. From the Menu, select Compliance summary.
2. Select the number of days of data you want to view.
3. Press the Save Data button.



4. Insert an SD card.
5. Press the tick icon.

A green tick in the SD card Icon is displayed if transfer is successful.

## Troubleshooting

Below is a list of common alarms or information messages and what to do if these occur while you are using the device. Please check the Clinician’s manual for a comprehensive list of alarms and troubleshooting.

Further information and tutorial videos can also be found at [www.EducationByBreas.com](http://www.EducationByBreas.com)

Alarm/Information Message	User Action Required
Power fail	All power sources have been lost - mains power has become disconnected and the batteries do not have enough charge to power the Clearo. Check all of the power connections, change to a new power source if possible.
High Pressure	120% of set pressure is detected for >2 seconds. This could be as a result of coughing into the breathing circuit during the insufflation phase. Acknowledge the alarm using the touchscreen and re-start your Clearo switching the power off then on again.
Incorrect Circuit in Use	No exhalation port is detected in the breathing circuit. This could be because the incorrect circuit is being used or that the exhalation port is blocked. Ensure the correct circuit type is being used and that it the exhalation port is not blocked during treatment.
Internal Over Temperature	Internal temperature of the Clearo is >60°C - this could as a result of high ambient temperature or that the device is placed in direct sunlight or close to a heat source. It could also be as a result of the air inlet filters being blocked with dust and dirt. Check for these issues.

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