

Quick Reference Guide for Lay Care Givers



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.



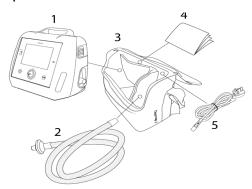
Preparing the Clearo for Use

- · 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.

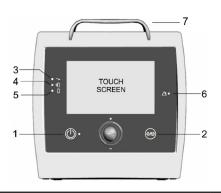
Main Components



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

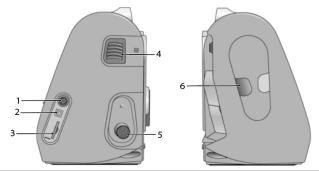
Front Panel

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

Side Panels



No.	Description
1	SpO ₂ Connection.
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.

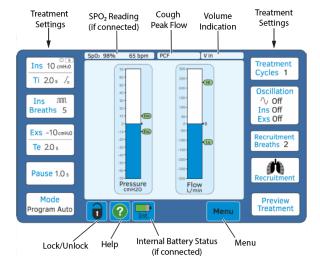


The device will be in standby mode. When the device has been switched on, a message appears asking the user to "ensure bacterial filter is fitted before use". This message must be acknowledged before continuing with any treatment.

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).



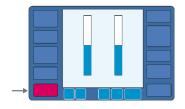
The treatment settings INS and EXS are displayed on the bar-graph to indicate the Insufflation and Exsufflation pressure, respectively, set by the user.

NOTE If the data collected from the sensor is corrupted or unreadable, the SpO_2 reading will display a "?" next to the reading.



Selecting a Mode

Press the Mode button to open the Mode Select screen.



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.



Mode Select

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.





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.

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

 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.

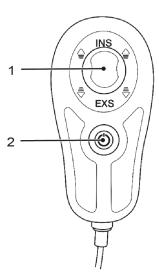


Using the Hand Control

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.

- 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

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 resolved or the alarm condition no longer exists.

If an alarm cannot be corrected, 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.

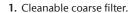
Cleaning the Exterior of the Clearo

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.
- 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.



- 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.

Troubleshooting

Below is a list of situations and what to do if these occur while you are using the device. Please check the Manual for a comprehensive list of alarms and troubleshooting.

Further information and tutorial videos can also be found at www.EducationByBreas.com

Situation	User Action
I cannot select the mode that I need.	Ensure that the desired mode is available. See "Selecting a Mode" on page 2
The device won't power on.	1. Check mains power is connected to the device, and the standby light is on 2. Ensure both batteries are charged if using battery power. 3. Send device for service.
The front switch is not working	 Ensure an MI-E (cough) mode is selected. Test function by connecting a hand control. Send device for service.
Set pressure is not reached	 Ensure that the mode is available. Ensure correct breathing circuit is attached. Check patient interface and fit. Send device for service.
Internal battery will not charge	 Ensure that the mode is available. Check mains power connection and the standby light is on. Send device for service.

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