Clearway 2

User Manual

009077 V6

Revised: MAR 2022

BREAS

Table of Contents

1 Introduction

WARNING!

Clearway 2 must only be used:

- **for the intended treatment in accordance with this operating manual and with the instructions given by the responsible clinical personnel**
- **in accordance with the operating conditions specified in this operating manual**
- **in original and unmodified shape and only with accessories specified or approved by Breas Medical Ltd.**

Every other use may lead to risk of personal injury!

CAUTION!

Read this operating manual thoroughly so that you completely understand how the Clearway 2 is operated and maintained before taking it into use, to ensure correct usage, maximum performance and serviceability.

Non-professional caregivers (e.g. family members and carers) should consult the medical equipment provider's respiratory therapist if they have any questions about the function, proper use, operation, service or maintenance of the Clearway 2.

Breas Medical Ltd reserves the right to make changes to this product without any prior notification.

U.S. Federal law restricts this device to sale by or on order of a physician.

1.1 Icons

Within this manual you will see the following icons. The meaning of each icon is explained in the table below

Icon	Explanation
	**Warning!** Risk of death or serious personal injury
	**Warning!** Risk of electrical shock
	**Warning!** Risk of cross-contamination
	**Warning!** Flammable material, risk of fire
	**Caution!** Risk of equipment damage, loss of data, extra work, or unexpected results
	**Note** Information that may be valuable but is not critically important
	**Reference** Reference to other manuals with additional information on a specific topic

1.2 What is the Clearway 2?

The Clearway 2 is an airway clearance device that provides the following therapeutic options:

- Mechanical Insufflation-Exsufflation (MI-E)
- Intermittent Positive Pressure Breathing (IPPB)
- Non-Invasive Ventilation (NIV) for therapeutic use

1.3 Intended Use

Only use the Clearway 2 as it is intended. Failure to do so may cause serious harm or injury to the patient.

Never use without the appropriate training and resuscitation equipment available. Please contact Breas Medical Ltd if training is required.

The Clearway 2 airway clearance device assists patients in loosening, mobilizing, and clearing secretions, as well as promoting lung volume recruitment by Mechanical Insufflation-Exsufflation (MI-E). The device can be used by adult or paediatric patients that have compromised secretion clearance and/or a reduced ability to cough effectively.

The device can be used for MI-E in both invasively and non-invasively ventilated patients as well as patients who are self-ventilating. The device may be used either with a facemask, mouthpiece, or with a suitable adapter to a patient's endotracheal (ET) or tracheostomy tube (MI-E only).

The device is intended for use within a hospital, institutional environment, or in the home.

The Clearway 2 must only be used under the direction and prescription of a physician, respiratory therapist, or other qualified persons.

The Clearway 2 device combines three therapy options;

- Mechanical Insufflation-Exsufflation (MI-E)
- Intermittent Positive Pressure Breathing (IPPB)
- Non-Invasive Ventilation (Therapeutic use only)

IPPB mode and NIV mode must only be used non-invasively.

When used as a mechanical 'insufflator-exsufflator' (MI-E), it provides a positive pressure to the airway, followed rapidly by a negative pressure to promote the removal of secretions. This is achieved through increasing the expiratory flow from the lungs, in order to replicate normal cough function. Optional oscillatory vibrations may assist in loosening and mobilising the secretions further while the remaining rapid shift to negative pressure results in achieving a sufficient expiratory flow rate from the central airway, which enables the clearance of respiratory secretions.

Individuals who may benefit from the use of the Clearway 2 include any patient with an ineffective cough due to;

- Muscular Dystrophy
- Amyotrophic lateral sclerosis (ALS) or Motor Neurone Disease (MND)
- Myasthenia Gravis
- Poliomyelitis
- Other Neurologic Disorders
- Spinal Cord Injury

The Clearway 2 can be used for Intermittent Positive Pressure Breathing (IPPB) and therefore may also be used in patients with bronchopulmonary disease to promote effective secretion removal and or lung volume recruitment, patient with the following conditions may benefit from using the Clearway 2 for IPPB;

- Cystic Fibrosis
- Bronchiectasis
- Emphysema
- Post-surgical patients (with no contraindications)

The Clearway 2 device can be used for MI-E in both invasively and non-invasively ventilated patients as well as patients who are self-ventilating. The Clearway 2 device may be used either with a facemask, mouthpiece, or with a suitable adapter to a patient's endotracheal (ET) or tracheostomy tube (MI-E only).
The Clearway 2 must only be used non-invasively when using the IPPB mode. Only a facemask or mouthpiece should be used to administer IPPB therapy with the Clearway 2.

Internal Memory

The Clearway 2 has an internal memory that holds the following data:

- Therapy (running) hours
- Technical and physiological alarms
- Device and treatment settings
- Treatment setting changes
- Device log of events
- Serial numbers

The internal memory data is maintained even during power failure. The data can be transferred to a computer, printed out, and analysed via Breas software products.

For more information about Breas software products, please contact your Breas representative.

1.4 Warnings & Cautions

Warnings!

- This device must only be used under the direction and prescription of a physician, respiratory therapist, or other qualified persons.
- Do not leave a patient unattended during any treatment
- Always check the prescription, time and pressure settings before each treatment or between patients, as different modes and profiles may have different prescription settings
- Only use the device with access to suction and the correct emergency resuscitation equipment in place
- Patients known to have cardiac instability should be monitored for pulse and oxygen saturation very closely and therapy terminated if the patient shows sign of deterioration
- Always follow this manual for use, service requirements and with advised accessories (see page 78)
- Monitor the device while in use and stop providing treatment if the device malfunctions
- The Clearway 2 must only be serviced by personnel certified by Breas
- Use only power cords supplied by Breas Medical Ltd for this device

- Do not use in the presence of flammable anaesthetics
- Unplug the device if it comes into contact with water
- Do not use the device if it has a damaged cord or plug, is not working properly, has been dropped, or immersed in water. In this event contact your local service centre
- Ensure all cables for the device and accessories are away from the patient to avoid risk of accidental strangulation.

- Do not operate device while in carry bag
- Always use a new, low resistance, bacterial filter when using the device on a new patient

Cautions!

- Always place the Clearway 2 on a hard, clean surface, not on the floor
- Always place foot pedal on dry surface. Ensure cable does not cause a trip hazard
- Always position the Clearway 2 so that the air inlets are not obscured or blocked
- Never use the device unless a bacteria filter is attached to the patient circuit
- Keep the power cord in good order and away from heated surfaces
- Device is not suitable for sterilisation. For instructions on cleaning the Clearway 2 see page 57
- In the event of a power failure or malfunction remove the mask or patient interface, and ensure airways are clear

This product does not contain latex in any of its components or accessories

1.5 Contraindications to Use

Before using the Clearway 2, ensure the patient does not have any of the following conditions.

The patient should be reviewed regularly to ensure that their condition has not altered. If the user of the Clearway 2 develops one of the below contraindications, contact your referring Clinician before continuing to use the Clearway 2:

- Patients with a history or risk of bullous emphysema
- Patients with a history or are susceptible to pneumothorax or pneumo-mediastinum
- Patients with cardiovascular instability
- Patients with tracheoesophageal fistula
- Recent or existing barotrauma
- Spinal instability
- Acute pulmonary oedema
- Active, untreated tuberculosis
- Active haemoptysis and frank haemoptysis
- Recent oesophageal surgery
- Increased intracranial pressure
- Acute lung injury
- Facial, skull or oral trauma and or surgery
- Fractured ribs with flail segments

Contraindications to IPPB Mode

Careful evaluation of the patient will need to be carried out prior to commencement of IPPB treatment. Contraindications to using IPPB mode include contraindications in page 11, and the following, but are not limited to:

- Tension pneumothorax
- Uncontrolled asthma
- Surgical emphysema
- Vomiting
- Cardiovascular instability
- Flail chest

1.6 Considerations before Use

Do not use the Clearway 2 with patients with the below conditions without specific instructions from your referring clinician.

A risk assessment and guidance should be provided. If the patient develops any of the below symptoms/conditions, you must consult the referring clinician before continuing use of Clearway 2.

- Bulbar insufficiency
- Nausea or risk of vomiting
- Gastrointestinal feed
- Changes in symptoms or effectiveness of the treatment

1.7 Undesirable Side Effects

If undesirable side effects are witnessed or reported, treatment should stop immediately, and the referring or responsible physician must be notified. If treatment becomes ineffective at clearing secretions and augmenting a cough, please contact your referring physician/clinician or home care provider.

1.8 About this Manual

Always read this manual in full before using the device or performing maintenance on the machine. This is to ensure correct and safe usage as well as maximum performance and serviceability.

Intended Audience

This manual is intended for the lay caregiver of a patient requiring medical use of the Clearway 2 device. The manual comprises information on general use of the Clearway 2. Patients and lay caregivers may read this manual for reference purposes, after appropriate guidance from the responsible care provider.

- Clinical personnel or medical professionals should read the Clinical Manual for thoroughly to completely understand how the Clearway 2 is operated and maintained before taking it into use, to ensure correct usage, maximum performance and serviceability.

- Service personnel may order the Clearway 2 Service Manual that contains detailed technical information for maintenance, service and repair.

1.9 Manufacturer Contact Information

To Contact Breas Medical Ltd:

Unit A2, Timothy's Bridge Road
Stratford-upon-Avon
Warwickshire, United Kingdom
CV37 9HW

Tel: +44 (0)1789 293460
email: uk@breas.com

www.breas.com

2 Safety Information

2.1 General User Precautions

Clearway 2 must only be used:

- For the intended treatment in accordance with this operating manual and with the instructions given by the responsible clinical personnel
- In accordance with the operating conditions specified in this operating manual
- In the original and unmodified form and only with accessories specified or approved by Breas Medical Ltd.
- If the patient is using the Clearway device 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 Clearway 2, there should always be access to suction and emergency resuscitation equipment available.
- If the patient is admitted to a hospital or is prescribed any other form of medical treatment, always inform the medical staff that the patient has been prescribed a Clearway 2 device for either MI-E or IPPB.
- Do not use the Clearway 2 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 Clearway 2 is abnormally hot or emits an odour. In these cases, contact the patient's responsible care provider for an inspection or Breas Medical Ltd.
- The Clearway 2 may not work properly if any part has been dropped, damaged or submerged in water.
- Inadequate use of device or accessories may cause loss of treatment or decreased performance.
- The Clearway 2 therapy settings must always be based on medical prescription and must be carried out by authorised clinical personnel only.

- Always perform the procedure "Inspecting the Clearway 2 before Use" (page 26) before use.
- Ensure all accessories are compatible with the Clearway 2 before use.
- Clinical personnel must read this manual before use.
- Handle the Clearway 2 with care.
- Do not use the Clearway 2 while in the carry bag.
- Do not use the Clearway 2 with nitric oxide, helium or helium mixtures.
- Prolonged exposure of the SpO_2 sensor can cause contact injuries to skin

NOTE: Any serious incident that has occurred in relation to this device should be reported to the competent authority and the manufacturer.

2.2 Electrical Safety

To ensure electrical safety is maintained ensure the following procedures are met:

- Do not operate the Clearway 2 if it has a damaged power cord or casing.
- To avoid electrical shock, disconnect the electrical supply to the Clearway 2 before cleaning. Do not immerse the Clearway 2 into any fluids.
- If a multiple portable socket-outlet is used, it must not be placed on the floor.
- Do not use more than one multiple portable socket-outlet or extension cord.
- The operator must not touch accessible contacts of connectors and the patient simultaneously.
- The aspects of electromagnetic compatibility must be considered.
- The Clearway 2 should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is necessary, the

Clearway 2 should be observed to verify normal operation in that configuration.

- Mobile or transportable radio transmitters may interfere with the Clearway 2 or performance of the display. Guidance for safe positioning of the Clearway 2 available on page 76.
- If a portable AC power supply is used, make sure that the voltage variations are within the operating limits of the Clearway 2. See "Electrical Information" on page 68 for AC operating limits.
- Use of accessories, transducers and cables other than those specified or provided by Breas could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

2.3 Environmental Safety

To ensure environmental safety is maintained ensure the below procedures are met

- Do not use the Clearway 2 in any toxic environment.
- Do not use the Clearway 2 in environments where there are explosive gases or other flammable anaesthetic agents present.
- The performance of the Clearway 2 may deteriorate at ambient temperatures below -4°F (-20°C) and above 104°F (40°C). However, the treatment shall always be started in an ambient temperature warmer than 41°F (5°C).
- Do not expose the Clearway 2 to rain or snowfall.

- Do not use or store in the presence of strong electromagnetic fields such as an MRI environment. Use of the Clearway 2 in an MR environment may result in malfunction of the Clearway 2 and pose unacceptable risk to the patient, medical staff, or other persons.

- Do not use the Clearway 2 positioned in a warm place, such as direct sunlight or close to a radiator.
- Do not use the Clearway 2 positioned near an open fire.
- The device complies with the EMC requirements of standards listed in "Compliance of Standards" on page 72. Necessary measures should be taken in order to assure field levels exceeding 20 V/m are avoided, since this may impair the safety and performance of the Clearway 2.
- Measures should include but not be limited to:
  - Normal precautions regarding relative humidity and conductive characteristics of clothing in order to minimize the build-up of electrostatic charges.
  - Avoiding the use of radio emitting devices closer than 1 m to the Clearway 2. Radio emitting devices include cellular or cordless telephones, microwave ovens and high-frequency surgery apparatus.
  - Avoiding the use of Clearway 2 in the presence of known EMI sources including RF emitters (e.g. RFID, surgical or therapeutic diathermy equipment). Please note some of these RF emitters may not be visible and the Clearway 2 can potentially be exposed to fields from these RF emitters without the user's awareness. If abnormal performance of the Clearway 2 is observed and the RF emitters cannot be identified and removed, the Clearway 2 may need to be reoriented or relocated.
  - The Clearway 2, any accessories and all replaced parts must be disposed of in accordance with the local environmental regulations regarding the disposal of used equipment and waste.
  - The performance of the Clearway 2 and treatment of the patient may deteriorate if the operational conditions in "Technical Specifications" (page 66) are not fulfilled.

2.4 The Usage of Oxygen if Prescribed

To ensure the safe use of oxygen, always adhere to these guidelines. Only use oxygen as directed and prescribed by your referring clinician.

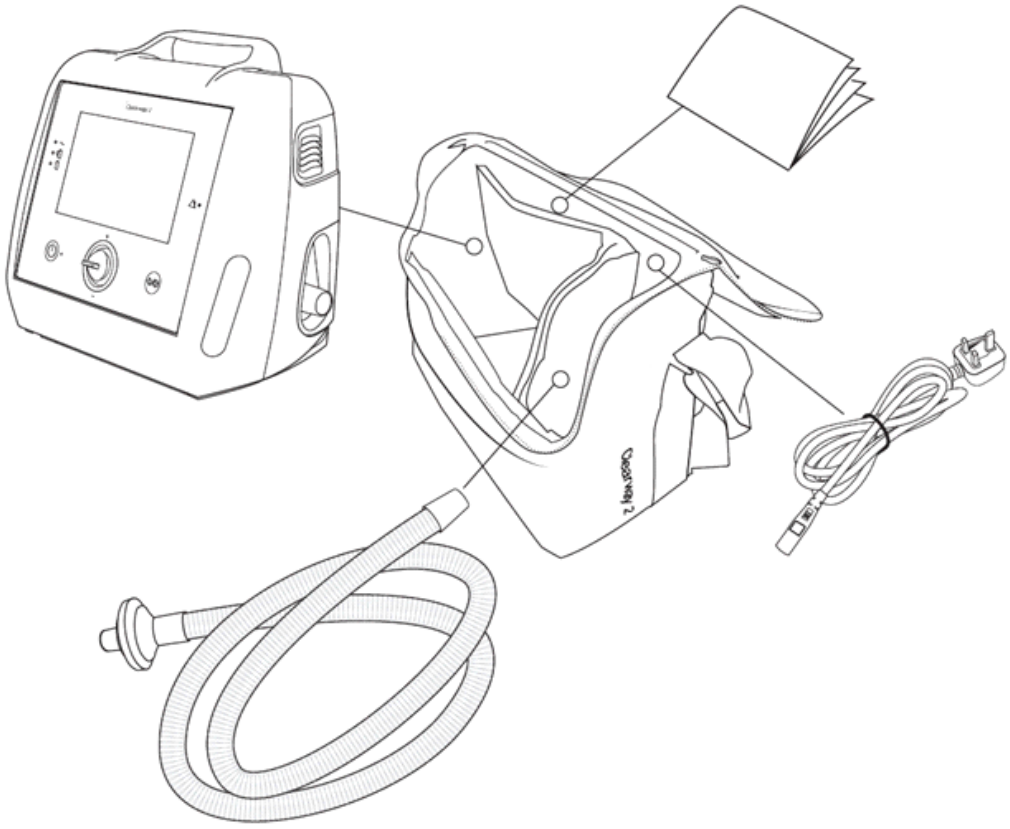
- Always follow the oxygen provider's instructions.
- The presence of oxygen can speed up combustion of inflammable materials.
- At a fixed rate of supplemental oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure delivered, the mode and settings, the patient's breathing pattern and leak rate.
- When oxygen is used with the Clearway 2, the oxygen flow must be turned off when the Clearway 2 is not operating. Oxygen delivered into the patient tubing may accumulate within the machine enclosure. Oxygen accumulated in the machine enclosure will increase the risk of fire.
- Ventilate the room adequately.
- Do not smoke in a room where oxygen is being used.
- Do not use the Clearway 2 positioned near or in a room with an open fire.
- Naked light bulbs and other sources of ignition must be kept a minimum of 6 feet (2 meters) away from the oxygen cylinder or any part of the patient circuit.
- Do not use aerosols or solvents close to the oxygen supply, even when the oxygen supply is shut off

2.5 Commonly Used Abbreviations and Terms

Abbreviation or Term	Clarification
BPM	Breaths Per Minute (Breath Rate)
IPPB	Intermittent Positive Pressure Breathing
NIV	Non-Invasive Ventilation
Doctor	Prescribing Health Care Professional e.g. Physician, Physiotherapist
Carer	Persons caring for the patient e.g. Nurse or Family/Friend
User	Main user of the device. Usually the carer, or the patient themselves
Patient	Persons prescribed the device for medical care/treatment
Insufflation	Inhale stage of a cough treatment cycle
Exsufflation	Cough (exhale) stage of a cough treatment cycle
Inspiratory	Inhale stage of a respiratory cycle
Expiratory	Exhale stage of a respiratory cycle
Cycle	A single run of a set number of insufflations, followed by an Exsufflation (unless used in NIV or IPPB)
Treatment	A treatment is a set number of cycles of the prescribed settings, at the frequency stated by the prescribing physician/physiotherapist/doctor

3 Product Description

3.1 Main Components

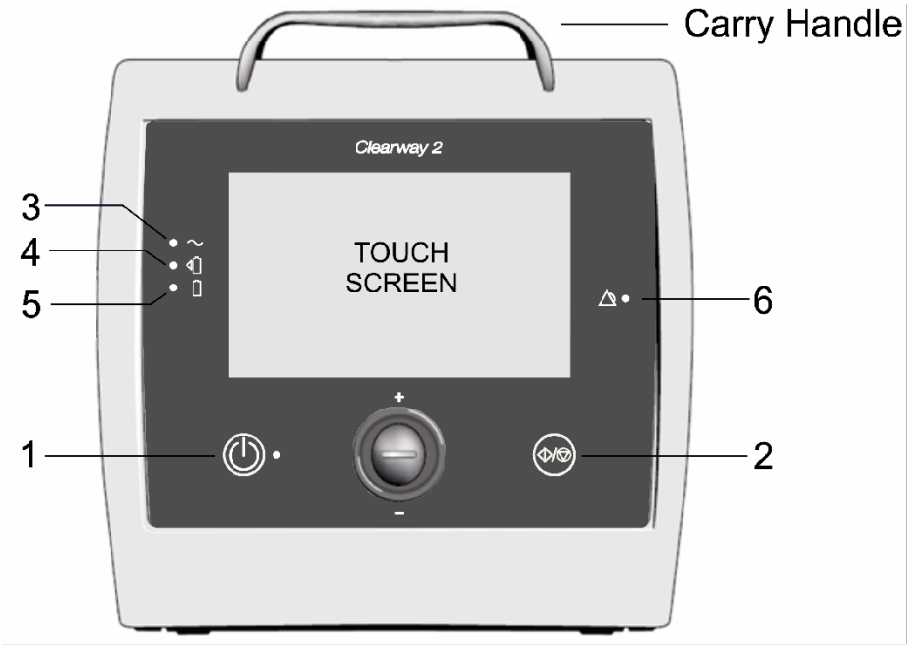


The main components of Clearway 2 are detailed below:

No.	Description	Product Code
1	Clearway 2 Device	232000
2	Clearway 2 Carry Bag	008284
3	AC Mains Power Cable	009074
4	User Manual	009077
5	Patient MI-E Circuit	008276

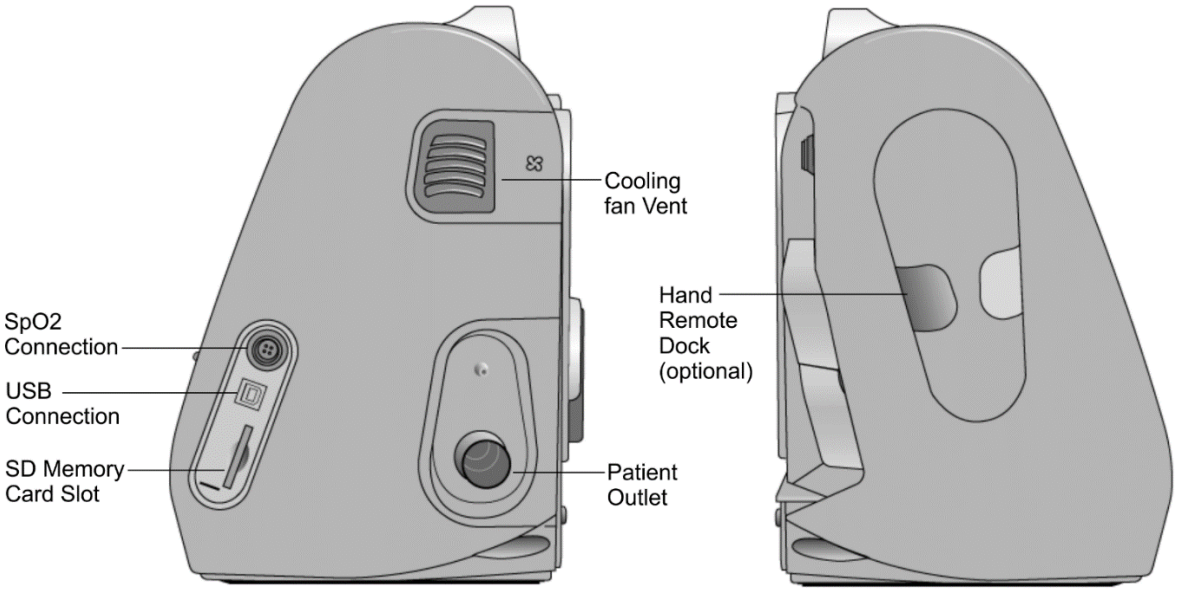
For more accessories please see section 10, Accessories

3.2 Front Panel



No.	Symbol	Description	LED
1		Standby ON/OFF	Green
2		Start/Stop Treatment	(None)
3		AC Power Source	Green
4		External Battery	Green
5		Internal Battery	Green
6		Alarm	Amber

3.3 Side Panels



USB connection is restricted to use with a computer to obtain patient compliance data and device logs, only.

SD Memory Card slot is restricted to be used to save patient compliance data to a memory card, only.

3.4 Back Panel

External Power is restricted to be used only to power the device using an external battery

3.5 Equipment Designation and Safety Labels

Below is a table of symbols that are used on the device.

No.	Symbol	Description
1		USB (Universal Serial Bus)
2		Memory Card
3	SpO_2	SpO_2 (Peripheral Capillary Oxygen Saturation)
4		Attention! For correct use, read "Intended Use" (page 6)
5		Class II Equipment; Double Insulation
6		Body Floating (IEC 60601-1 Type BF, Isolated Applied Part)
7		Read Disposal section
8		Read User Instructions before use
9		Manufacturer
10		Date of Manufacture: YYYY-MM-DD
11		AC Power input
12	**No SpO_2 Alarm**	No SpO_2 alarms fitted to the device
13	**IP 22**	Ingress protection rating against solids and liquids
14		Meets all requirements for CE marking according to applicable European health, safety and environmental protection legislation

15	UK CA	Meets all requirements for UKCA marking according to applicable United Kingdom health, safety and environmental protection legislation
16	REF	Product catalogue number
17	SN	Serial number
18	MD	This product is a medical device
19	EC REP	EU authorized representative
20		General warning symbol
21	60°C	Indicates the maximum temperature limits at which the product shall be stored, transported or used
22		Product shall be kept away from rain and in dry conditions.
23	Li-ion	The product or its material is part of a recovery or recycling process

4 Preparing the Clearway 2 for Use

Ensure you have read chapter 2 'Safety Information' on page 14 before setting the Clearway 2 up for use.

4.1 Checking the Device before Use

When using the Clearway 2 for the first time, follow the instructions below:

- Read chapter 2 "Safety Information" (page 14) before setting up the Clearway 2.
- Check that all main components and ordered accessories have been delivered with the device. (Refer to the packing note or the invoice, if available.)
- Ensure that the equipment is in good condition.
- If stored more than one month, connect the Clearway 2 to the power supply to recharge the internal battery (if fitted with a battery). See "Using Batteries", page 47 for further instructions.
- Check that both white and grey air filters are installed within the air inlet (see "Changing the Air Inlet Filter" page 59).

4.2 Placing the Clearway 2 Ready for Use

Always ensure AC mains power plug is accessible to easily disconnect

- Read the chapter "Environmental Operating Conditions" (page 69) to make sure all conditions are met and considered.
- Place the Clearway 2 on a solid, stable, flat surface.
- The Clearway 2 should be placed lower than the patient in order to prevent the device from falling on the patient.
- Make sure that nothing can block the patient air inlets.
- Do not place the Clearway 2 on a soft, or dusty surface, as this could make the device unstable, or result in dusty air to be drawn into the device.
- Never cover the device.

4.3 Connecting to AC Power (Mains Power)

Read the chapter "Electrical Safety" on page 15 carefully to make sure all conditions are considered and met.

AC Mains cable must be fitted with a 10 (A) amp fuse.

Always use the correct AC mains cable (part number 009074).

Ensure nothing is blocking the AC power cable that may cause difficulty disconnecting the mains power.

4.4 Inspecting the Clearway 2 before Use

Inspection of device before use

- Check that there is no visible damage.
- Check that the surface is clean.

Inspection of Cables

- Check that all cables are recommended by Breas Medical Ltd. (see "Accessories" page 78)
- Check that the cables are undamaged.
- Check that the cables are properly connected.

Inspection of Placement

- The Clearway 2 shall be placed on solid flat surface below the patient level. (See "Placing the Clearway 2 Ready for Use" on page 25.)
- Make sure that nothing can block the air inlets on rear and side of the device.

5 How to Use the Clearway 2

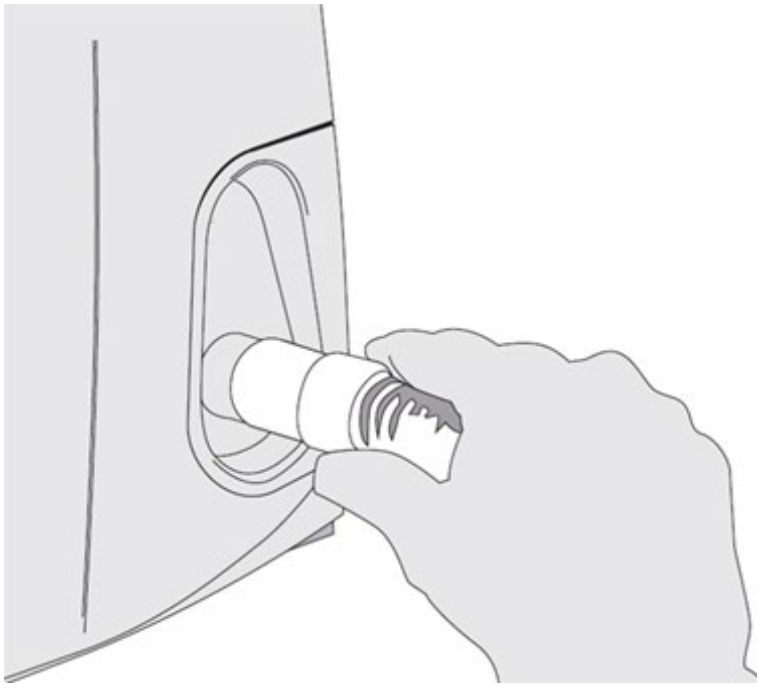
The Clearway 2 should only be used by trained carers/users of the device. Using the device without training may cause serious harm or injury to the patient.

If you have not been trained on the device, contact the referring clinician or home care provider.

You must only use the device as instructed by the referring physician. Failure to do so may cause harm to the patient.

5.1 Connecting the Patient Circuit

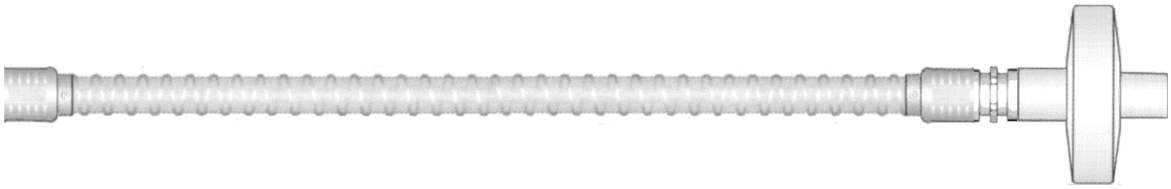
Always inspect the circuit prior to use. Connect the circuit to the device as per the diagram below.
Connect the circuit to the air outlet as below.



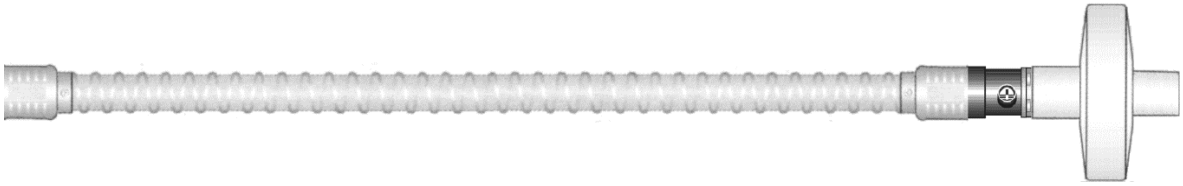
Fit a bacterial filter close to patient mask, to minimise contamination of the Clearway 2 device and circuit.

5.2 Circuits

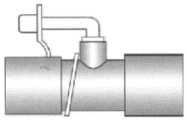
Standard MI-E Circuit with Filter
Part Number: 008276



NIV and IPPB Circuit with Leak and Filter
Part Number: 008277



Additional 'Oxygen Coupler' accessory available to entrain Oxygen to the IPPB and NIV circuit
Part Number: 008285

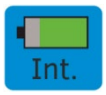


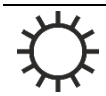
5.3 Turning the Device On/Off

To turn the device on, plug the device into the mains (AC), or use the internal or external battery as required, and then press the 'standby' button *(page 21)*. 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 continuously for twenty seconds.

5.4 On-Screen Symbols

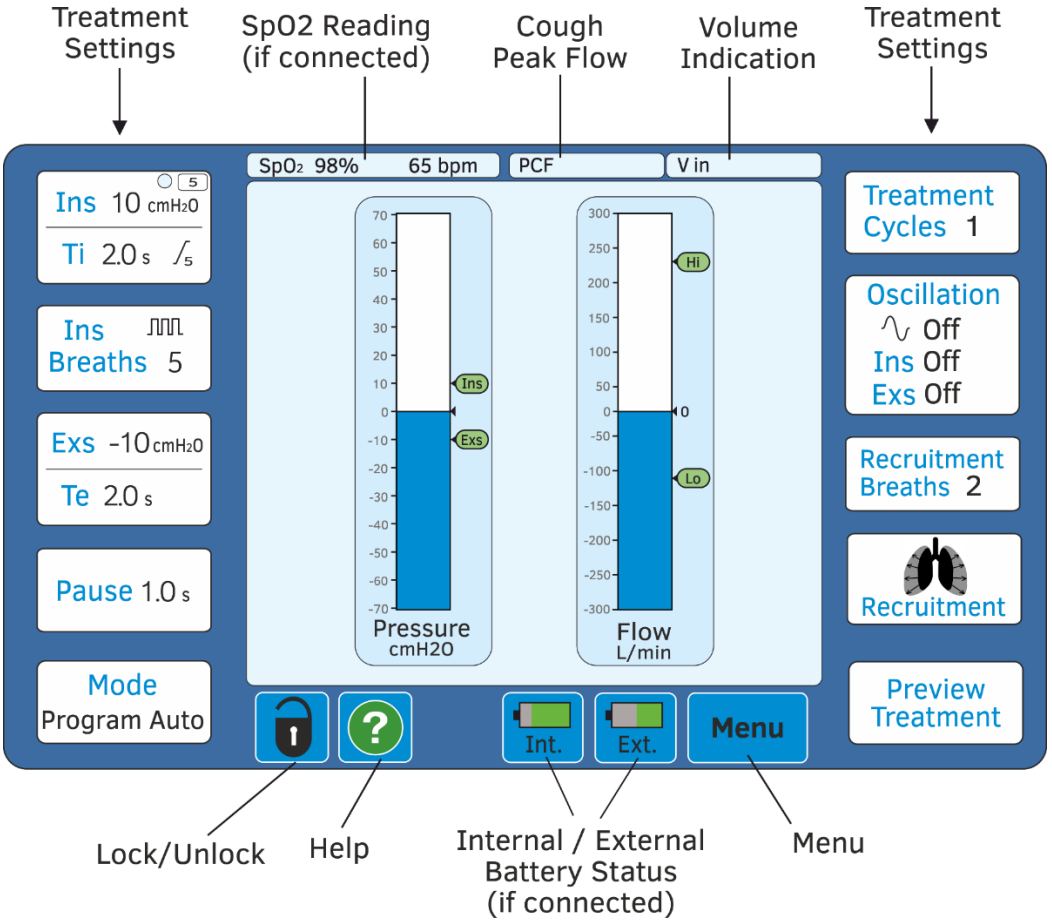
The Clearway 2 screen can contain the symbols and settings below. A summary of their meaning is included in the below table.

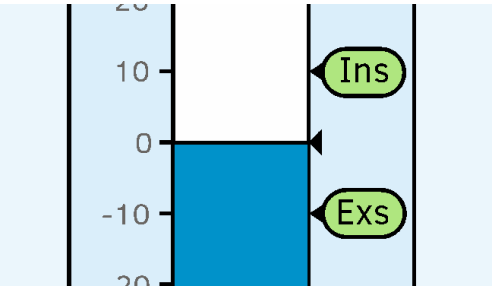
Symbol	Description
	Help button – where available, can be pressed to gain information or help
	Hide button – to hide the current screen
	Confirm an option or selection (not used for dynamic settings)
	Delete – Delete the current selected value
	Plus – Increase a value or parameter
	Minus – Decrease a value or parameter
	Lock – Indicates the device is locked
	Unlocked – Indicates the device is unlocked
	Alarm is active (alarming) / Alarm has occurred
	Indicates the status of the Internal Battery (if fitted)

	Indicates the status of the External Battery (if fitted)
	Brightness level of the screen
	Sound level of the alarms and device audio
	Synchrony Beep® – Audible tone to signal the start of the Exsufflation phase
	Recruitment Breaths

5.5 General Functionality and Display

The **Clearway 2 is a touch screen device**, and all settings and parameters are changed on-screen. 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.

The Clearway 2 uses a **Resistive Touchscreen** enabling operation with users wearing gloves as part of their PPE.

Resistive touch screen may not feel as responsive to users familiar with touchscreens and may require slightly more force to use than common devices such as smart phones.

Cough Peak Flow

Cough Peak Flow (CPF) is indicated by a marker on the Flow Bar as a live reading. The marker will be reset following each Exsufflation (cough), and a new CPF marker will be displayed.

The figures displayed should only be used to assess effectiveness of treatment by reviewing comparisons on the device.

If required, peak expiratory flow levels should be obtained using equipment compliant with EN ISO 23747:2015 Anaesthetic and respiratory equipment

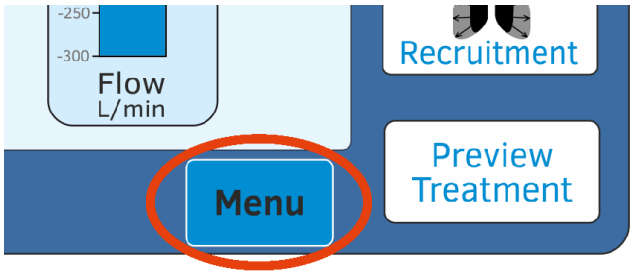
Pin Symbol

The pin symbol indicates the settings window must be manually closed and will not timeout after 10 seconds.

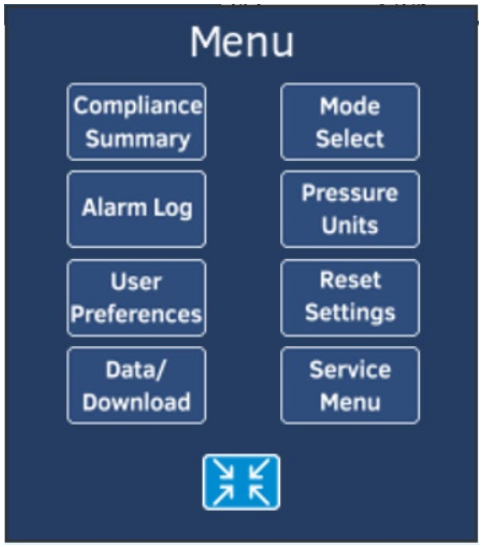
The pin can be activated by pressing the desired setting twice to make the setting window stay visible on screen, even during treatment for live adjustments to the treatment settings.

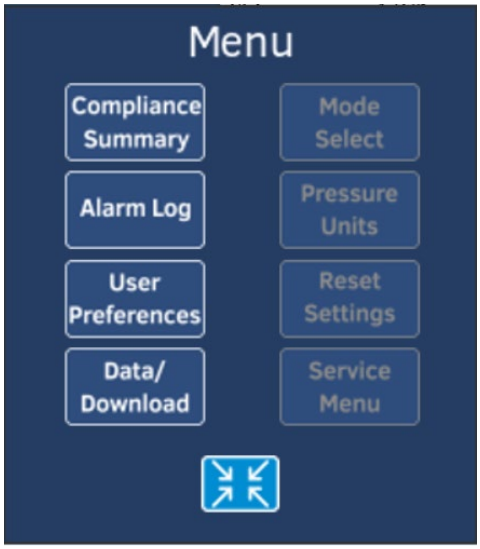
5.6 Main Menu

The Menu is accessed using the 'Menu' button at the bottom of the screen.

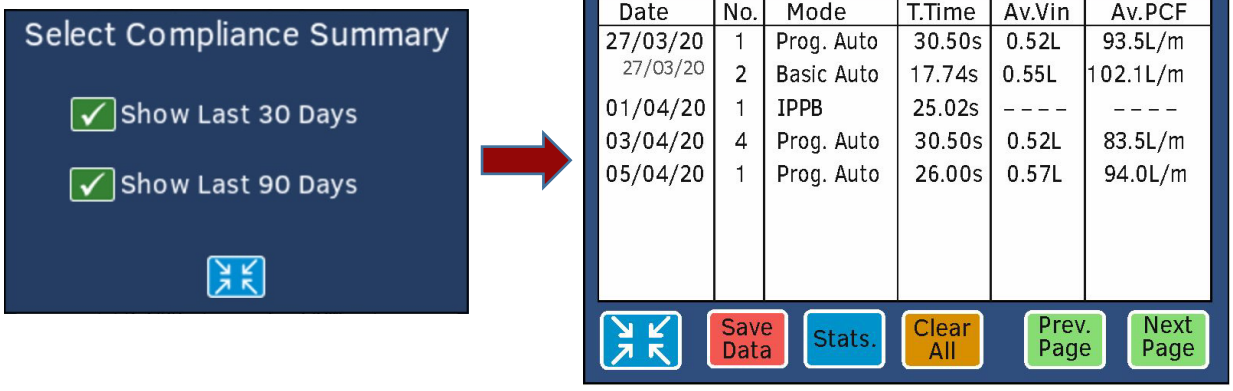


The options available in the Menu are limited if the device is locked.

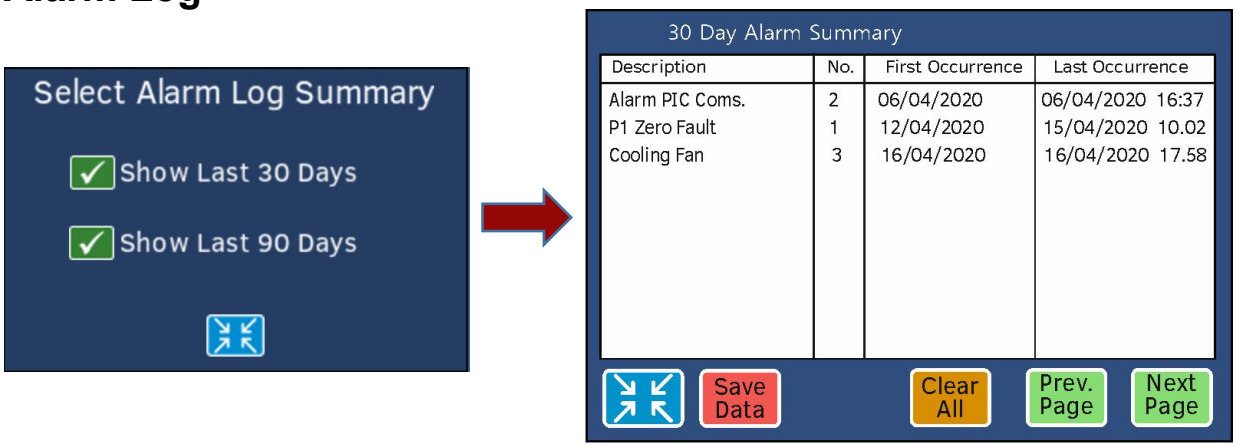




Compliance Summary

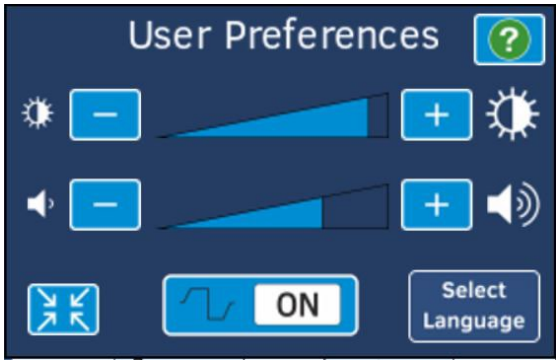


Alarm Log



User Preferences

Some limited user settings are available in the locked 'user' mode.
To access User Preferences, press Menu, followed by User Preferences.



Screen Brightness

Adjust the brightness of the screen using the plus and minus buttons, to increase or decrease the brightness.

Alarm Volume

Adjust the Volume of the speaker using the plus and minus buttons, to increase or decrease audible alarms and tones.

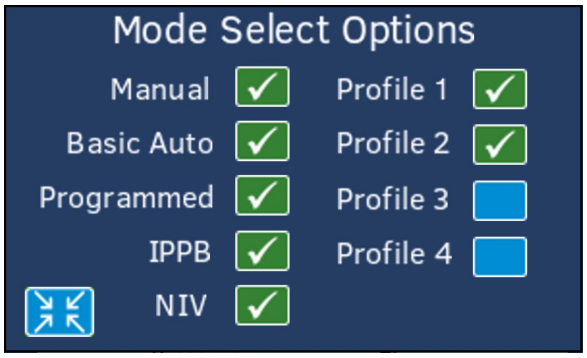
Synchrony Beep®

The synchrony beep is intended to assist the patient and therapist/carer to synchronise their treatment, and hence improve effectiveness of the therapy.

This may be to help the patient cough in synchrony with the negative pressure delivery, or for the therapist/carer to time delivery of any appropriate manual techniques.
The synchrony beep can be de-activated/activated as required by pressing the synchrony button to toggle synchrony beep on and off.

Mode Select Options

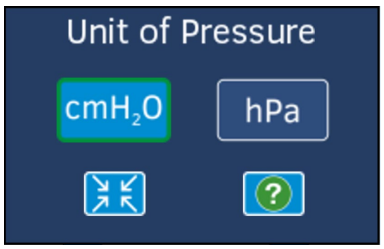
The Mode Select Options screen can be used to select each mode that is available to the user from the Mode Select screen.



The example screen (above) shows all modes available, except for Profiles 3 and 4, because no MI-E treatments or Treat Repeats have been saved to these profiles. See page **Error! Bookmark not defined.** for more information on Treat Repeat and Saved Profiles.

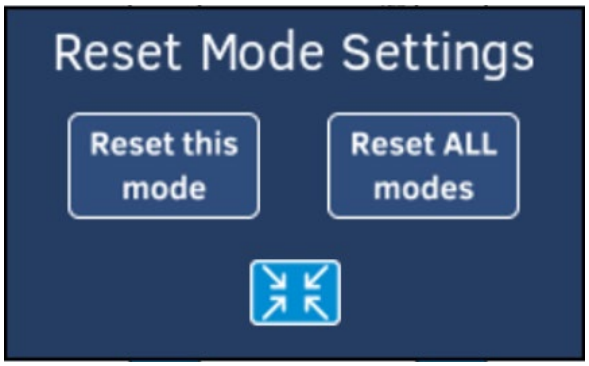
Pressure Units

The Pressure Units setting changes the measurement units for Pressure throughout the device, between cmH_2O and hPa.



Reset Mode Settings

The Reset Settings function allows the user to clear all user settings to defaults in the current mode, or all modes.



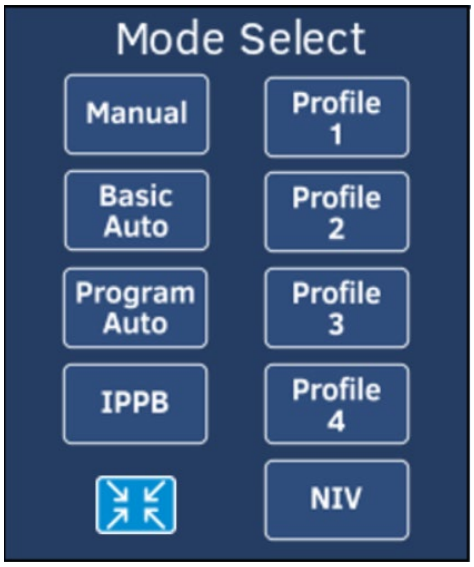
Service Menu

The service menu is accessed by a service code.
Refer to Service Manual for Service Menu information.

5.7 Treatment Settings

Selecting a Mode

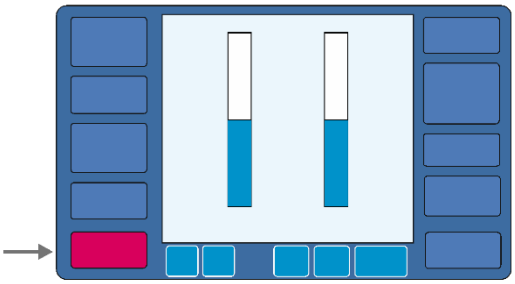
Options available in the Mode Select screen are limited if the device is locked.



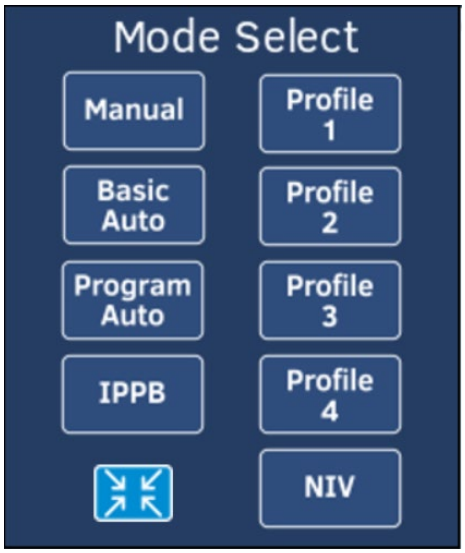
If the Clearway 2 device is unlocked, the prescribing physician or doctor is able to select any mode that is checked in the mode select screen.

5.8 Profiles

Unless the clinician has restricted access to specific modes *(see Mode Select Options, page 35)* you can access any mode or saved profile by pressing the Mode button.



Profile 1 – 4 will only be available to select if a prescription has been saved to a profile. A profile can be used to save either: a prescription within an MI-E mode, or a valid manual treatment that has been recorded and saved using TreatRepeat



5.9 Saving a Treatment Profile

A cough treatment programmed in any of the MI-E modes, can be saved as a profile. Saving a treatment or TreatRepeat is only available when the Clearway 2 is unlocked.

5.10 Starting and Stopping Treatment

If required, you can override a treatment while it is being delivered by using either the manual hand control or the front switch.
During a programmed mode you can terminate treatment at any time by pressing the stop treatment button.
In manual mode the treatment can be stopped by releasing the front switch or manual hand controller.
Once you are satisfied the device is set as required, you can start and stop therapy using the following methods:

For Automatic Programmed Modes:

- Pressing the start/stop treatment button, this will start and stop the pre-set programmed treatment.

Or,

- Pressing the start/stop button on the hand control, this will start and stop the pre-set programmed treatment.

For Manual Treatment Options:

- Using the front switch to manually activate therapy

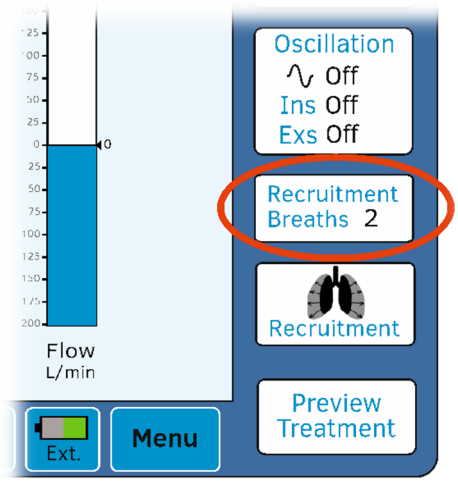
Or,

- Using the hand control to manually activate therapy

5.11 Recruitment Breaths

If Recruitment Breaths have been set, the Recruitment Breaths button will display the number of breaths that have been set.

Recruitment Breaths are <u>only</u> available in the Basic Auto and Program Auto mode

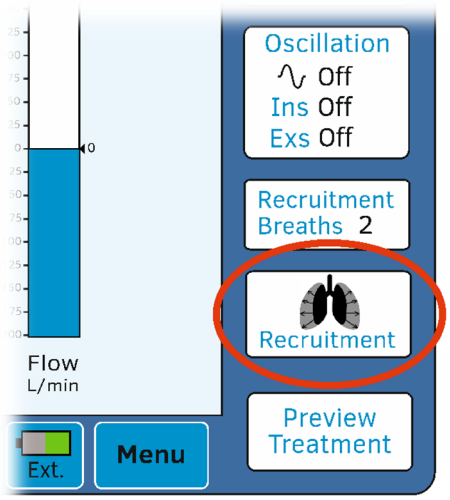


Recruitment Breaths can be used before or after the treatment, to promote re-recruitment and help the patient recover following treatment. Use only as advised by the referring physician.

Recruitment Breaths are delivered at the same insufflation pressure set for the treatment.

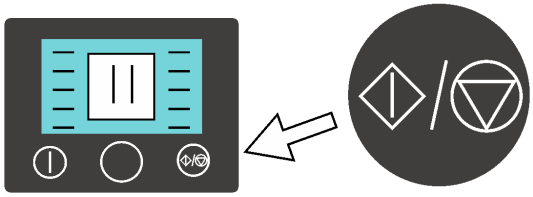
When set to OFF, Recruitment Breaths cannot be activated for treatment.

Inspiratory pressure of the Recruitment Breaths are the same as the treatment insufflation pressure, set by the user



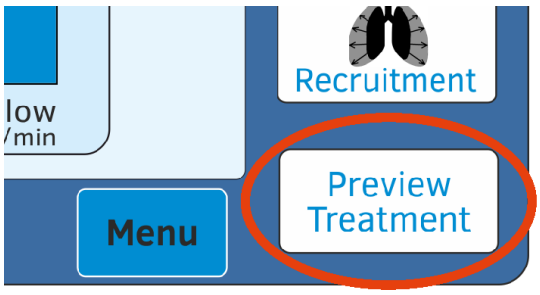
To activate the Recruitment Breaths, simply press the 'Recruitment' button to display the Recruitment screen, then use the 'START/STOP' button to begin recruitment.

To stop the treatment for any reason, simply press the START/STOP button again.



Always ensure the patient has cleared any large airway secretions through expectorating, or suction, prior to starting the Recruitment Breaths, to prevent the secretions being pushed distally.

5.12 Preview Treatment

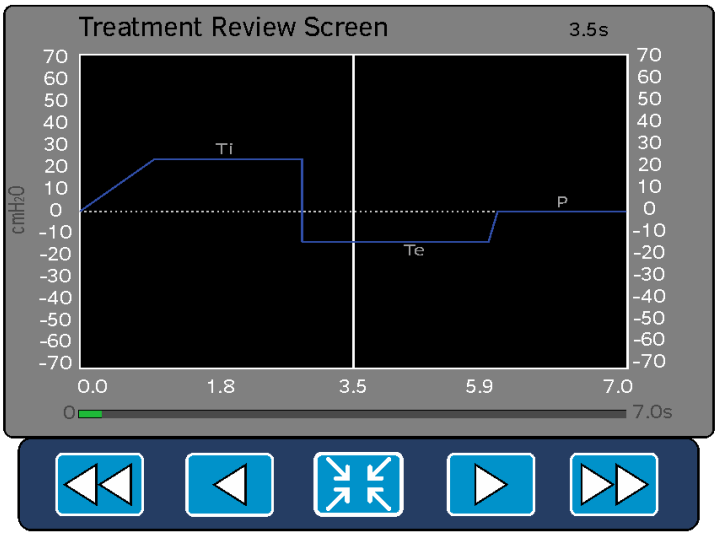


When the Clearway 2 is in standby and in any of the automatic MI-E modes, including a saved TreatRepeat programme, or NIV mode the programmed treatment waveforms can be previewed by pressing the Preview Treatment button. Pressing the arrow buttons moves the view forward or backward through the treatment programme. In Manual Mode it is only possible to View Treatment that is being delivered by the manual switches.

It is not possible to Preview Treatment in the IPPB mode

Active Treatment Display

When the Clearway 2 is delivering treatment in an automatic Mi-E mode, you can press the Preview Treatment button to see a visual representation of the programmed treatment.



A vertical line follows the treatment as it is being delivered. This may help patients to synchronise with the Clearway 2 when using it by allowing them to keep track of the treatment programme.

In the Manual Mode, users can press the View Treatment button to see live feedback waveforms of the pressure being delivered.

5.13 Entraining Oxygen

Please ensure you read the "The Usage of Oxygen if Prescribed" section (page 18) before using oxygen with the Clearway 2.

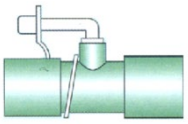
Oxygen is a prescribed medicine and must only be authorised by a competent clinician.

Always referrer to the oxygen provider's instructions for safety.

It is possible to use up to 15 litres per minute of low flow oxygen with the Clearway 2 if prescribed by your referring clinician. Only use the amount of oxygen as advised.

Never turn the oxygen on before turning the device on, as oxygen may pool around the machine.

To entrain Oxygen into the device safely, connect the oxygen into the circuit as close to the patient as possible using an oxygen connector *(see Accessories, page 78)*.

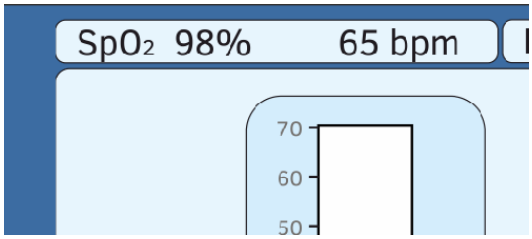


Once the treatment has finished, ensure the oxygen is turned off, before turning off the device.

5.14 Use with SpO_2 Sensor

The SpO_2 displays the patient's oxygen saturation, if measured with SpO_2 module accessory. When using the Clearway 2 with the SpO_2 sensor accessory *(see Accessories, page 78)* it is calibrated to display functional oxygen saturation.
To use the SpO_2 sensor with the Clearway 2, it must be connected to the side of the device *(see Side Panels, section 3.3)*.

The SpO_2 reading will be displayed live on the main screen of the Clearway 2.



The user will be notified with an alarm if the SpO_2 sensor becomes disconnected. If the data collected from the sensor is corrupted or unreadable, the SpO_2 reading will display a "?" next to the reading.

Warning: Prolonged use of the SpO_2 sensor can cause contact injuries to the patient's skin

The following information concerns the light emitted by the SpO_2 sensor:

- Peak Wavelength (red): 660 nm
- Peak Wavelength (infrared): 905 nm
- Maximum Optical Output Power: ≤ 15 mW
- For more information regarding the oxygen probe's range of peak wavelengths, max optical power and usage, please refer to the respective probe manual.

Environmental factors may influence the function or accuracy of the pulse oximeter such as ambient light, physical movement, diagnostic testing, low perfusion, electromagnetic interference, dysfunctional haemoglobin, presence of certain dyes and inappropriate positioning of the pulse oximeter probe.

A functional tester cannot be used to assess the Accuracy of a Pulse Oximeter Probe or a Pulse Oximeter.

5.15 Accessing User Data

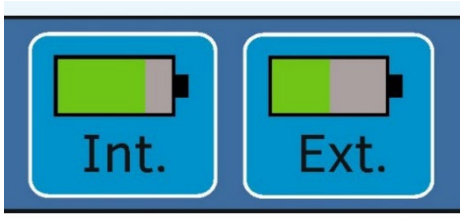
The clinician who is managing the patient's care has access to detailed data about the therapy and the amount of time the device is used each day.
Some data is also available for you to review in the locked, home mode of the device.

5.16 Using Batteries

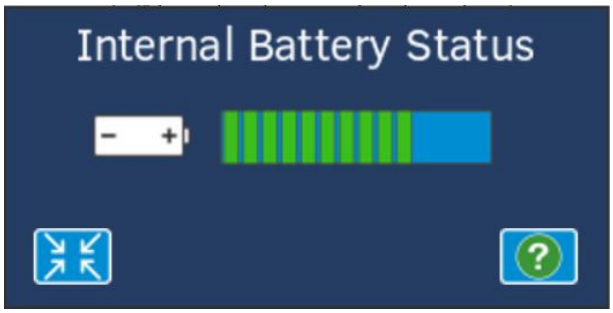
Only use the batteries described in Accessories (page 78). Use of any other battery may lead to improper or unsafe operation. The internal battery is not designed to be user replaceable. Please contact technical support if a replacement is required.

The Clearway 2 may be powered by an internal or an external battery. The Clearway 2 monitors the condition of the internal battery (if fitted) and automatically charges it as required when connected to the AC mains, and not in use.

The Internal battery and External battery icons will be visible at the bottom of the main screen only if a battery is connected.

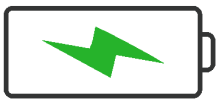


The icons will display the state of charge and can be pressed to show the battery status.



The state of charge is displayed as a bar graph and will change colour depending on the charge level.
A yellow charge level means the battery level is below 50%, and a red charge level means the battery is very low.

The battery symbol will change depending on the state of the battery.

Symbol	Description
	Internal battery Connected
	Battery Charging
	Battery Not Connected
	Battery Fault. Contact your provider
	Battery Under/Over Temperature <10°C or >45°C

The battery LEDs on the front of the Clearway 2 will be solid if the battery is in use, and flash if the battery is charging.

Internal Battery

If available, an internal battery can be fitted inside the Clearway 2 *(see Back Panel, section 3.4)*. The battery pack is not designed to be replaced by the user. If you experience improper function or replacement is required, contact your homecare provider, or Breas.

An internal battery will run for: >30 minutes in MI-E modes (based on settings of +40/-45 cmH_2O, and Ti, Te, and Pause times of 2 seconds). The capacity of lithium-ion batteries degrades over time and use, therefore older batteries and/or those that have been used extensively may not deliver the same running times as stated. Users that require battery back-up should regularly monitor the run-time they are able to achieve and replace the battery when necessary.

External Battery

If available, the external battery may be connected to the Clearway 2 using the external battery connector at the rear *(see Back Panel, section 3.4)*. An external battery may be connected and disconnected as required.

Power source priority

1. AC Mains
2. External Battery (if fitted)
3. Internal Battery (if fitted)

AC mains is the preferred power source. If the mains power supply is removed or fails, then Clearway 2 will switch to the External battery (if fitted) or internal battery (if fitted), in that order. Switching to battery power is indicated by an on-screen message, and the power source is indicated by an LED.

Charging the batteries

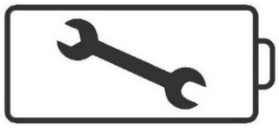
Clearway 2 monitors the internal battery and charges it automatically when the AC mains is connected. The external battery is not charged by the Clearway 2.

The Clearway 2 will not charge the battery when treatment is being performed.

Storing Batteries

If the Internal or external battery is to be stored for a period of longer than 1 month it should be initiated at between 15-50% charge and stored at a temperature between +5 to + 30°C. This will ensure the battery retains maximum capacity. A battery that is not used will slowly discharge; this rate of discharge will increase when stored at higher temperatures.

Battery Maintenance



This battery symbol will be shown in the battery status screen if the battery requires a replacement. An alarm will also be shown.

5.17 Transferring data

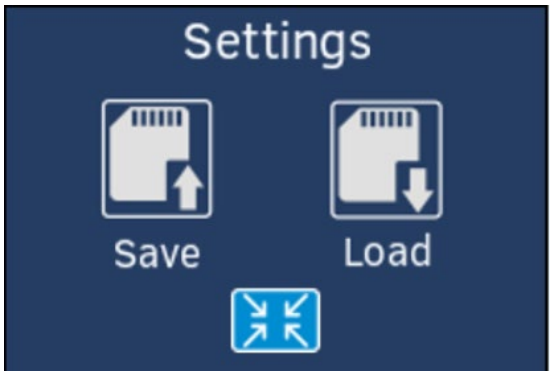
Do not connect an SD card to the Clearway 2 during treatment. Downloading of data is prohibited by software during treatment.

Compliance Data

Patient compliance data may be downloaded to a PC via USB cable or SD card, by selecting 'Compliance Summary' from the Main Menu.
Select the number of days data you want to view
Press the "Save Data" button
Insert an SD card and press the tick icon
A green tick in the SD card Icon is displayed if transfer is successful.

Settings Data

To save or load device settings, select 'Data/Download' in the Main Menu. Select either 'Save' or 'Load'.



Insert an SD card, and press the tick button. A green tick represents a successful data transfer. If the data transfer was unsuccessful, a red cross will be displayed instead.

6 Alarms

6.1 Alarm Function

The alarm function of the Clearway 2 consists of a yellow LED on the front panel, an audible alarm and a message box on the front LCD screen. Section 3.2, Front Panel, indicates the position of the LED. The visual alarm indicators are visible within a distance of 4 metres and to within an angle of 30^0 facing the front panel. The operator must be within audible range to receive the audible alarm.

6.2 Alarm Indication

Medium Priority alarm

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

Low Priority alarm

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

Warning message

LED – none
Audible – none
Message – Blue box on screen with description of warning.

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

6.3 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 corrected, stop using the Clearway 2 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.

6.4 Alarm and Warning descriptions

High Pressure Alarm

Item	Description
Definition	120% of set pressure is detected for > 2 seconds
Priority	Medium
Modes	All
Possible Cause	Cough during inspiration
Clearway 2 action	Treatment stops. The on-screen message must be acknowledged. Treatment cannot be started until message has been acknowledged
On Screen Message	"High Pressure Alarm! Treatment has stopped! - Restart the Clearway 2 - Contact your supplier if fault persists"

Incorrect Circuit in Use

Item	Description
Definition	No exhalation valve is detected in the breathing circuit
Priority	Medium
Modes	IPPB
Possible Cause	Exhalation valve not fitted. Incorrect breathing circuit being used.
Clearway 2 action	Treatment continues. Alarm continues until condition resolved or treatment ends
On Screen Message	"Incorrect Circuit in use! - Ensure IPPB valve is fitted"

Internal Over Temperature

Item	Description
Definition	Internal temperature is > 60° C.
Priority	Low
Modes	All
Possible Cause	Ambient temperature is high. Device is positioned in sunlight or close to a heat source. Air inlet filters are blocked (e.g. placed on a bed or soft surface)
Clearway 2 action	Treatment will continue
On Screen Message	"Over Temperature! Switch device OFF. Leave for 30 minutes"

Low Alarm Battery

Item	Description
Definition	Internal alarm battery must be replaced.
Priority	Low
Modes	All
Possible Cause	Alarm battery voltage is low. Connect Clearway 2 to mains to charge battery. If message persists, contact technical support for battery replacement.
Clearway 2 action	Treatment is still possible. Power fail alarm may be low volume or not functioning. (contact technical support for battery replacement)
On Screen Message	"Low Alarm battery! - Connect Mains power and leave to charge - Contact your supplier if fault persists"

Low Leakage

Item	Description
Definition	Insufficient intentional leak has been detected in the breathing circuit
Priority	Medium
Modes	NIV
Possible Cause	Intentional leakage port is not fitted. Incorrect breathing circuit is being used.
Clearway 2 action	Treatment continues. Alarm continues until condition resolved or treatment ends
On Screen Message	"Low leakage! Incorrect patient circuit for NIV - Ensure leak is fitted to the circuit"

Machine Fault

Item	Description
Definition	Internal function fault
Priority	Medium
Modes	All
Possible Cause	Internal machine fault. See service manual for details or contact technical support
Clearway 2 action	Treatment will stop.
On Screen Message	"Machine Fault! Treatment has stopped! - Restart the Clearway 2 - Contact your supplier if fault persists" (Fault Code displayed is used to diagnose specific fault with the device)

A Machine Fault can be caused by several different faults with the device. All Machine Faults require the user to restart the device, or to contact the supplier if the fault persists

NIV Treatment Ending Soon

Item	Description
Definition	NIV treatment is about to end
Priority	Warning
Modes	NIV
Possible Cause	NIV mode is ending soon
Clearway 2 action	Treatment continues and message will disappear after 5 seconds.
On Screen Message	"NIV Treatment is ending soon"

NIV Treatment has Ended

Item	Description
Definition	NIV treatment has finished
Priority	Warning
Modes	NIV
Possible Cause	NIV mode has finished
Clearway 2 action	Message will disappear after 5 seconds.
On Screen Message	"NIV Treatment has ended"

Power Fail

Item	Description
Definition	All power sources have been lost.
Priority	Medium
Modes	All
Possible Cause	All power sources have been lost. Mains not connected, and batteries discharged
Clearway 2 action	Treatment not possible. Constant audio alarm and flashing LED
On Screen Message	*N/A*

Pressure Measurement Fault

Item	Description
Definition	Fault detected in pressure measurement
Priority	Medium
Modes	All
Possible Cause	Internal pressure measurement fault
Clearway 2 action	Treatment stops. The on-screen message must be acknowledged. Treatment cannot be started until message has been acknowledged
On Screen Message	"Pressure measurement fault! Treatment has stopped! - Restart the Clearway 2 - Contact your supplier if fault persists"

Pressure Sensor Fault

Item	Description
Definition	Mismatch between pressure sensor 1 and 2
Priority	Medium
Modes	All
Possible Cause	Internal Pressure measurement fault
Clearway 2 action	Treatment stops. The on-screen message must be acknowledged. Treatment cannot be started until message has been acknowledged
On Screen Message	"Pressure sensor fault! P1 and P2 Difference - Treatment has stopped! - Restart the Clearway 2 - Contact your supplier if fault persists"

SpO_2 Sensor Disconnected

Item	Description
Definition	SpO_2 sensor has been disconnected
Priority	Low
Modes	All
Possible Cause	SpO_2 sensor has been disconnected either at in-line connector or at Clearway 2 SpO_2 sensor has failed
Clearway 2 action	Treatment continues Message must be acknowledged to clear
On Screen Message	"SpO_2 sensor disconnection! Patient SpO_2 sensor has been disconnected"

Treatment too Long

Item	Description
Definition	Treatment performed is too long to be saved in TreatRepeat
Priority	Warning
Modes	Manual
Possible Cause	The performed manual treatment is too long to be saved as a valid treatment in TreatRepeat
Clearway 2 action	Treatment is not saved
On Screen Message	"Treatment too long! Try recording a shorter treatment"

Treatment has Finished

Item	Description
Definition	Selected treatment has finished
Priority	Warning
Modes	Basic Auto, Program Auto
On Screen Message	"Treatment has Finished!"

7 Cleaning & Maintenance

WARNING!

The Clearway 2 should be cleaned and maintained in accordance with this manual.

- **The Clearway 2 should undergo maintenance, service, and control procedures, as well as any applicable upgrades, in accordance with the Breas Clearway 2 Service Manual.**
- **The Clearway 2 shall only be repaired or modified in accordance with the Breas, Clearway 2 Service Manual, technical bulletins, and any special service instructions, by service technicians that have been certified to do so after completing Breas Clearway 2 Technical Training.**
- **Do not under any circumstances attempt to service or repair the Clearway 2 yourself. If you do so, the manufacturer will no longer be responsible for the performance and safety of the device. Furthermore, no guarantees will be valid.**
- **Do not attempt to autoclave the Clearway 2 main unit.**

DEVIATION FROM THESE SERVICE INSTRUCTIONS MAY LEAD TO RISK OF PERSONAL INJURY!

The patient-connected parts and the filter must be cleaned and replaced regularly to ensure correct function of the Clearway 2.

All replaced parts must be disposed of in accordance with local environmental regulations regarding the disposal of used equipment and waste.

7.1 Cleaning the Clearway 2

To avoid electrical shock, disconnect the mains supply to the Clearway 2 before cleaning. Do not immerse the device into any fluids.

- Always be careful when cleaning the ensure that you do not damage any equipment.
- Fluid must not be allowed to enter the Clearway 2.
- Never apply any liquids directly on the Clearway 2 by spraying, splashing, or pouring. Use a moistened lint-free cloth when cleaning.
- Do not use an excessive amount of liquid when cleaning the Clearway 2.
- Do not autoclave the Clearway 2.

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

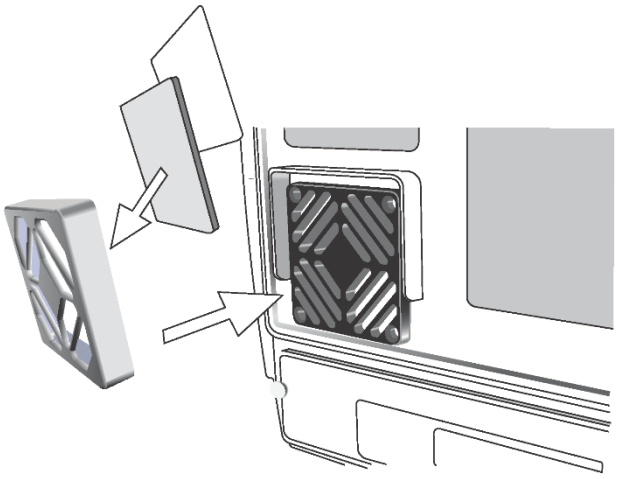
Cleaning the Exterior of the Clearway 2 unit

1. Turn off the Clearway 2 and disconnect the mains supply.
2. Remove the patient circuit.
3. Disconnect all electric cables.
4. Clean the outside of the Clearway 2 using disinfection wipes containing ethanol 70%.
5. Reconnect the patient circuit. Make sure all parts are dry before the Clearway 2 is put into operation.

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

7.2 Changing the Air Inlet Filter

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



There are two types of filter to be used:

1. cleanable filter
2. disposable filter

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

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

Cleanable Filter (grey)

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

1. Remove and separate the two filters.
2. Carefully vacuum the cleanable filter to remove any build-up of dust. Extra care should be taken to ensure the filter media is not damaged during cleaning. Alternatively, simply replace the grey filter.

Disposable Filter (white)

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

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

7.3 Change of Patient

If the Clearway 2 is used in a clinic by several patients, use of a low resistant bacterial filter is essential between the air outlet and the patient tube to prevent patient cross-contamination.

1. Follow the instructions in "Cleaning the Clearway 2" *(page 57)*.

2. Replace the patient filters according to "Changing the Air Inlet Filter" *(page 59)*.

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 dual insert when the Clearway 2 is used by a new patient.

Cleaning a device suspected to contain pathogens cannot be carried out by the lay operator in the homecare environment.

The device must be returned to the manufacturer for disposal or disposed of in the correct way (see Disposal**, page 62).**

Clearway 2 is not suitable for sterilisation.

7.4 Essential and Regular Maintenance Control

Essential maintenance is required for the Clearway 2 after 5 years of service (please see Clearway 2 Service Manual for further details). Breas advise annual checks to the Clearway 2 to ensure electrical safety as well as flow and pressure calibration. The Service Manual outlines the test instructions for Electrical Device Safety Testing which should be carried out by trained service personnel.

Service and/or repair activities must not be carried out when a patient is connected to the Clearway 2 or receiving treatment.

Do not use the device and contact your responsible care provider for an inspection of the device in the event of:

- **Unexpected patient symptoms during treatment.**
- **Unexpected or sudden pressure, performance, or sound changes during operation**
- **Suspected damage to the device, including the occurrence of machine fault / failure alarms**
- **Suspected damage to the internal or external battery, including evidence of battery cell leakage**

7.5 Service and Repair

The service and repair of the Clearway 2 must only be carried out by service personnel certified by Breas, in accordance with the Breas service instructions. Service inspections must always be carried out following any repairs to the device.

Authorised service workshops can order the Clearway 2 Service manual that contains the technical documentation required for the maintenance and service of the Clearway 2.

7.6 Storage

Store the Clearway 2 device in a dark room, where the temperature range is within -20°C to +60°C (-4°F to +°140F). For instructions on how to charge the batteries after long time storage, see "Using Batteries" (page 45).

- The Clearway 2 must not be stored in a warm place, such as direct sunlight, close to a radiator or in a vehicle in sunlight.
- If stored in a cold environment, let the Clearway 2 adapt to room temperature for at least 1 hour before using the device.

7.7 Transport

The Clearway 2 is a portable-operable device, and can be used during general transport by car, boat, or train. During transport it is advised to use the Clearway 2 carry bag when not in use.

Do not power the device from a vehicle. Only use the Internal and External batteries supplied by Breas during transport, if available

7.8 Disposal

The Clearway 2, any accessories and all replaced parts must be disposed of and recycled in accordance with the local environmental regulations regarding the disposal of used equipment and waste.

Batteries used with the Clearway 2 shall be recycled in accordance with the local environmental regulations

8 FAQ's & Troubleshooting

8.1 FAQ's

1. Can I travel with my device?

You should always notify your prescribing clinician if you intend to travel.
If you are traveling to a country with different voltage to the one you are currently using, you may require a different power cord or an international plug adaptor to ensure your power cord is compatible with the power outlets of the country to which you are traveling.
If you are planning to fly, or go on a cruise, you should always contact the company prior to travel. Documents can be downloaded from:
www.breas.com
See section 7.7 for further transport information.

2. What is the service life of the Clearway 2?

The service life of the Clearway 2 is 7 years if it is continuously regularly serviced and maintained.
All other Breas parts and accessories included or used with the Clearway 2 have a 7-year service life. Disposable parts such as circuits and masks have a separate shelf life, and will be clearly labelled on the packaging of the disposables. Please refer to the packaging for shelf life.

3. Does the Clearway 2 have any SpO_2 alarms?

There is an SpO_2 sensor disconnection alarm. However, there are no alarms for low SpO_2 or any other SpO_2 related alarms.

4. Can the Clearway 2 be used with Oxygen?

Yes, please refer to section 2.4 *(page 18)* for Oxygen Safety, and section 5.12 *(page 42)* for Entraining Oxygen.

5. Can oxygen be used with IPPB?

Yes, oxygen therapy can be used with IPPB *(refer to section 2.4)*. Please be careful to deliver the lowest level of oxygen required to maintain oxygen saturation as patient may be sensitive to oxygen therapy and at risk of CO_2 retention *(refer to section 5.12)*.

6. What interfaces can you use for IPPB?

The suggested interface for IPPB mode is a mouthpiece. If the patient cannot seal around the mouthpiece an oronasal mask can be used.

8.2 Troubleshooting

1. I cannot select the mode that I need.
    a. Ensure the mode has been unlocked *(see Mode Select Options, page 35)*

2. The device won't power on.
    a. Check mains power is connected to the device, and the standby light is on
    b. Ensure both batteries are charged if using battery power
    c. Send device for service

3. The front switch isn't working
    a. Ensure an MI-E (cough) mode is selected
    b. Test function by connecting a hand control
    c. Send device for service

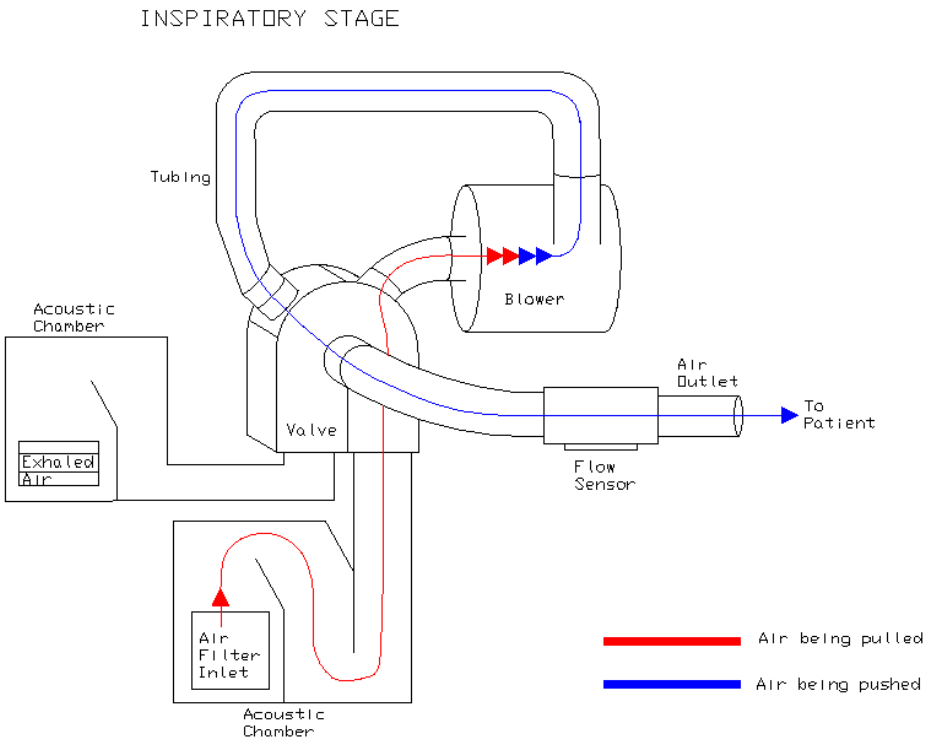
4. Set pressure is not reached
    a. Ensure correct breathing circuit is attached
    b. Check patient interface and fit
    c. Send device for service

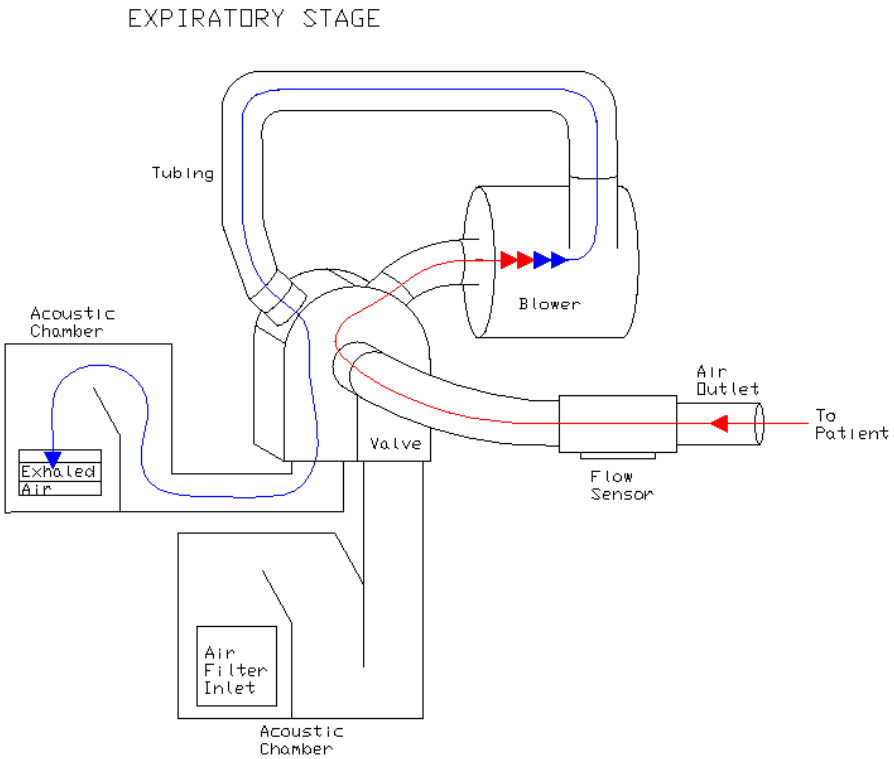
5. Internal battery will not charge
    a. Check mains power connection and the standby light is on
    b. Send device for service

6. External battery will not charge
    a. Check mains power connection and the standby light is on
    b. Check battery connector is inserted correctly to the Clearway 2
    c. Replace External battery
    d. Send device for service

9 Technical Specifications

9.1 System Description





9.2 Data Parameters

SETTING/VALUE	RANGE/PERFORMANCE
Cough Modes	• Manual Mode • Basic Auto Mode • Program Auto Mode • TreatRepeat (as a saved profile)
Theraputic Modes (Not ventilation)	• IPPB Mode • NIV Mode
Device Modes	• Clinical (unlocked) • Home (locked)
Insufflation Pressure	3 to 70 cmH_2O Resolution 1 cmH_2O Tolerance: ± 5% FS
Exsufflation Pressure	-3 to -70 cmH_2O Resolution 1 cmH_2O Tolerance: ± 5% FS
Insufflation time (Ti)	0.5 – 5.0 seconds Resolution 0.1 second Tolerance ± 0.25 seconds
Exsufflation time (Te)	0.5 - 5.0 seconds Resolution 0.1 second Tolerance ± 0.25 seconds
Pause time	0.0 - 9.0 seconds (mode dependant) Resolution 0.1 second Tolerance ± 0.25 seconds
Oscillation Frequency	0 – 20 Hz Resolution 1 Hz Tolerance ± 1 Hz
Oscillation amplitude	0 - 10 cmH_2O Resolution 1 cmH_2O Tolerance ± 1 cmH_2O

Measurable Flow	0 - 500 l/min Resolution 1 L/m Tolerance ± 10%
Breath Rate (NIV)	6 - 60 BPM Resolution 1 BPM Tolerance ± 1 BPM
SpO_2	85 - 100% Tolerance ± 3 digits No motion or flex sensor
Pulse Rate	18 - 300 BPM Tolerance ± 3 digits. No motion or flex sensor

ALARM	MEASURED SOUND LEVEL	INDICATION
Medium Priority Audible Alarm	45 - 50 dB(A)	± 4 dB(A) Measured at 1 m
Low Priority Audible Alarm	45 - 50 dB(A)	± 4 dB(A) Measured at 1 m

9.3 Electrical Information

ELECTRICAL FEATURE	SPECIFICATIONS
AC Voltage Source	100 to 240 V AC, tolerance +10%/-20%, 50 to 60 Hz, max 260 W
Type of protection against Electric Shock	Class II
Degree of protection against Electric Shock	Type BF Applied Part
Ingress Protection Rating	Ingress Protection rating: IP22
Mode of Operation	Continuous

9.4 Environmental Operating Conditions

ENVIRONMENTAL CONDITIONS	SPECIFICATIONS
Operating Temperature Range	5 to +40°C (41 to 104°F)
Storage and Transport Temperature	-20 to +60°C (-4 to +140°F)
Applied Parts Maximum Operating Temperature	+43°C (109.4°F)
Ambient Pressure Range	700 hPa to 1,060 hPa
Humidity	15% to 90%, non-condensing

OPERATING CONDITIONS	SPECIFICATION
Sound level at 70 cmH_2O in Manual Mode	Less than 74 dB(A) Measured at 1 m

INGRESS PROTECTION	EXPLAINATION
IP22	Solid particle protection: Hazardous parts are protected from touch by fingers and by objects greater than 12 mm. Liquid ingress protection: The protection withstands dripping water less than 15 degrees from vertical. The ingress protection has been tested by water drips equivalent to 3mm rain/minute for 10 minutes (2.5 minutes for each tilting direction)

9.5 Dimensions

CLEARWAY 2 DIMENSIONS	SPECIFICATIONS
W x H x D	285 x 285 x 195 mm
Weight	3.75 kg (without internal battery)
Patient air outlet	22 mm male, 15 mm female conical standard connector

9.6 Emissions and Immunity Declaration

Note: The 'Essential Performance' of the Clearway 2 is defined as follows:

Clearway 2 Essential Performance

The Clearway 2 will deliver therapeutic treatment via the patient-connection port (outlet) at the set pressure (+/- 10% of full scale).
Under the immunity test conditions of IEC 60601-1-2 4th Edition, the following allowances are acceptable:

- If the SpO_2 sensor accessory is connected, the Clearway 2 will provide SpO_2 readings within its published accuracy specifications or, indicate abnormal operation. Any temporary degradation of SpO_2 performance following transient immunity test exposure shall recover from any disruption within 30 seconds.

Additionally, the following shall not be allowed:

- Permanent damage or unrecoverable loss of function
- Changes in programmable parameters or settings
- Reset to default settings
- Change of operating mode
- Initiation of unintended operation, or change of operation

9.7 Compliance of Standards

Guidance and Manufacturer's Declaration

Safety Standards

Safety Standard
IEC EN 60601-1
IEC EN 60601-1-1
IEC EN 60601-1-2
IEC EN 60601-1-6
IEC EN 60601-1-8
IEC EN 60601-1-11
IEC ISO 80601-2-61

Electromagnetic Immunity

The Clearway is intended for use in the electromagnetic environment specified below. The user of the device should ensure it is used in such an environment.

Immunity Test	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	The relative humidity should be at least 5 %.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV Not applicable for input/output lines	Mains power quality should be that of a typical commercial, hospital and residential environment.
Surge IEC 61000-4-5	±1 kV line to line	Mains power quality should be that of a typical commercial, hospital and residential environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital and residential environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT, 0.5 cycle (multiple phase analysis); 0% UT, 1 cycle; 70% UT, 25/30 cycles (50/60 Hz); 0% UT, 250/300 cycles (50/60 Hz);	Mains power quality should be that of a typical commercial, hospital and residential environment. If the user of the Clearway 2 requires continued operation during power mains interruptions, it is recommended that the unit be powered from an uninterruptible power supply.

UT is the mains voltage prior to application of the test level.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Clearway 2, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Immunity Test	IEC 60601 Test Level	Recommended Separation Distance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	d=1.2*√P m at 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	d= 1.2*√P m at 80 MHz to 800 MHz d= 2.3*√P m at 800 MHz to 2.5 GHz **Equation description:** P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with this symbol 

Notes

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF

transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the ME equipment is used exceeds the applicable RF compliance level above, the ME equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the equipment.

b) Over the frequency range 150 KHz to 80 MHz, the field strengths should be less than 10 V/m.

Electromagnetic Emission

The Clearway is intended for use in the electromagnetic environment specified below. The user of the device should ensure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Clearway 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Clearway 2 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emission IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the Clearway 2

The Clearway 2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Clearway 2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Clearway 2 as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to the Frequency of Transmitter (M)		
	150 kHz to 80 MHz $d= 1.2*\sqrt{P}$ (meters)	80 MHz to 800 MHz $d=1.2*\sqrt{P}$ (meters)	800 MHz to 2.5 GHz $d=1.2*\sqrt{P}$ (meters)
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Recommended separation distances between external power conductors and the Clearway 2

Rated Maximum Current in Conductor (A)	Separation Distance (M)
	50-60 Hz d= I/2πH= I/188
1	0.005
10	0.05
30	0.16

For conductors rated at a maximum current not listed above, the recommended separation distance d in metres (m) can be estimated using the equation d=I/2πH, where I is the maximum current rating of the conductor in amperes (A) according to the transmitter manufacturer; H is the Clearway 2 immunity compliance level to electromagnetic fields in the 50-60 Hz frequency span (30 A/m).

Portable RF devices (e.g. mobile phones) should be used no closer than 30 cm (12 inches) to any part of the ME Equipment, including any cables

9.8 Clearway 2 in other countries

If you are traveling to a country with a line voltage which is different to where you were issued the device, then a different power cord or an international plug adaptor may be required to ensure your power cord is compatible with the power outlet of the country where you are travelling.

10 Accessories

Only use accessories recommended by Breas Medical Ltd. Breas Medical cannot guarantee the performance and safety for the use of other accessories with the Clearway 2.
Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations must comply with the valid version of the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part is configuring a medical system and is therefore responsible for ensuring the system complies with the requirements of the valid version of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

10.1 Package Contents

The Clearway 2 may include the following components.
Some components are optional accessories that may not be sent with your device from the referring clinician or home care provider, please see Accessories, section 10.2 for further information on optional accessories.

- Clearway 2 Device
- Patient Circuit, including bacterial filter
- Carrying Bag
- AC Power Cord
- Air Inlet Filters
- User Manual (this manual)

10.2 Optional Accessories

White Air Inlet Filters	008281
Grey Air Inlet Filters	008282
Carry Bag	008284
UK / EU Mains Cable	009274 / 008383
Hand Control	009279
MI-E Circuit	008276
IPPB & NIV circuit	008277
Oxygen Connector	008285
SpO_2 Sensor Module	006369
SpO_2 Sensor Adult	006589
SpO_2 Sensor Paediatric	006590
Memory Card	006705
USB Cable	004886
Internal Battery	008424

Use with other manufacturer's accessories or non-approved Breas accessories supplied or recommended by Breas may cause the device to malfunction.

Patient Settings

This page can be copied and used for noting the patient's settings.

Patient Settings – Breas Clearway 2

Patient ……

Date ……

Clinic ……

Set by ……

Patient Circuit ……

Mode ……

INS Pressure …… Ins Trig ……..…… EXS Pressure……

Ti ……. Ramp …… Te ……

Ins Breaths ……... Step …… Pause……

Treatment Cycles …… Oscillation Frequency ……...

Insufflation Amplitude ……. Exsufflation Amplitude ……

Recruitment Breaths ……

(NIV mode)	(IPPB mode)
IPAP ……. EPAP ……	INS Max ……..
Ti ……. Trigger ……	Flow ……. Trigger ……
Back up …….	Plateau Time ……

Notes ……

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……

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Glossary of Terms

Basic Auto Mode	Provides an Insufflation, followed by an exsufflation and a pause, may be repeated in multiple cycles, and is a mode of therapy within MI-E
EveryWare™	Breas cloud-based Compliance Software
Insufflation Estimated Tidal Volume	Indicates the estimated lung volume during insufflation (ml)
Intermittent Positive Pressure Breathing Mode (IPPB)	IPPB assists expansion of the lungs, therefore providing an increased tidal volume for patients with a variety of pulmonary conditions. It may be used to increase tidal volumes, prevent atelectasis, reduce work of breathing in patients who are tachypnoeic and may be fatiguing
Mechanical Insufflation-Exsufflation (MI-E)	Mechanical insufflation-exsufflation is a form of therapy in which the device delivers positive flow to inflate the lungs (insufflation), followed by an immediate and rapid change to negative pressure, which produces an exhalation (exsufflation), which simulates a cough and thus moves secretions towards the large airways to be cleared
Cough Peak Flow (CPF)	Estimated calculation of the strength of the patient's cough (l/min). Cough peak flow may give an indication of effectiveness of MIE treatment
Synchrony Beep®	The Synchrony Beep is designed to assist both the patient and therapist/carer to time the cough and/or manual treatment with the exsufflation, to help improve synchrony
Therapeutic Non-Invasive Ventilation (NIV)	Non-Invasive Ventilation, to be used as a form of therapy, for maximum of 15 minutes. The patient should always be supervised due to the lack of alarms, and a vented mask with an exhalation port should be used at all times
TreatRepeat®	TreatRepeat® is the ability to save a manual treatment performed into a pre-set programme, therefore reducing time for titration as well as enhancing patient synchrony

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Clearway 2, User Manual

ENGLISH – EU

EC REP

Breas Medical AB
Företagsvägen 1
SE-435 33, Mölnlycke
Sweden
Phone: +46 31 868800
Email: breas@breas.com

Breas Medical Ltd · UNIT A2, The Bridge Business Centre, Timothy's Bridge Road
Stratford-upon-Avon, England, CV37 9HW
Phone: + 44 (0) 1789 293 460
E-mail: uk@breas.com
www.breas.com

Company registered in England and Wales
Company number: 07190611
Registered office:
Barclays Bank Chambers
Bridge Street, Stratford-upon-Avon
CV37 6AH
United Kingdom

CE 2797

UKCA 0086

(01)5060405720168