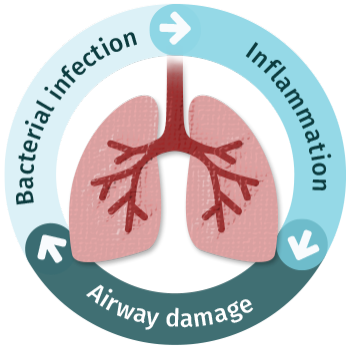




a breath of fresh care™

A Patient Guide to BiWaze® Clear System

Why is airway clearance important?



When airways become inflamed and weak, mucus can build up and enable bacteria to grow, leading to infections that can cause damage to the airways. Over time, airways can become so damaged they aren't able to properly move air in and out of the lungs. This is referred to as the vicious cycle of lung infections. If the vicious cycle continues, the damage to the airways can become irreversible, leading to chronic respiratory failure and other serious health complications.

Airway clearance techniques (ACTs) loosen thick, sticky mucus so it can be cleared from your lungs by coughing. The goal is to reduce the likelihood of infections and help you breathe easier.

Many ACTs use percussion (clapping) or a wearable vest externally to loosen mucus so it can be cleared out of the lungs by coughing. Other ACTs use lung expansion and high frequency oscillations internally to loosen mucus.



How does BiWaze® Clear help with airway clearance?



BiWaze® Clear System provides oscillating lung expansion (OLE) therapy to help loose mucus, decrease inflammation and open airways so you can breathe easier.

BiWaze Clear expands and clears the airways through a combination therapy in just 10 minutes. Lung expansion therapy expands the airways, high frequency oscillation therapy mobilizes secretions and aerosol therapy delivers a medication deep into the lungs. Alternating therapies of lung expansion and high frequency oscillation combined with aerosol helps maximize therapy effectiveness.

Visit our website to learn more: www.abmrc.com

Overview of BiWaze® Clear

TOP AND FRONT PANEL

1. Touch Screen Allows you to view settings, system status information, therapy settings, and logs. You can also modify settings from the touch screen.

2. Device Mode LED Light Provides different color code lights.

Green = Manual Mode

Blue = Auto Mode

Red = Error or Shutdown Mode

3. Patient Port Connection point for the Dual Lumen Breathing Circuit.

SIDE PANEL

4. Air Inlet Filter Filters air being brought into the control unit.

5. Cooling Fan Cools the main control board.



BACK PANEL

6. Power Switch Turns the control unit on and off.

7. AC Power Inlet Connection port for the AC power cord to power the control unit and charge the battery. The red light to the right of the connection port indicates if the power cord is fully connected in the port.

8. Handle Allows easy carrying of the control unit.

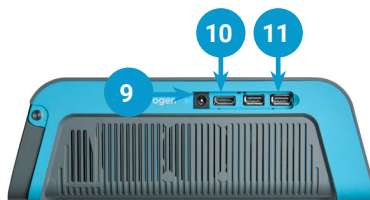
SIDE PANEL

9. Aerogen® Power Port Connection port for the Aerogen controller cable which powers the Aerogen Solo nebulizer.

10. HDMI Port Allows external display of the touch screen through an HDMI cable.

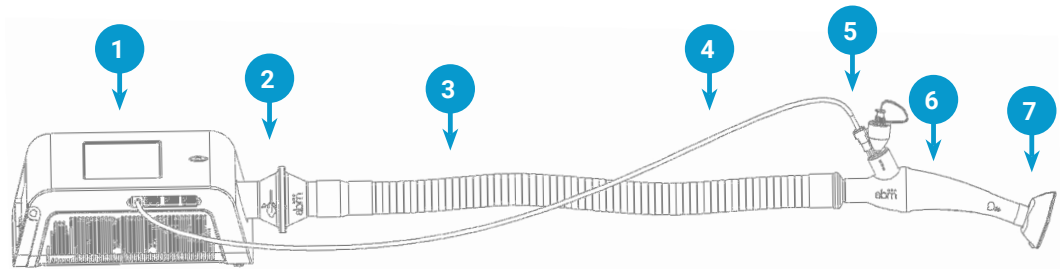
11. USB Ports Connection port for USB flash drives and SpO2 external sensors.

Caution: Do not attach any unapproved devices. Failure to do so may damage the system.



Dual Lumen Breathing Circuit Setup

1. **BiWaze Clear** Main therapy control unit.
2. **Coaxial Bacterial/Viral Filter** designed to filter bacterial and viral particles from flowing in and out of the control unit.
3. **Coaxial Breathing Tube** separates the inhalation (outer path) from the exhalation (inner path).
4. **Aerogen® Power Cable** powers Aerogen Solo nebulizer
5. **Aerogen® Solo Nebulizer** vibrating mesh nebulizer for prescribed medication
6. **Handset** provides a comfortable grip for therapy delivery and a spacer for the nebulizer.
7. **Patient Interface** there are three patient interface options available; face mask, mouthpiece, and a flexible trach adapter.



PATIENT INTERFACES

Leaks in the patient interface can decrease the effectiveness of the therapy.

Some people may need to have their head supported from behind to prevent leaks when using a face mask.

When using a mouthpiece, you may need to use a nose clip to prevent leaks.

Note: Always follow the prescribed therapy protocol from your physician.

Prepare for Therapy

SYSTEM SETUP

1. Assemble the Dual Lumen Breathing Circuit.
2. Switch on the power at the back of the control unit and plug in the AC power cable to the control unit if necessary.

Note: During each startup the control unit self-calibrates.

3. The screen will display the last therapy completed. You may have different therapy options as pre-programmed therapies in the drop-down list under Auto.
4. Position the control unit on a firm, flat surface within arm's length of the patient. The control unit should be placed below elbow level for the best visibility of the screen.

Note: Make sure that the air inlet areas on the left and right of the control unit are not blocked. Air must flow freely around the control unit.

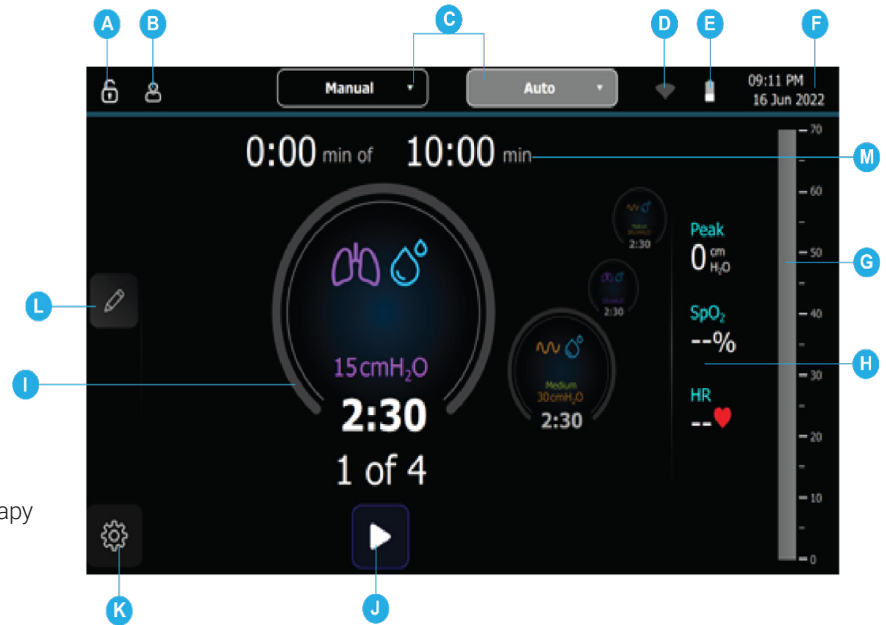


Therapy Screen

When the BiWaze Clear system powers on the screen will display the last therapy completed. Below are the components of the therapy screen.


- A. Lock icon (blue is locked and grey is unlocked)
- B. Patient Name or ID (optional)
- C. Therapy Modes:
 - Auto Mode: pressures and times are preprogrammed
 - Manual Mode: pressures are set and the therapy time is controlled by the user. (Mode may be hidden)
- D. WIFI allows data transmission to Arc Connect and data/time synchronization with the BiWaze Clear control unit's physical location local time zone
- E. Battery status
- F. Date and Time
- G. Pressure Manometer (may be hidden)
- H. Peak Pressure (may be hidden)
- I. Progress Circles to track current phase and next phase of therapy
- J. Start or Pause icon
- K. Settings
- L. Edit Therapy (may be hidden)
- M. Therapy Time

Note: BiWaze Clear has a lock feature which can be set by the healthcare team. When the system is locked, some therapy components may be hidden.




Run Therapy

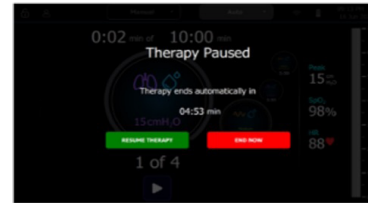
AUTO THERAPY

1. Select Auto on the top menu bar. You may have pre-programmed therapy options to choose from in the drop-down list under Auto.
2. Ensure the patient interface is securely in place.
 - Face mask—tightly, but comfortably, cover the mouth and nose of the patient. Make sure the narrow end of the mask is over the patient's nose.
 - Mouthpiece—put the mouthpiece lightly in the patient's mouth. Make sure that the patient maintains a tight seal on the mouthpiece during the therapy.
 - Flexible tracheostomy adapter—if the patient has a tracheostomy tube or endotracheal tube, use the flexible tracheostomy adapter to connect the tracheal tube to the breathing tube.
3. Press Start to begin therapy. 
4. Use the therapy timer (A) and phase circles (B) on the screen to follow along with the therapy.

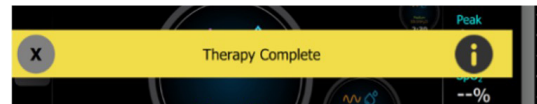


5. To Halt therapy press Pause 
6. Press RESUME THERAPY to continue the therapy or END NOW to stop the therapy.

Note: The therapy will remain in a pause state for 5 minutes before automatically ending.



7. When the therapy is complete, you'll see a therapy completed ribbon across the screen. The ribbon contains details of the therapy delivered and can be closed by pressing the X.



TYPICAL THERAPY

A therapy is typically a 10-minute session with the goal of expanding the airways and moving secretions from the lower lobes to the upper airways so they can be coughed out.

The 10-minute therapy is composed of 2.5 minutes of PEP (positive expiratory pressure), 2.5 minutes of OSC (high frequency oscillation), and these two therapies are repeated for the same amount of time to complete the 10-minute session.

Note: The Aerogen® Solo can only be run with saline while using it with BiWaze® Clear.



INSPIRATORY TRIGGER

Your clinical team may have enabled 'allow user adjustments' on your system which allows changes to be made to the programmed therapy profiles while the device is locked. If enabled, therapy pressure can be adjusted up to 5 cmH₂O per phase, depending on what your clinical team configured. When a therapy is adjusted, the profile will reset to the original saved therapy profile settings after the therapy is run.



If the ability to adjust pressure is enabled, the pen icon will be visible. Press the pen icon to open the therapy settings.



From the therapy settings screen you can edit the therapy phases in the therapy line. Press on a phase you want to edit.



The edit phase settings box will appear and you can change pressure based upon what has been enabled by your clinician. Press the arrow to edit the pressure and press the green check mark to save the updated pressure.

Cleaning and Maintenance

CONTROL UNIT AND BREATHING CIRCUIT

1. Switch off the power at the back of the control unit and unplug the power cord.
2. Disconnect the breathing circuit from the control unit.
3. Wipe the exterior of the control unit, the patient port adapter, and power cord with an approved cleaning agent (see the BiWaze Clear User Manual BK0381 for a list of approved cleaning agents).

Note: Allow the device to completely dry before plugging in the power cord.



4. Disconnect all the components of the Dual Lumen Breathing Circuit including the coaxial viral/bacterial filter, coaxial breathing tube, handset and patient interface.
5. Examine the coaxial viral/bacterial filter and discard if it is damaged by sputum or trapped moisture. If it is not damaged, gently wipe the exterior with an approved cleaning agent and set aside. Do not wash the coaxial viral/bacterial filter.



6. The coaxial breathing tube, handset, and patient interface should be washed thoroughly with liquid dishwashing soap and warm water.
7. Let the components air dry completely before reuse.

Note: Replace the breathing circuit after 30 days or 90 therapy cycles, whichever comes first.

PREVENTATIVE MAINTENANCE

BiWaze Clear does not require routine servicing. The system performs a self-calibration upon every startup.

AIR INLET FILTER

Under normal usage, you should clean the inlet air filter at least once every month and replace it with a new one every six months. If BiWaze Clear is used in an environment with animal hair or high amount of dust, it is recommended to clean the air inlet filter more frequently.

1. Switch off the power at the back of the control unit and unplug the power cord.
2. Remove the filter from the enclosure by pinching it with your fingers.
3. Examine the filter for integrity. Replace the filter if it is torn or damaged.
4. Wash the filter in warm water with a mild detergent like liquid dish soap.
5. Rinse thoroughly to remove all detergent residue.
6. Reinstall the filter after it is completely dry.

Note: Only Air Inlet Filters (BC21274) from ABM Respiratory Care should be used as replacement filters. The filter package includes 3 filters but only use one filter at a time.



STORAGE AND TRANSPORTATION

Store in a dust free location outside the reach of children.

Use the carrying bag provided with the system to protect the control unit and the accessories. When traveling, the carrying bag is for carry-on luggage only. The carrying bag will not protect the system if it is put through checked baggage. Do not place other baggage on top of the system.



This Patient Guide contains information extracted from the BiWaze Clear user manual (BK381). For complete instructions for use please refer to the BiWaze Clear user manual.

If you have questions about your BiWaze Clear system or therapy, please contact your local Home Health Equipment company or healthcare team.



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www.abmrc.com or call customer support: 1-877-ABM-RC01 (877-226-7201)