BiWaze® Clear
SYSTEM

USER MANUAL

BK0381 Rev: 5.0

abm
RESPIRATORY CARE

Contents

1 Introduction

1.1. Indication For Use

The BiWaze® Clear System is indicated for the mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with an oxygen supply.

Patient Population

The BiWaze Clear System is indicated to deliver therapy to adults and children over the age of 2 years in the acute care setting.

The BiWaze Clear System is indicated to deliver therapy to adults and children over the age of 5 years in the home care setting.

1.2. Overview

The BiWaze Clear System helps to mobilize secretions from the lower airways to the upper airways where they can be coughed or suctioned out of the lungs.

This User Manual includes instructions for setup, use and maintenance of BiWaze Clear. Before you operate the system, make sure you have read and understand in detail the contents of this manual. It is important that you read and strictly obey the safety aspects contained in this manual.

This User Manual is applicable for BiWaze Clear and is intended for a patient, caregiver, and medical professional for all care environments.

Note: ABMRC LLC is the legal manufacturer of BiWaze Clear. ABMRC LLC is part of the corporate group, ABM Respiratory Care.

1.3. Product Package Contents

The BiWaze Clear System includes the following components.

- BiWaze Clear control unit
- Dual Lumen Breathing circuit kit that includes a bacterial/viral filter, breathing tube, connecter, handset, handset cap, Aerogen Solo nebulizer, and patient interface (Mouthpiece)
- AC Power Cord
- User Manual
- Quick Reference Guide
- Air inlet filter
- Aerogen Solo Power Cable
- Carry Bag (home care only)
- Mobile Cart (acute / post-acute care only)

Following components are optional accessories that are available for BiWaze Clear

- Other Dual Lumen Breathing circuit kit with patient interface options (face mask-various sizes and flexible trach adapter)
- SpO2 Oximeter
- SpO2Sensor (size options: small, medium and large)

WARNING

- Use BiWaze Clear only as directed by a physician or healthcare provider.
- Use BiWaze Clear only for the intended use as described in this manual. Advice contained in this manual does not supersede instructions given by the prescribing physician.
- Read the entire manual before using BiWaze Clear.
- Setup and configure BiWaze Clear in accordance with the instructions provided in this guide.

CAUTION (For USA only)

Federal law restricts this device to sale/use by or on the order of a physician.

1.4. Theory of Operation

The BiWaze Clear System helps to mobilize secretions and provide lung expansion therapy for the treatment and prevention of pulmonary atelectasis and has the ability to provide supplemental oxygen when used with an oxygen supply. The airway clearance therapy creates airflow bias which expands the airways and dislodges

retained mucus in the lungs and helps treat and prevent atelectasis. BiWaze Clear provides three respiratory therapies: PEP, OSC, and NEB.

- **Positive Expiratory Pressure (PEP):** During PEP, the system delivers a programmed positive pressure which the patient exhales against to open and expand the patient's airways. The nebulizer can be configured to run during PEP therapy to help move the medicated aerosol throughout the airways.
- **Oscillation (OSC):** During OSC, the system oscillates the airways with pulses of positive pressure to thin secretions and mobilize them from the lower airways to the upper airways so they can be coughed or suctioned out. The nebulizer can be configured to run during OSC therapy to help move the medicated aerosol throughout the airways.
- **Nebulize (NEB):** During NEB, the system powers only the Aerogen solo vibrating mesh nebulizer. This therapy gives the patient a break from PEP or OSC while the patient receives their nebulized medication.

1.5. Intended Use

The BiWaze Clear System assists patients in loosening and mobilizing secretions as well as treating and preventing atelectasis by providing lung expansion and high frequency oscillation therapies. The BiWaze Clear System may be used with a patient interface like face mask, mouthpiece, a trach adapter to a patient's endotracheal or tracheostomy tube, or in line with a ventilator. It is for use on adult or pediatric patients in acute, post-acute, and home care environments.

1.6. Contraindications

The BiWaze Clear System is contraindicated in patients with the following pre-existing conditions:
Absolute Contraindication

The BiWaze Clear System is contraindicated if this patient condition exists:

- Untreated tension pneumothorax

Relative Contraindication
When you use the BiWaze Clear System, patients with these conditions should be carefully evaluated before a decision is made to use the therapy:

- History of pneumothorax
- Pulmonary air leak
- Recent pneumonectomy
- Pulmonary hemorrhage
- Myocardial infarction
- Vomiting

Possible Adverse Conditions
When you use the BiWaze Clear System, patients may experience one or more of these effects:

- Hyperventilation
- Gastric distension
- Decreased cardiac output
- Increased intracranial pressure
- Increased air trapping
- Hyperoxygenation
- Pneumothorax
- Pulmonary air leak
- Pulmonary hemorrhage

1.7. General Warnings and Cautions

When using electrical products, especially when children are present, basic safety precautions should always be followed, including the following important safeguards.
READ ALL INSTRUCTIONS BEFORE USING.
The following are general warnings and cautions. Further specific warnings, cautions and notes appear next to the relevant instruction in the manual.

WARNING

Obey all warnings throughout the manual and also those below to help prevent injury and/or equipment damage.

A WARNING alerts you to possible injury. The operator should read and understand this entire manual before using the device.

- **WARNING** - Federal USA law restricts this product to sale by or on the order of a physician. Sale by or on the order of unauthorized persons can cause patient injury.
- **WARNING** - We recommend the first use of this product be in a supervised setting such as a doctor's office or at home with a clinical trainer.
- **WARNING** - This system should only be used by trained personnel.
- **WARNING** - Use this product only for its intended use as described in this manual. Do not use attachments not recommended by the manufacturer.
- **WARNING** - Do not operate this system if it shows any signs of physical damages, faulty conditions, or malfunction (such as damaged power cord or plug, dropped, dropped in water, or if the touchscreen does not operate).
- **WARNING** - Do not use the system near to any heat source or ignition source such as a fireplace or radiant heater.
- **WARNING** - Never drop or insert any object into any opening or hose.
- **WARNING** - Adult supervision is required to use the therapy on children.
- **WARNING** - Close supervision throughout the treatment is necessary when this product is used by children or patients with physical limitations or impaired cognitive abilities.
- **WARNING** - Make sure the position of the control unit is such that you can quickly, without obstruction, disconnect the power cord from the power outlet on the wall, if required.
- **WARNING** - If it is necessary to disconnect/isolate the product from the main power supply, disconnect the power cord plug from the power inlet on the back of the control unit or disconnect the power cord from the power outlet on the wall.
- **WARNING** - Do not operate the system under harsh conditions (such as extreme temperature or excessive moisture).
- **WARNING** - Do not operate the system if fluid is spilled on the control unit.
- **WARNING** - Do not use the system near flammable chemicals or products, including flammable anesthetics.
- **WARNING** - Keep the tubing, cables and power cords away from toddlers and children to avoid strangulation.
- **WARNING** - Keep the small parts provided with this product away from children to avoid swallowing and causing a choking effect.
- **WARNING** - Do not store or use the system around pets, pests, or unsupervised children.
- **WARNING** - Keep the control unit, battery, AC/DC power adapter, and power cord away from heated surfaces.
- **WARNING** - Use only the supplied Aerogen® Solo nebulizer with the Dual Lumen Breathing Circuit's handset.
- **WARNING** - Only the Aerogen® Solo Controller Cable should be used to connect to and power the Aerogen® Solo nebulizer with the BiWaze Clear system.
- **WARNING** - Use only the recommended SpO2 sensor with the BiWaze Clear System.
- **WARNING** - Only ABM Respiratory Care authorized persons should open and service this system.
- **WARNING** - Do not use the device in the presence of a flammable anesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- **WARNING** - Therapy should not be conducted when the device is in the carrying bag.
- **WARNING** - Do not modify this equipment. No modification of this equipment is allowed by any unauthorized personnel.
- **WARNING** - When using the device on a new patient, always use a new Dual Lumen Breathing circuit.
- **WARNING** - Always use bacterial/viral filter with BiWaze Clear System.

CAUTION

A CAUTION explains special measures for the safe and effective use of the device.

- **CAUTION** - Read this User Manual before use.
- **CAUTION** - Do not expose the device to excessive force, dropping or shaking.

- **CAUTION** - Keep the power cord and device away from any potential heat sources like room heater, hot iron, kettle steam etc.
- **CAUTION** - Make sure that all the air inlets on the side of the device are unobstructed. If the device is placed on the floor, make sure the area is free from dust and clear of bedding, clothes, or other objects that could block the air inlets.
- **CAUTION** - Do not operate the device in direct sunlight for better visibility and avoid heating the LCD screen. Do not place the device on a hot surface.
- **CAUTION** - Hair from pets, spillage of food, and infestation by pests can cause the device to have clogged filters. Keep the device away from children, pets and ensure that operating and storage environment is free from any pests.
- **CAUTION** - Do not operate the device in very dusty environment outside the room or in an environment with small fibers, lint or airborne material which can clog the filters.
- **CAUTION** - The device has an ingress protection rating of IP21, it can withstand minor vertical spills and wiping for cleaning. Do not splash/spray water or submerge the device in water.
- **CAUTION** - Use only parts and accessories from ABM Respiratory Care. Do not use any unauthorized parts or accessories with this device.
- **CAUTION** - Disconnect the nebulizer and store it safely after use.

1.8. Symbols & Acronyms

The following symbols appear on the labelling of this device/accessories:

Symbol	Definition
	AC Power
	USB Connector
	Type BF Applied Part
	Class II (Double Insulated)
	Power On/Power Off
IP21	Protected against solid objects over 12.5mm (e.g., a finger) and protected against vertically falling drops of water or condensation
	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE). Should not be disposed in landfill.
	Temperature limit
	Follow instructions for use
REF	Catalogue/Reference number
SN	Product serial number
R_x ONLY	Prescription use only
	Manufacturer*
	Power on/off or Stand-by
	CAUTION
	WARNING
	Not made with natural rubber latex

UDI	Unique Device Identification
	Consult Instruction for Use

**The year of manufacture is written under this symbol on the BiWaze Clear device.*

The following acronyms are used in BiWaze Clear.

Acronym	Meaning
PEP	Positive Expiratory Pressure
OSC	Oscillation
SpO2	Blood Oxygen Saturation
HR	Heart Rate
NEB	Nebulizer
B/V Filter	Bacterial and Viral Filter

2. BiWaze Clear System Overview

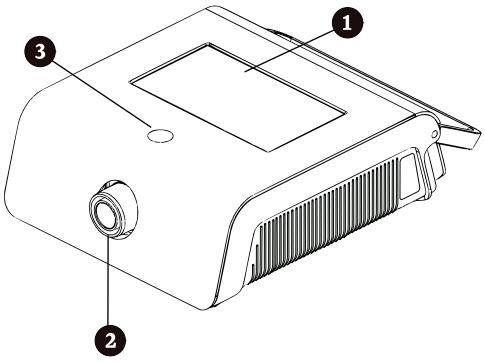
2.1. Description

The BiWaze Clear System helps patients loosen and mobilize secretions, as well as treat and prevent atelectasis, by providing lung expansion and high frequency oscillation therapies. The BiWaze Clear System may be utilized with various types of patient interfaces such as a face mask, mouthpiece, trach adapter to a patient's endotracheal or tracheostomy tube, or in line with a ventilator. It is intended for use with adult or pediatric patients in acute, post-acute, and home care environments.

2.2. Control Unit Features

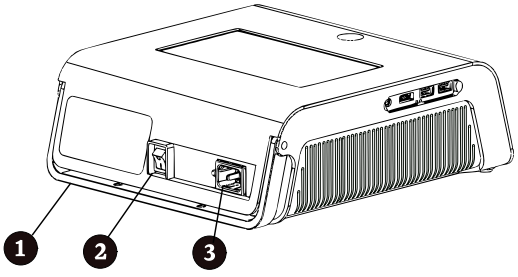
2.2.1. Top Panel

No	Item	Description
1	Touch Screen	The touch screen allows you to view and edit therapy settings, system status information, real-time patient data, and data logs
2	Patient Port	The Dual Lumen Breathing Circuit is connected to this port for therapy delivery
3	Therapy Mode Light	This LED light provides different color code lights: Green for Manual Mode, Blue for Auto Mode and Red for Error The button within the LED light provides the ability to Start and Pause therapy



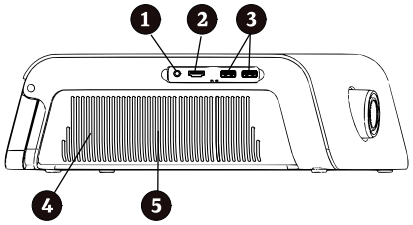
2.2.2. Back Panel

No	Item	Description
1	Handle	Handle to carry the device
2	Power Switch	Switch to power on or off the device
3	AC Power Inlet	Connection port for the AC power cord

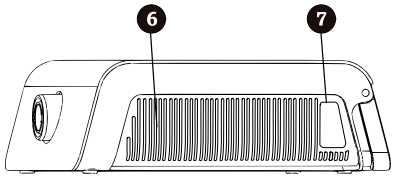


2.2.3. Side Panel

No	Item	Description
1	Aerogen® Solo Nebulizer Power Port	Connection for the Aerogen® Solo Controller Cable to power the Aerogen® Solo nebulizer
2	HDMI port	Connection for external HDMI display
3	USB ports	Connection for USB memory sticks and external SpO2 sensor
4	Air outlet	Expiratory air outlet port
5	Power supply cooling Fan location	Cooling fan for the power supply
6	MCB Fan	Main control board fan
7	Air Inlet Filter	Inspiratory air inlet port with a filter



Device Left Side

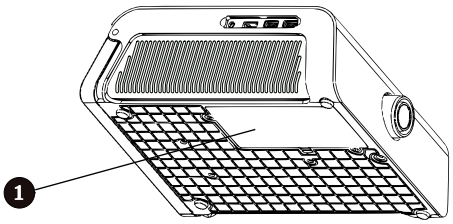


Device Right Side

⚠ **CAUTION** - Do not attach unapproved devices to any of the ports. Use only ABM Respiratory Care approved parts.

2.2.4. Bottom Panel

No	Item	Description
1	Battery Access Cover	Location of the internal battery

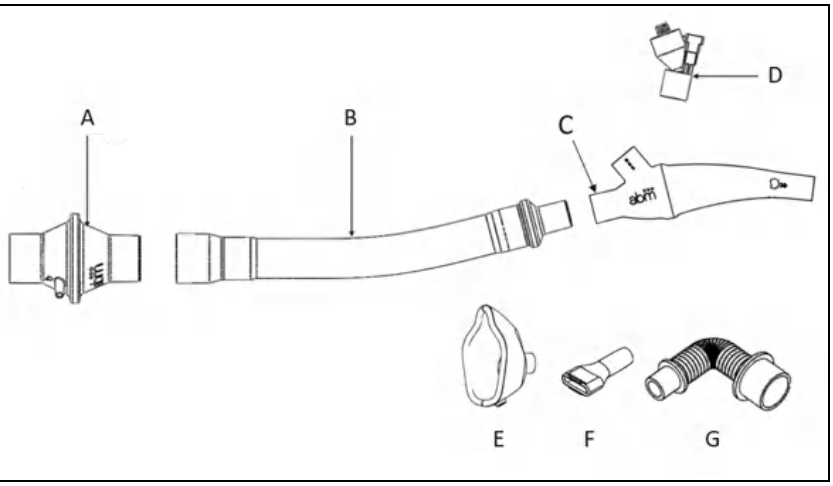


⚠ **WARNING** - Do not open the battery cover, only authorized service personnel can open and replace the battery. Only use ABM Respiratory Care approved batteries.

2.3. Single Patient Circuit Components

The single patient use circuit is orderable as a Dual Lumen Breathing Circuit and can be ordered with different patient interfaces based upon patient need.

Item	Meaning
A	Coaxial Bacterial/Viral Filter (B/V Filter)
B	Coaxial Tubing
C	Handset
D	Aerogen® Solo Nebulizer
E	Face Mask (optional)
F	Mouthpiece (optional)
G	Trach Adapter (optional)



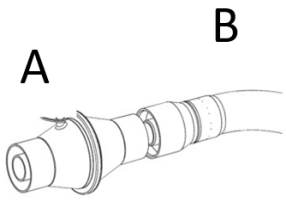
3. Assemble The Dual Lumen Breathing Circuit

- **WARNING** - Do not operate the system without B/V filter
- **WARNING** - Do not apply excessive force to assemble or disassemble the Dual Lumen Breathing Circuit to avoid damage to the components.
- **WARNING** - Always use a new Dual Lumen Breathing Circuit when using the system on a new patient to avoid cross-contamination.
- **WARNING** - Do not sterilize the circuit for reuse.

Note: Each Dual Lumen Breathing Circuit is for use by a single patient and intended for 30 days of treatment or a maximum of 90 treatment sessions.

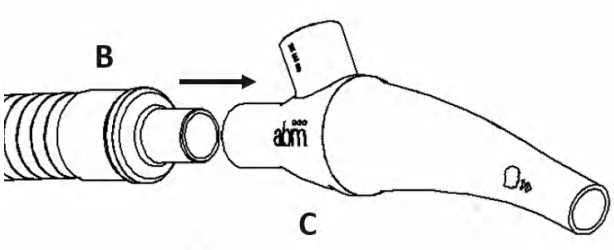
3.1. Connect the components

1. Attach the larger end of the coaxial tube (B) to the end of the B/V filter (A) that has the company logo.



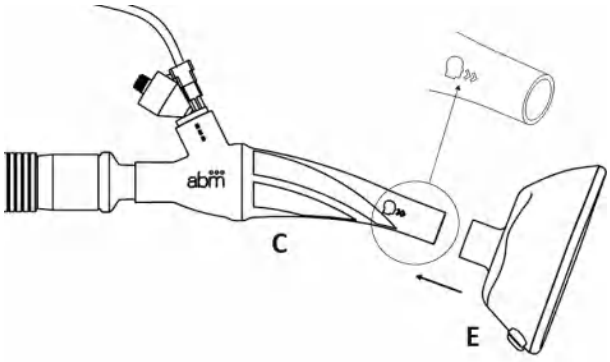
2. Attach the end of the B/V filter (A) that has the oxygen port to the patient port of the control unit.

3. Connect the smaller end of the coaxial tube (B) to the end of the handset (C) closest to the nebulizer port.

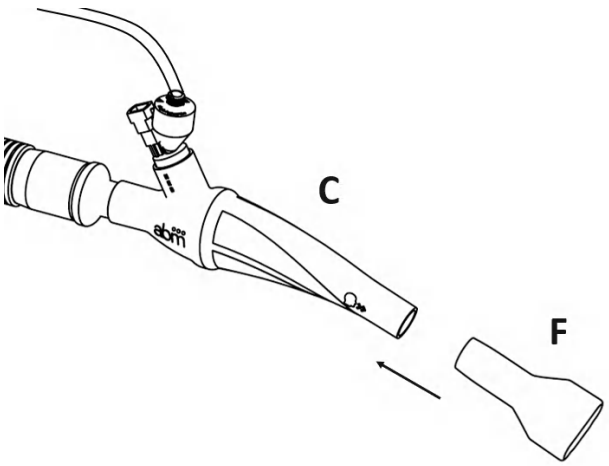


4. Attach the applicable patient interface:

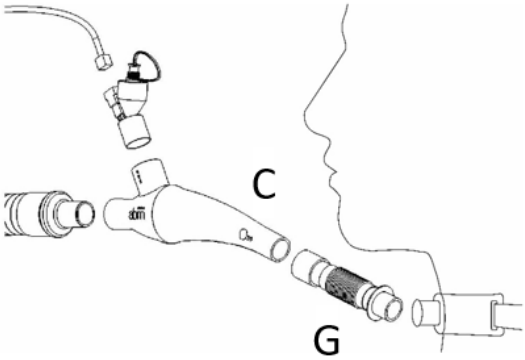
- **Face Mask**
  i. Insert and gently twist the face mask (E) to the handset (C) patient interface end



- **Mouthpiece**
  Insert and gently twist the mouthpiece(F) with the handset (C).



- **Trach Adapter**
  i. Connect the handset (C) to the flexible trach adapter (G)
  ii. Connect the other end of the flexible trach adapter to the patient's tracheostomy tube



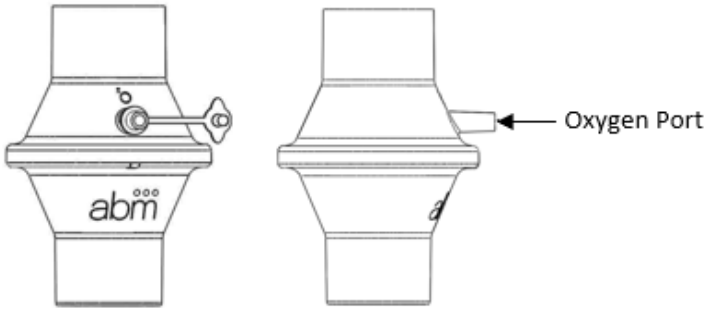
3.2. Connect to an Oxygen Source

To prevent injury or equipment damage, read these warnings before assembly

- **WARNING** - Always use a new Dual Lumen Breathing Circuit when using the system on a new patient to avoid cross-contamination.
- **WARNING** - Do not connect the system to an unregulated or high-pressure oxygen source.

CAUTION - When using oxygen with this system, power on the system before you turn on the oxygen source. Before you power down the system, turn off the oxygen source. This helps prevent oxygen from accumulating in the system.

1. Follow the steps in *Section 3.1 Connect the components*
2. Connect the oxygen tubing from the oxygen source to the oxygen port present in the B/V Filter



3.3. Aerogen® Solo Nebulizer Assembly and Add Medication

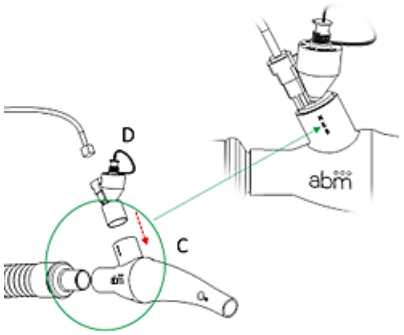
To prevent injury or equipment damage, read these warnings before assembly

- **WARNING** - Only use Aerogen® Solo nebulizer with BiWaze Clear.
- **WARNING** - Always use a new Dual Lumen Breathing Circuit when using the system on a new patient to avoid cross-contamination.
- **WARNING** - Aerogen® Solo is a single patient use device not to be used on more than one patient to prevent cross-infection.
- **WARNING** - The components and accessories of the Aerogen® Solo, as packaged, are not sterile.
- **WARNING** - Do not autoclave any component or accessory of the Aerogen® Solo System.
- **WARNING** - Do not use or store outside of specified environmental conditions.

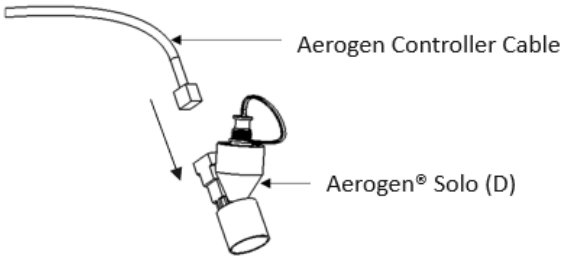
Note: The components and accessories of the Aerogen® Solo are not made with natural rubber latex.

3.3.1 Connect Controller Cable

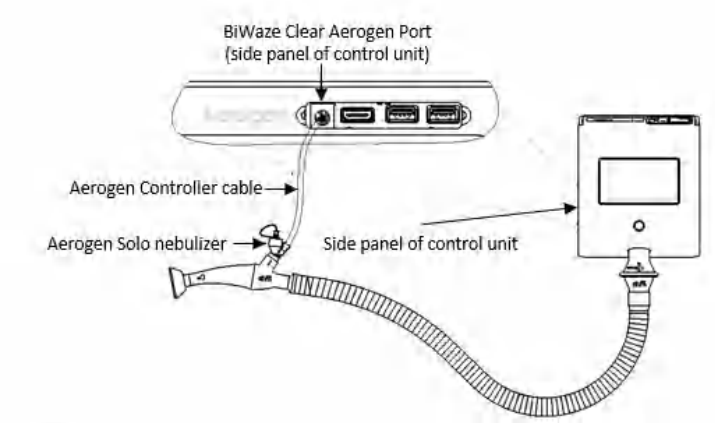
1. Follow the steps in *Section 3.1 Connect the components*
2. Insert Aerogen® Solo nebulizer (D) to the nebulizer port of the Handset (C)



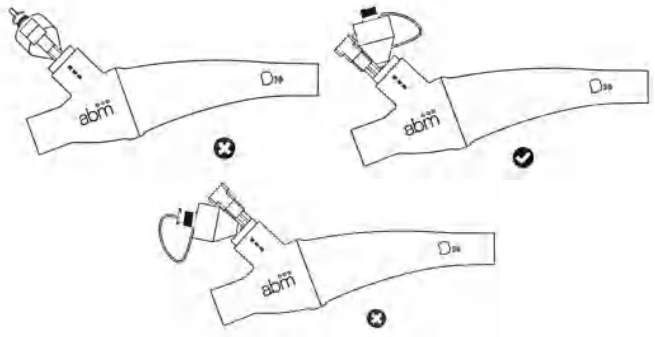
3. Connect the flat end of the Aerogen® Solo Controller Cable into the Aerogen® Solo (D) nebulizer



4. Connect the round end of the Aerogen® Solo Controller Cable to the Aerogen® Solo port located on the side panel of the control unit



Note: For optimum use of the Aerogen® Solo, ensure it is correctly orientated on the handset as shown below



3.3.2 Adding Medication to Aerogen® Solo

- **WARNING** - To avoid damage to the Aerogen® Solo, do not use a syringe with a needle.
- **WARNING** - During use observe for correct functioning of the nebulizer.
- **WARNING** - The maximum capacity of the nebulizer is 6 ml.

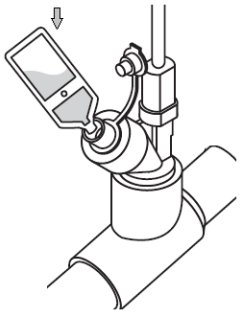
To avoid damage to the Aerogen® Solo Nebulizer:

- Do not apply undue pressure to the domed aperture plate in the center of the nebulizer.
- Do not push out the Aerogen® Solo Vibronic® aerosol generator.
- Do not attempt to clean the nebulizer.

For intermittent doses less than or equal to 6 mL:

1. Open the medication port cap on the Aerogen® Solo
2. Use a pre-filled ampoule or syringe to add medication into the filler port of the Aerogen® Solo
3. Close the port cap

Note: Medication can be added to the Aerogen® Solo during therapy.

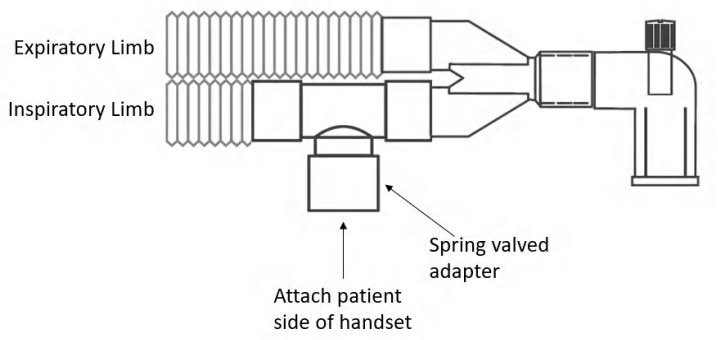


3.4. Using In-line with a Ventilator

To prevent injury or equipment damage, read these warnings before assembly

- **WARNING** - Always use a new Dual Lumen Breathing Circuit when using the system on a new patient to avoid cross-contamination.
- **WARNING** - Only trained person on BiWaze Clear and the ventilator should provide the therapy to ventilated patients.

1. Follow the steps in *Section 3.1 Connect the components*
2. Connect a spring valved adapter on the inspiratory limb of the ventilator's dual limb breathing circuit
3. Connect the patient side of the handset on to the spring valved adapter



4. Power On and Off the Control Unit

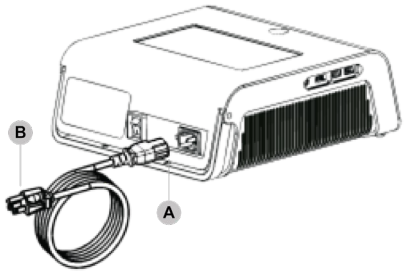
The control unit can operate on external AC power or internal battery when charged.

4.1 Using AC Power

An AC power cord is included with the control unit.

1. Plug the socket end of the power cord (A) into the AC inlet on the back of the control unit.
2. Plug the pronged end (B) into an electrical outlet not connected to a wall switch.

Note: Ensure all connections are secure.



4.2 Internal Battery

BiWaze Clear comes with an internal Lithium-ion battery pack. The battery can power the device with active therapies for up to 2 hours* on full charge.

The internal battery can charge simultaneously while the device is operating on the AC power and switches to battery power source when AC power is disconnected.

*Subjected to default settings, the actual run time can vary depending on age of the battery, settings and actual active therapy time.

Note: The battery shall be fully charged before using the device for the first time or when device is unused for an extended period of time.

Note: Do not dispose the battery in landfill.

WARNING - Only authorized service personnel should replace the battery in the control unit.

4.3 Power Source Indicators

Power source indicators are presented on the control unit and the display screen. These indicators are described in detail below.

4.3.1 AC Power Indicators

When AC power is applied to the control unit, a red LED indicator is illuminated next to the Master Switch. If the display screen is on, a charging indicator icon appears on the battery symbol located on the top menu bar. The battery charging indicator icon disappears when the AC power cord is not inserted into the control unit.

4.3.2 Battery Level Indicators

When the battery is connected to the control unit, battery symbols will appear on the top menu bar. The shading in the battery icon indicates the power remaining in the battery.

4.4 Power On the Control Unit

1. Press the Power Switch on the back of the control unit to the ON position. Refer to *Section 2.2.2* for more details on back panel of the device.
   Note: BiWaze Clear conducts a self-test upon each power-up. Once the self-test is complete, you will be able to start therapy. If there is an issue with the self-test, an error will appear, and it may require a restart of the system so the system can re-test. See *Section 13 Troubleshooting* for the description of the error messages. If the error appears for the second time, contact your local distributor or customer support.

4.5 Power Off the Control Unit

1. Press the Power Switch on the back of the control unit into the OFF position.
2. Disconnect the Dual Lumen Breathing Circuit and accessories from the control unit.
3. Clean the control unit, Dual Lumen Breathing Circuit, and accessories. Follow the instructions in *Section 8 Cleaning and Maintenance,* or according to facility protocols.
4. Store the control unit, Dual Lumen Breathing Circuit, and accessories as instructed in *Section 8.5 Storage and transportation*, or according to facility/hospital protocols.

5. BiWaze Clear Therapy

When you switch on the power at the back of the control unit, the system will perform a self-test. During the self-test, the ABM Respiratory Care's logo will appear, and you will hear a series of tones. After the test is complete, the therapy screen will appear so the user can begin therapy immediately.

Note:

- If the control unit was stored at a temperature below 40 F (5 °C) or above 95 F (35 °C), allow the device to normalize for 15 minutes at room temperature (~20 °C) before using the device.
- Position the control unit on a firm, flat surface within the arm's length of the patient or caregiver. The control unit should be placed below elbow level for the best visibility of the screen. 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 for the system to work properly.

Item	Description
A	Lock icon, a closed blue padlock means the software is locked and open grey padlock means the software unlocked.
B	Patient ID is an optional field where the user can enter their patient descriptor.
C	Therapy Modes, two therapy modes are available Manual and Auto. Manual mode may not be visible for home users if the system is configured to not show it when the software is locked.
D	Wi-Fi icon is gray when not connected and white when connected.
E	Battery icon shows the charge level remaining on the battery.
F	The date and time can be updated manually or if connected to WIFI it will update automatically to the local date and time.
G	Pressure manometer shows the pressure being delivered during the therapy.
H	Monitoring values of Heart Rate (HR), SpO2 (oxygen level) and Peak Pressure are displayed in this section. These monitoring values may not be visible for home users if the display settings are not enabled under Lock Device Options. An external sensor is required for heart rate (HR) and oxygen level (SpO2) measurements.

I	Therapy section displays information about the therapy being delivered.
J	Play / Pause icon allows the user to start and pause the therapy.
K	Device Settings icon allows the user to make some configuration changes, view log files and access administrative screens.
L	Edit icon allows the user to edit Auto Therapy. This icon is only visible for Auto Therapy Mode and if the software is unlocked or Allow User Adjustment is enabled in Lock Device Options.

5.1 Therapy Modes

Therapy can be delivered in two modes:

Therapy	Description
Auto	In this mode, the therapy delivery is preprogramed and require no/minimal human intervention throughout the therapy. There can be up to 10 pre-programmed therapies available in the drop-down list under Auto. Each therapy is a combination of therapy phases (PEP, OSC and NEB) and each phase can have a different set pressure and time. Each therapy phase is initiated after the completion of the previous phase for the set time. This mode is suitable for the majority of applications whereby users with various levels of training would be able to deliver the therapy with proficiency.
Manual	In this mode, the therapy phase is initiated based on user input through LCD display touchscreen. The device delivers the set PEP, OSC and NEB therapy based upon the pressure set for PEP and OSC (NEB pressure is not adjustable) and the duration is based upon the duration of time set by the user. This mode is suitable to find optimal therapy parameters for the patient. It is also helpful to use with patients who require frequent pressure changes during their therapy to assist with comfort and coaching.

Select the therapy mode on the top menu bar.

Note: If the lock icon is blue and closed then the software is locked. If the lock icon is white and open then the software is unlocked. See *Section 7 Locking and Unlocking Feature* for more information about locking and unlocking the software.

5.2 Auto Therapy Mode

Note:

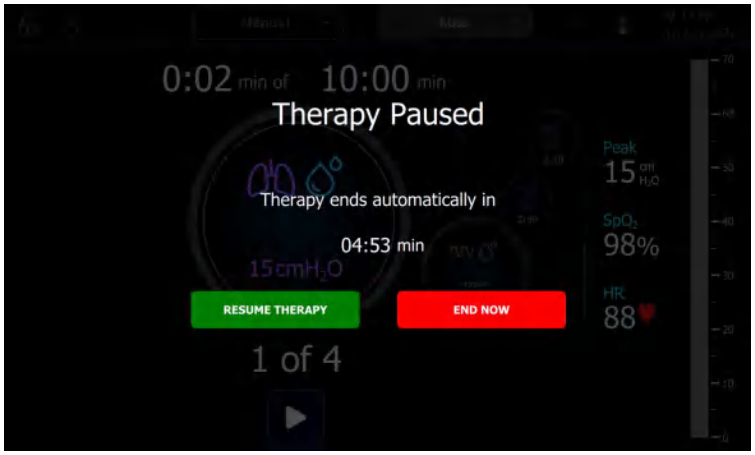
- Always use the therapy settings prescribed by the physician.
- When BiWaze Clear powers on, the last delivered therapy will be shown on the screen.
- If possible, have the patient in an upright position prior to starting therapy.

⚠ **CAUTION** - Ensure the Breathing Circuit and the Patient Port are dry before delivering the therapy.

1. Ensure the BiWaze Clear control unit and Dual Lumen Breathing Circuit are setup per the instructions in *Section 3 Assemble Dual Lumen Breathing* circuit and *Section 4 Power On and Off the Control Unit.*
2. Select Auto from the top menu bar. You will notice the Therapy Mode Light around the Play/Pause button will turn blue
3. Ensure the patient interface is in place on the patient.
   a. Face Mask—firmly, but comfortably, cover the mouth and nose of the patient. Make sure the narrow end of the mask is over the patient's nose.
   b. Mouthpiece—put the mouthpiece in the patient's mouth. Make sure that the patient maintains a tight seal on the mouthpiece during the therapy.
   c. 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 system.
4. You can run the existing therapy or select a profile from the dropdown list under Auto. There can be up to 10 therapy profiles available. See *Section 6.2 Therapy Profiles* for instructions on how to create a profile

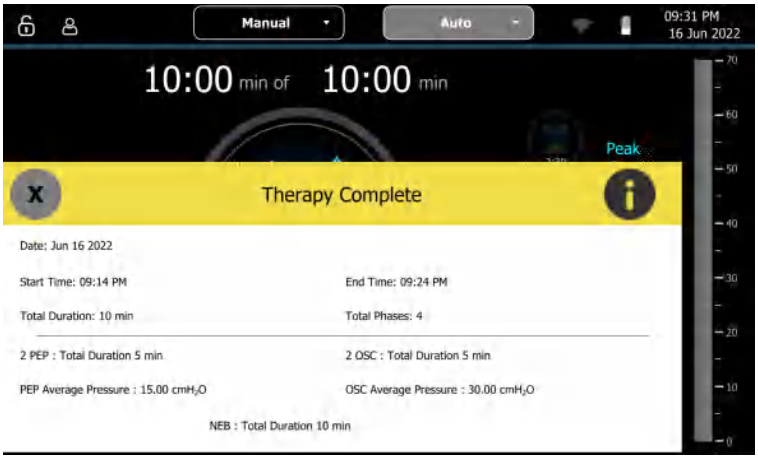
5. The current phase being delivered will appear in the large circle and future phases will appear in the smaller circles to the right. The smaller circle on the left is the previous phase.
   a. Total number of phases and current phase appears under the large circle.
   b. Above the large circle is the therapy time completed out of the total therapy prescribed.

6. Press the Play button or the Therapy Mode Light to start therapy
7. Once the therapy is running, it can be paused at any time by pressing the pause button or the Therapy Mode Light.

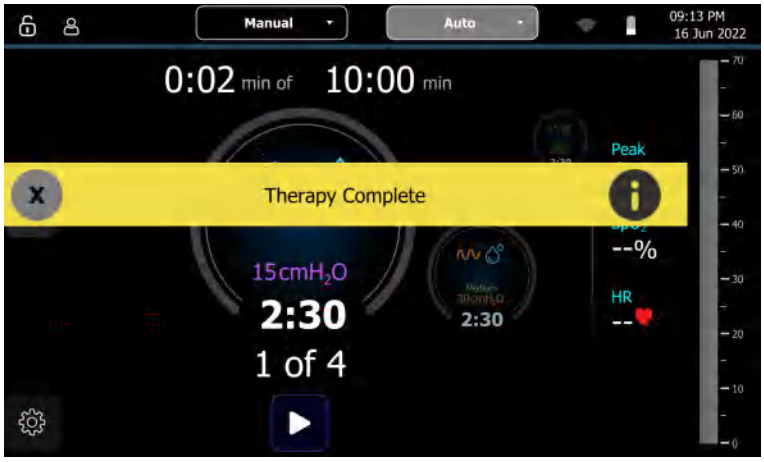


Note: The therapy can be paused for 5 minutes. A countdown timer will appear on the screen. You can choose to resume therapy or end therapy. If the timer reaches 5 minutes the therapy will automatically end.

8. When the therapy is complete, a ribbon will be displayed across the screen.
   8.1. Press the  to view the therapy summary.



   8.2. Press the  on the left to close the ribbon.



5.2.1 Edit Auto Therapy

Auto therapy can be edited if the system is unlocked or if Allow User Adjustment is enabled under Lock Options. Typically, healthcare providers will lock the software when BiWaze Clear is used in the home environment. See *Section 7 Locking and Unlocking Feature* for more information about locking and unlocking the software.

The editable parameters include the following:

Parameter	Description
PEP Pressure	Set the peak pressure from 0 to 30 cmH_2O in increments of 1.
PEP Time	Set the phase time from 0:05 to 30:00 minutes in increments of 5 seconds.
PEP Neb	Set the nebulizer to be on or off during this phase of therapy.
OSC Pressure	Set the peak pressure from 5 to 70 cmH_2O in increments of 1.
OSC Time	Set the phase time from 0:05 to 30:00 minutes in increments of 5 seconds.
OSC Frequency	Set the frequency of oscillations to be Low (3 hertz), medium (4 hertz) or high (5 hertz) for this phase.
OSC Neb	Set the nebulizer to be on or off during this phase of therapy.
NEB	Set the phase time from 0:05 to 30:00 minutes in increments of 5 seconds. This phase is for running the nebulizer only, no adjustment in pressure or oscillations.

Steps to edit Auto Therapy:

1. Press the Pen icon (A) to enter the edit auto therapy.

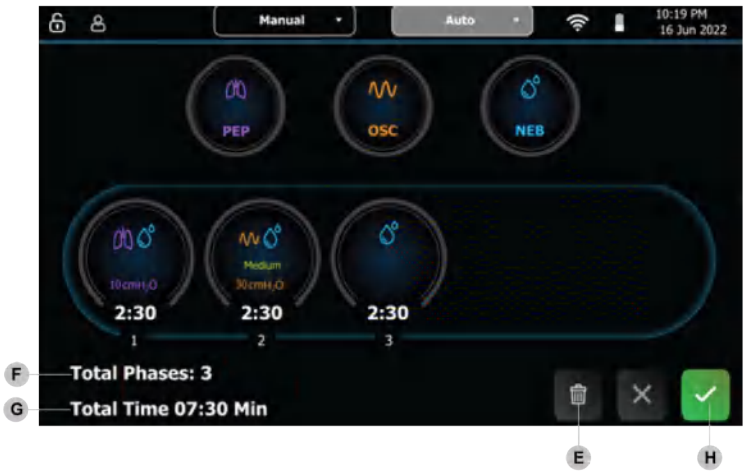
2. You will see three therapy phases options (B) across the top of the screen. The therapy line across the middle represents the phases of therapy that will delivered.

3. To add a therapy phase to the therapy line, press the phase you want to add from (B) and drag it into the therapy line (C).
4. To rearrange the phases in the therapy line, press on the phase until it glows, then drag it to the new location in the therapy line. You will see the other phases shift accordingly in the therapy line.
5. To delete a phase from the therapy line, press on the therapy you want to delete and then press the trash can on the top left (D).

Note: There are two other options to delete phases:

- From the therapy line, press on the phase you want to delete until it glows, then drag it out of the therapy line. A delete phase confirmation will appear.
- To delete all the phases in the therapy line, press the trash can on the bottom right (E).

Note: The total number of phases (F) in the therapy line and the total therapy time (G) of all the phases is on the bottom left.



6. When the therapy settings are edited to match the prescription, press the green checkmark (H) to save and close.

7. The therapy can be saved as a Profile. See *Section 6.2 Therapy Profiles* for instructions on how to create a Profile.

5.3 Manual Therapy

Note:

- Always use the therapy settings prescribed by the physician.
- When BiWaze Clear powers on, the last delivered therapy will be shown on the screen.
- If possible, have the patient in an upright position prior to starting therapy.

⚠ **CAUTION** - Ensure the Breathing Circuit and the patient port adapter are dry before delivering the therapy.

5.3.1 Deliver Manual Therapy

1. Ensure the BiWaze Clear control unit and Dual Lumen Breathing Circuit are setup per the instructions in *Section 3 Assemble Dual Lumen Breathing* circuit and *4 Power On and Off the Control Unit*.
2. Select Manual from the top menu bar. You will notice the LED light around the Play/Pause button will turn green.

3. Ensure the patient interface is in place on the patient.
   - Face Mask—firmly, 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 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 system.
4. You can run the therapy on the screen, edit the therapy (if the software is unlocked) or select a therapy profile from the dropdown list under Manual.
   - There can be up to 10 therapy profiles. See *Section 6.2 Therapy Profiles* for instructions.

5. The three therapy phases are each represented by a circle on the screen.
   - The parameters for PEP and OSC are visible within each therapy circle.
   - The parameters are editable if the software is unlocked or if Allow User Adjustment is enabled in the Lock feature.

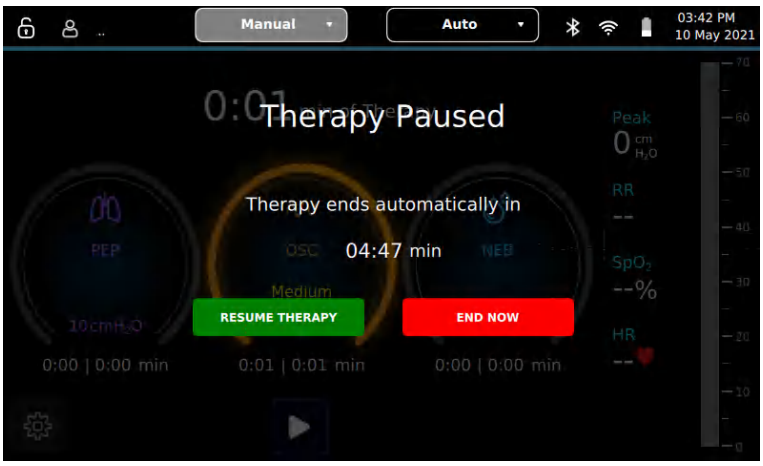
6. Press the Play button to engage the blowers for therapy.

7. Press the therapy phase you want to deliver PEP, OSC or NEB. You will know which phase is running because the circle will glow, and the timer will begin counting under the circle.
   - You can deliver NEB with either PEP or OSC, otherwise NEB can be delivered as a stand-alone therapy phase. The NEB will glow blue when it is running.
   - If NEB is running and you want it to stop delivering the nebulizer, press the NEB circle. You'll see the timer stop below the circle and the circle will no longer glow.

8. You can switch between PEP and OSC by pressing the therapy phase you want to deliver. You will know which therapy is running because the circle will glow, and the timer will increase under the circle.
   - Under each circle the current therapy phase time is represented on the left and the total phase time is represented on the right.
   - Total therapy time is shown above the circles.
9. You can edit the settings of the PEP and OSC while delivering therapy (if the software is unlocked or allow user adjustment is enabled when the software is locked) by performing a long press on the therapy phase you want to edit.
   - Therapy changes occur real time.
   - Press the check to close the phase edit window.

10. Once the therapy is running, the therapy can be paused at any time by pressing the Pause button or the Therapy Mode Light.

Note: The therapy can be paused for 5 minutes. A countdown timer will appear on the screen. You can choose to resume therapy or end therapy. If the timer reaches 5 minutes the therapy will automatically end.



11. When you have completed the Manual therapy, press the Pause button and then select END NOW.
12. A ribbon will be displayed across the screen letting you know the Therapy is Complete.
    a. Press the to view the therapy summary.
    b. Press the on the left to close the ribbon.

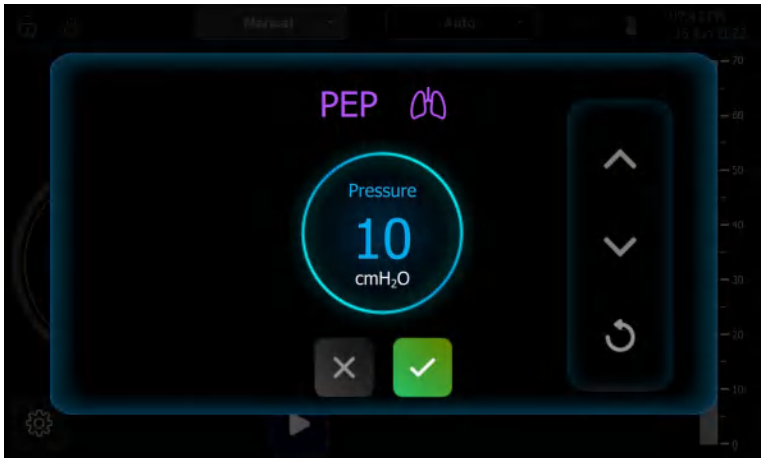
5.3.2 Edit Manual Therapy

Manual therapy can be edited if the software is unlocked. Typically, the software will be locked when the BiWaze Clear is in the home environment. See *Section 7 Locking and Unlocking Feature* for more information about locking and unlocking the software.

The editable parameters include the following:

Parameter	Description
PEP Pressure	Set the peak pressure from 0 to 30 cmH_2O in increments of 1.
OSC Pressure	Set the peak pressure from 5 to 70 cmH_2O in increments of 1.
OSC Frequency	Set the frequency of oscillations to be Low (3 hertz), medium (4 hertz) or high (5 hertz) for this phase.

1. To edit PEP, press the phase circle
2. Press the up arrow to increase the pressure and the down arrow to decrease the pressure
3. Press the checkmark to save the parameter and return to the therapy screen
4. To edit OSC, press the phase circle
5. Press the up and down arrows to edit the pressure
6. Press next to the frequency you want to deliver: Low, Medium or High
7. Press the checkmark to save the parameters and return to the therapy screen

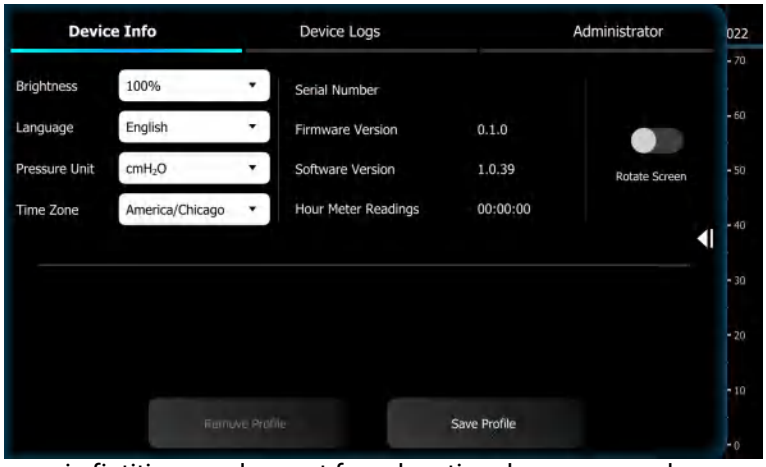


8. When Manual Therapy is programmed, the therapy can be saved as a profile, see Section 6.1.2 Save Profile or deliver the therapy. To deliver Manual therapy See *Section 5.3.1 Deliver Manual Therapy* for instructions.

6. Device Settings

6.1. Device Info Screen

The Device settings screen appears after you press the settings icon on bottom left corner of main screen when the system is not delivering therapy.



Note: Version information depicted on the screen is fictitious and meant for educational purposes only. Following settings are available under device settings.

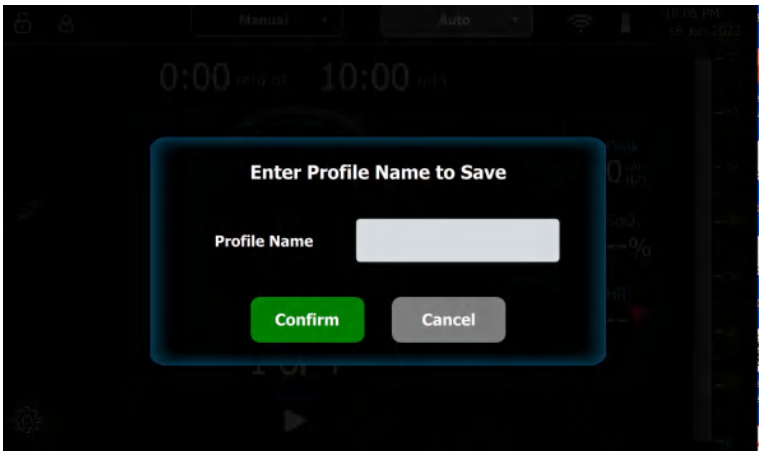
Setting	Description
LCD Brightness	Brightness of the screen backlight from 10% -100%, with 10% being the dimmest setting and 100% being the brightest
Language	Language of the user interface. The available languages will differ based upon the country in which the device was prescribed
Pressure Units	Pressure unit of measure
Time Zone	Time zone list
Serial Number	Serial Number assigned to the control unit
Firmware Version	Firmware version installed
Software Version	Software version installed
Hour Meter Reading	Hour meter reading (HMR) displays the total time the device has delivered therapy
Device Logs	Access all the device related logs
Administrator	Access the device administrator screen
Remove / Save Profiles	Remove the selected Profile or Save the therapy parameters on the previous screen into a Profile

6.2 Therapy Profile

6.2.1 Save Therapy Profile

1. Once a therapy is entered into either Auto or Manual Mode, the settings can be saved as a Profile.
2. Press the Device Settings icon ⚙.
3. Press the Save Profile button.
4. Enter the name of the Profile, up to 11 characters.
5. Press Confirm to save the Profile.

Note: The system can save up to 10 Profiles between Auto and Manual therapy modes.

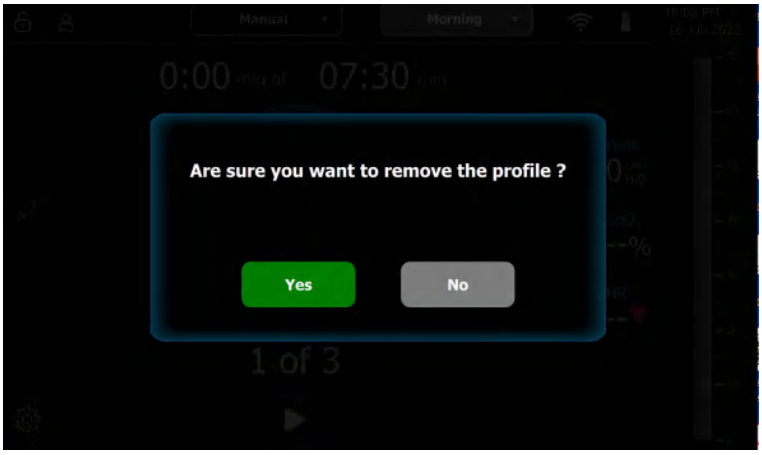


6.2.2 Remove Therapy Profile

To remove a therapy profile:

1. Select the profile you want to remove
2. Press the Device Settings icon ⚙.
3. Press Remove Profile

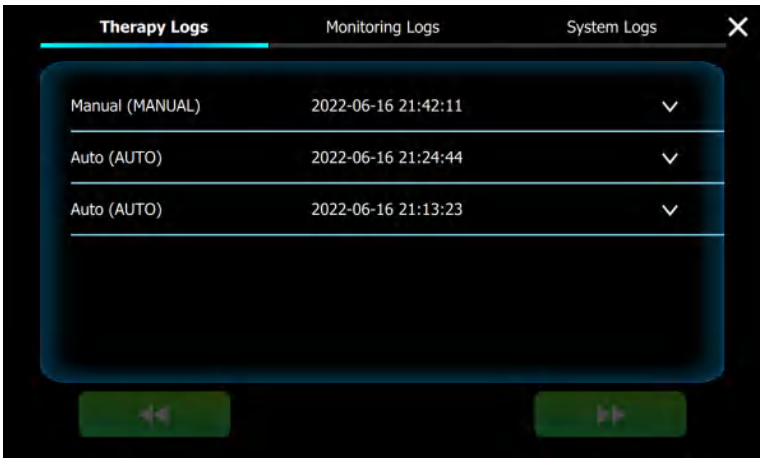
4. Press Yes in the confirmation window

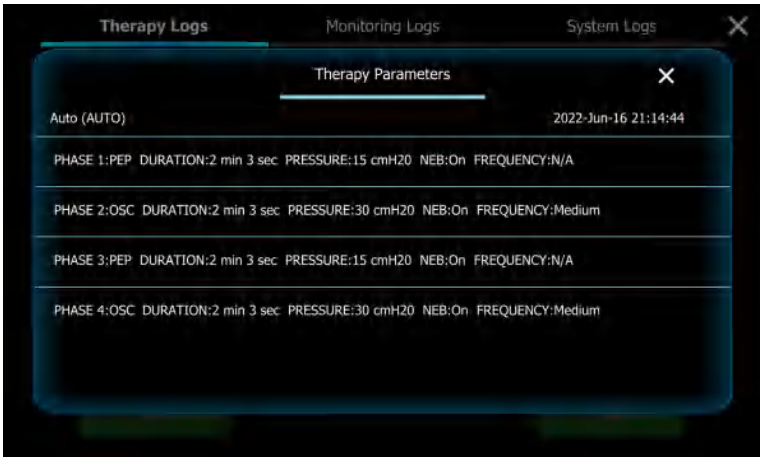


6.3 Device Logs Screen

The device logs contain information about therapies performed and system related events.

6.3.1 Therapy Logs



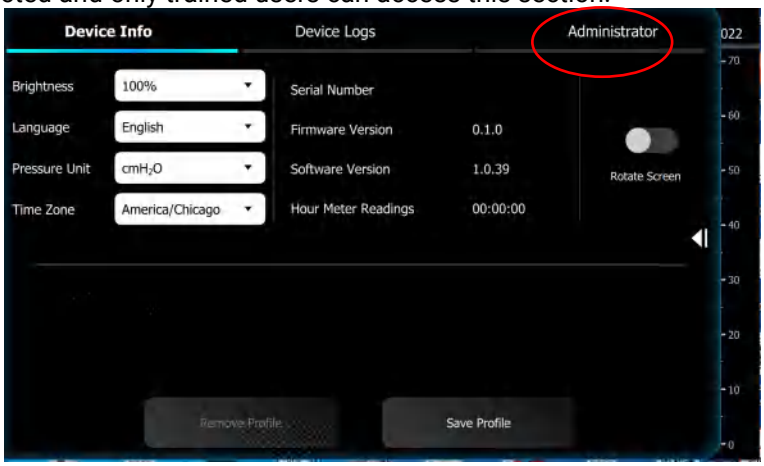


6.3.2 Monitoring Logs

6.3.3 System Logs

6.4 Administrator Section

The Administrator section is password protected and only trained users can access this section.



The following settings are available within the Administrator section.

6.4.1 Remote Server Settings

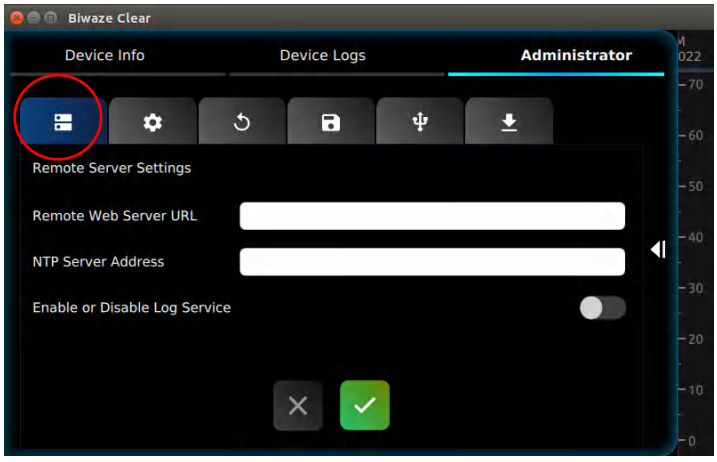
CAUTION - Do not change the Remote Web Server URL

Remote Web Server URL is the address to Arc Connect.

NTP Server Address is set within the software but it can be configured to a different server if one is entered into this field.

To send data to Arc Connect, Log Service needs to be enabled. When the Log Service is disabled, the toggle is white and when it enabled the toggle is blue.

Note: A WI-FI connection is required to send data to Arc Connect.

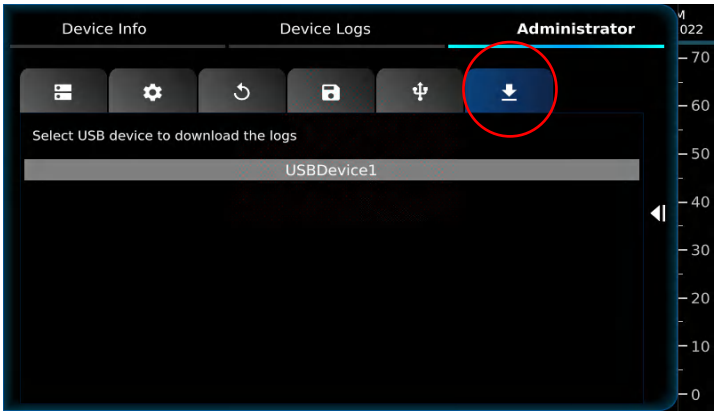


6.4.2 Download Therapy Logs

The therapy logs can be downloaded to a USB thumb drive. The file is encrypted and can be decrypted in the Arc Connect portal.

Download a therapy log file:

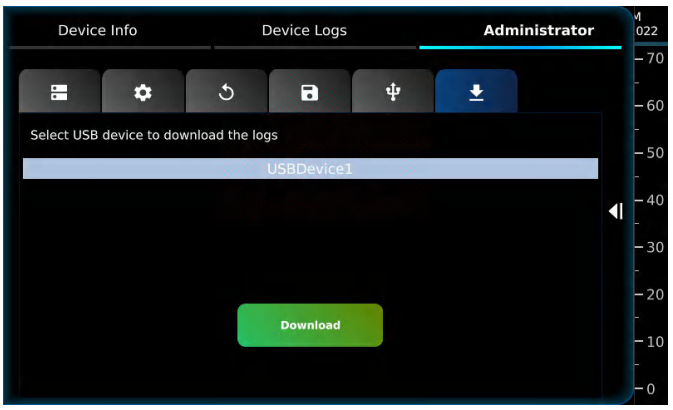
1. Press the icon that looks like a down arrow.



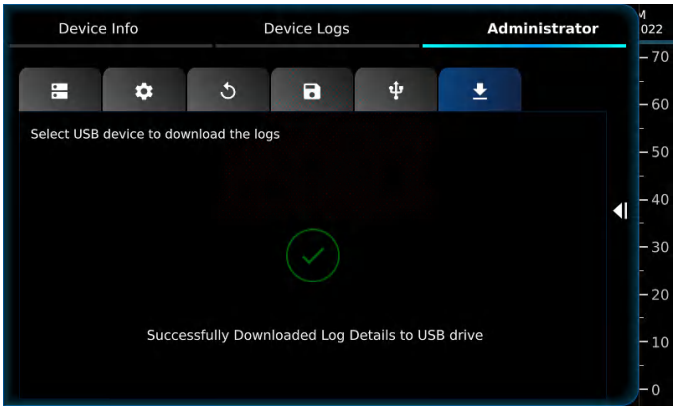
2. Insert a USB thumb drive in either of the two available slots in the control unit.

3. Once the software detects the USB, you will see USBDevice1 appear on the screen. Press on USBDevice1.

4. Press the Download button to save the encrypted therapy log file to the USB.



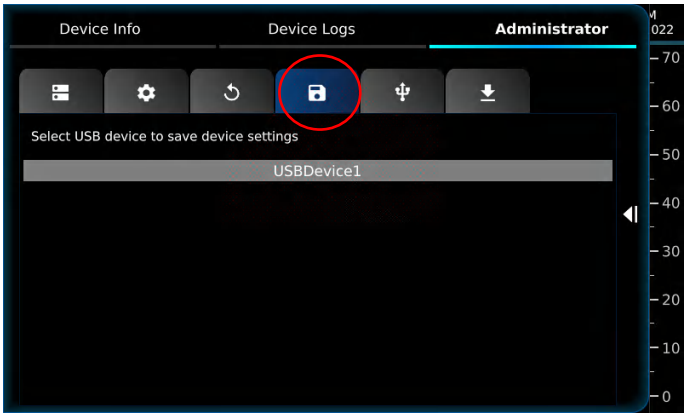
5. Once the download is complete, you'll see a notification stating the file was successfully downloaded. You can remove the USB thumb drive.



6.4.3 Download Device Settings

Settings can be shared with another BiWaze Clear so you don't need to individually program each BiWaze Clear system. Settings are downloaded to a USB thumb drive so they can be shared with other BiWaze Clear systems.

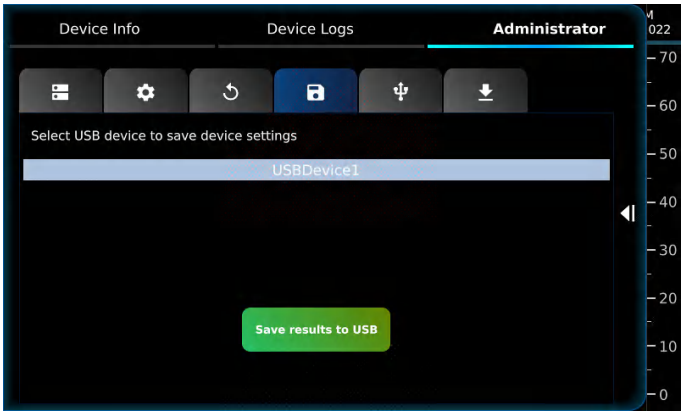
1. Press on the symbol that looks like a computer disk



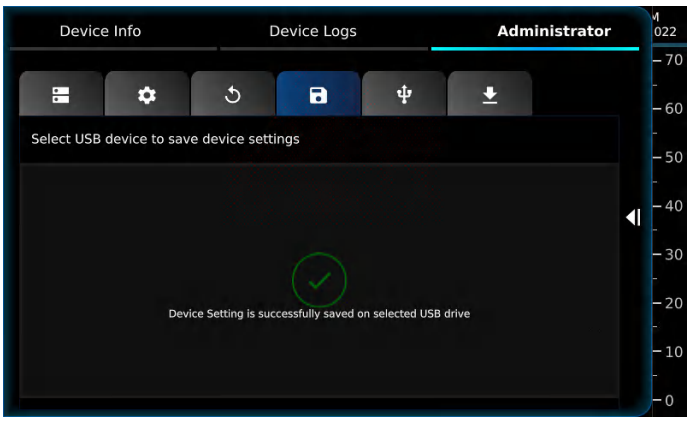
2. Insert a USB thumb drive in either of the two available slots in the control unit.

3. Once the software detects the USB, you will see USBDevice1 appear on the screen. Press on USBDevice1.

4. Press the Save results to USB button to save the encrypted device settings file to the USB.



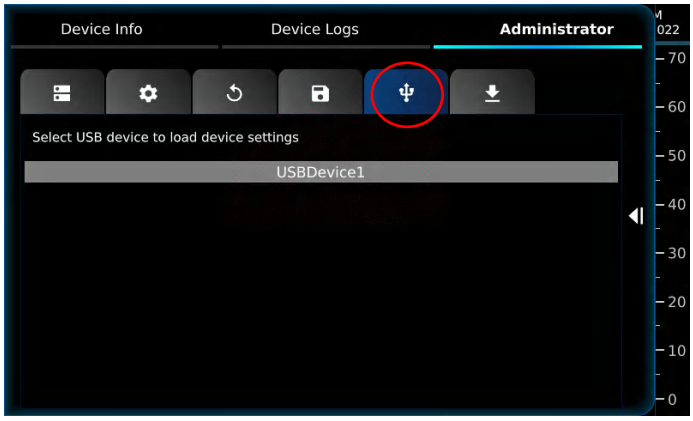
5. Once the download is complete, you'll see a notification stating the file was successfully downloaded. You can remove the USB thumb drive.



6.4.4 Restore Device Settings

This option allows you to upload device settings from another BiWaze Clear.

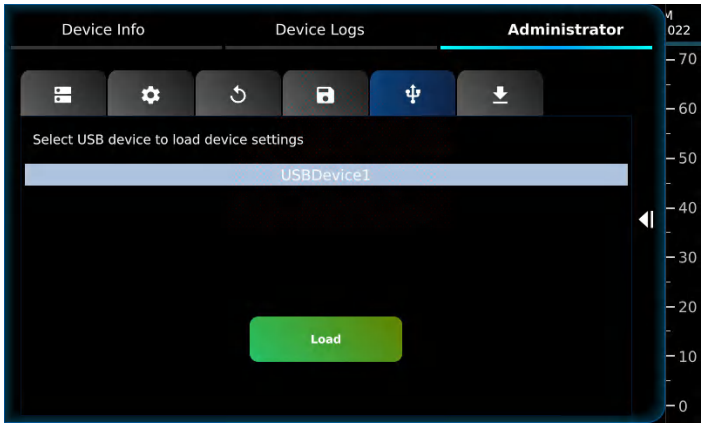
1. Select a tab with the USB icon.



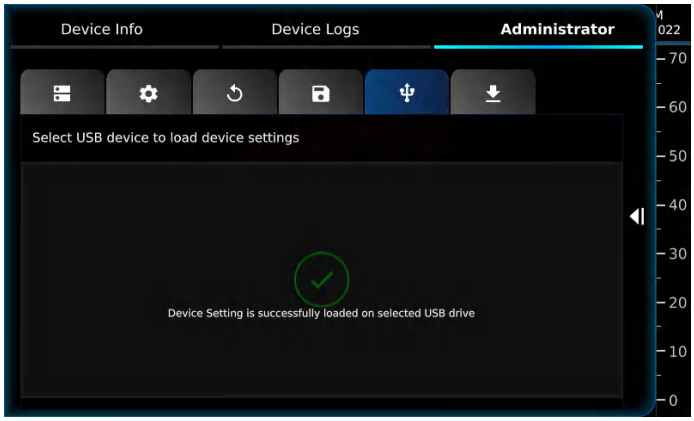
2. Insert a USB thumb drive in either of the two available slots in the control unit.

3. Once the software detects the USB, you will see USBDevice1 appear on the screen. Press on USBDevice1.

4. Press the Load button to upload previously backed settings BiWaze Clear.



5. Once the download is complete, you'll see a notification stating the file was successfully downloaded. You can remove the USB thumb drive.

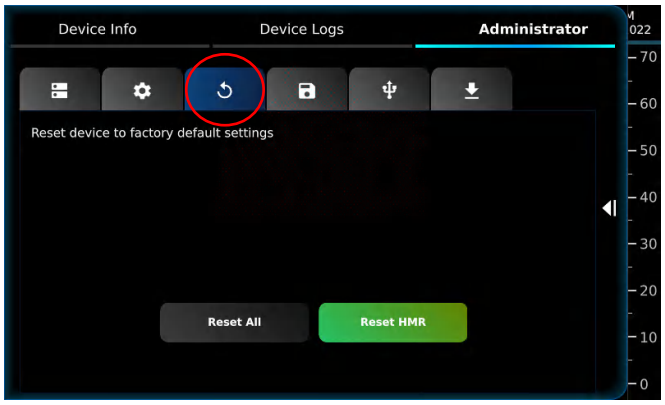


6.4.5 Reset Settings

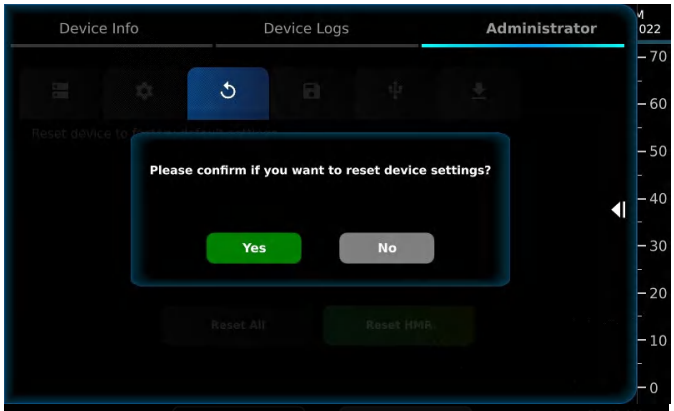
You can reset BiWaze Clear to the factory default settings or only the hour meter reading.

1. Press the tab with an arrow in a circle icon

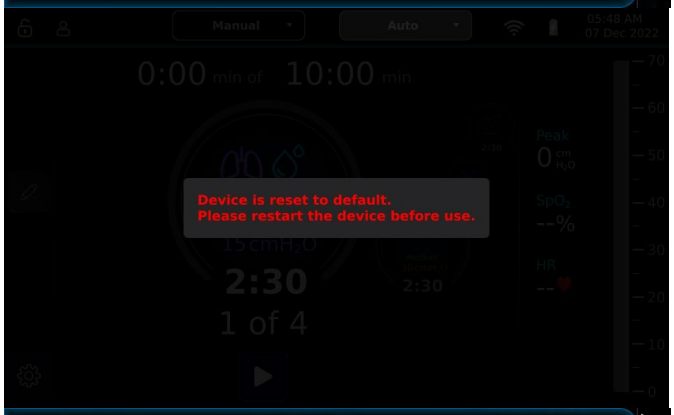
2. Press the Reset All button to reset all settings to the factory default or Reset HMR button to only reset the Hour Meter Reading.



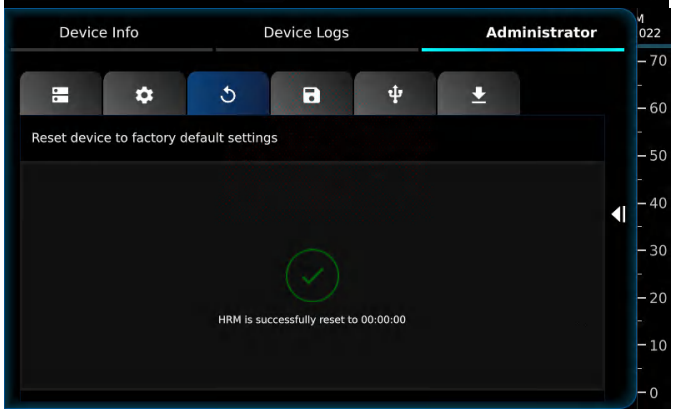
3. Press “Yes” to proceed further with the reset.



   a. If you reset to factory defaults, a confirmation will appear once the reset is complete.



   b. If you reset the Hour Meter Reading, a confirmation will appear once the HMR value is set to zero.



6.5 Wi-Fi Configuration

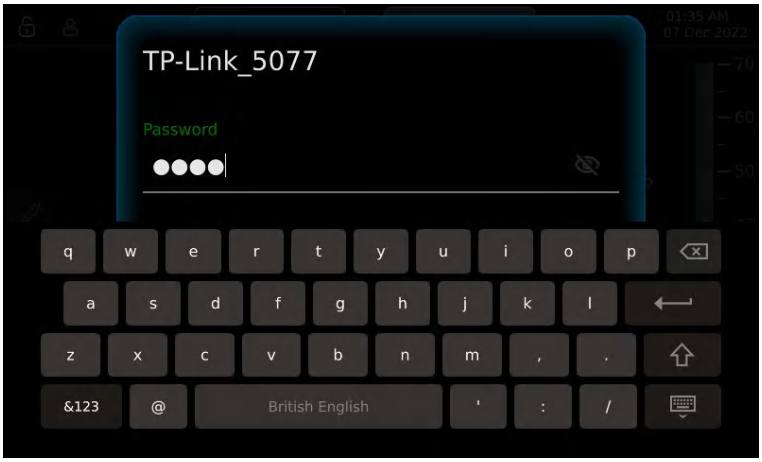
WARNING - Connecting the control unit to public or unknown networks could result in unidentified risks.

1. Press the WI-FI icon on the top menu bar.

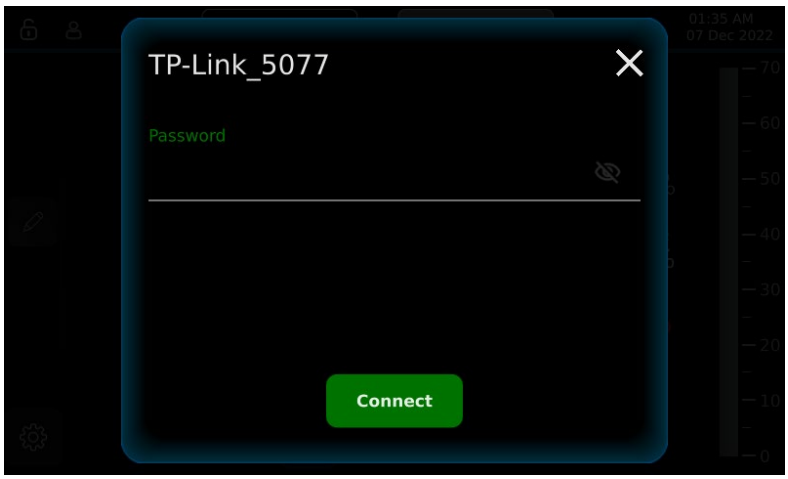
2. Press the toggle to turn on the Wi-Fi search. The toggle will be blue when the control unit is searching for a Wi-Fi network.

3. Select the Wi-Fi network.

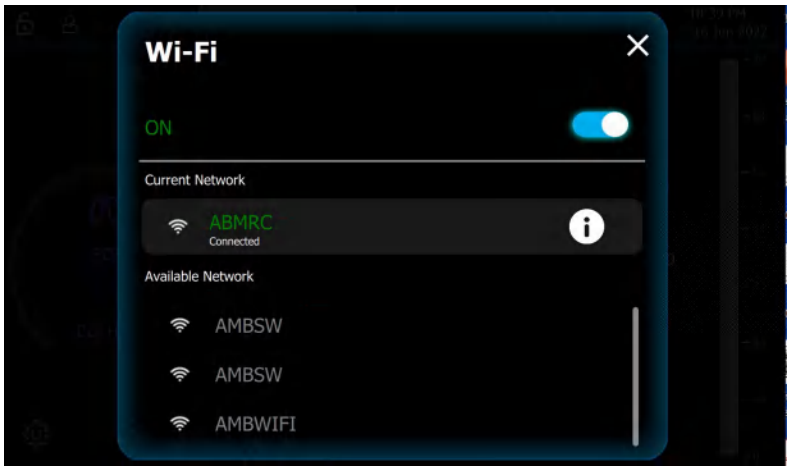
4. Enter the password.



5. Press Connect.



6. Once the Wi-Fi network is connected, the connected network name will appear under Current Network.

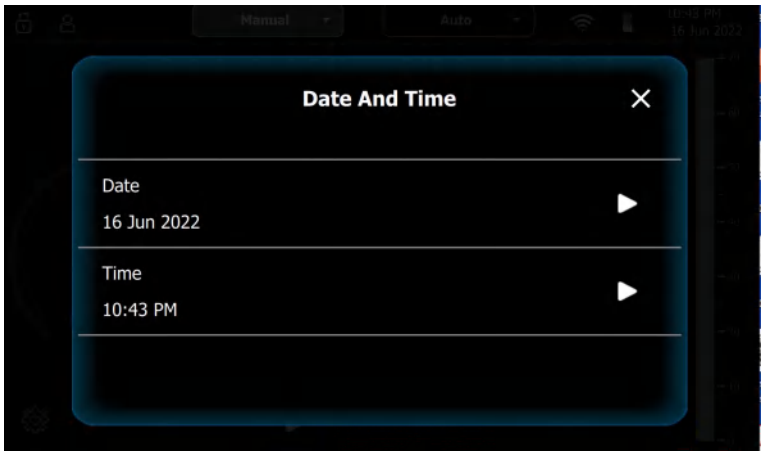


6.6 Date and Time Configuration

Note: If connected to a WI-FI network, the date and time will be updated automatically based upon the network location and the selected time zone.

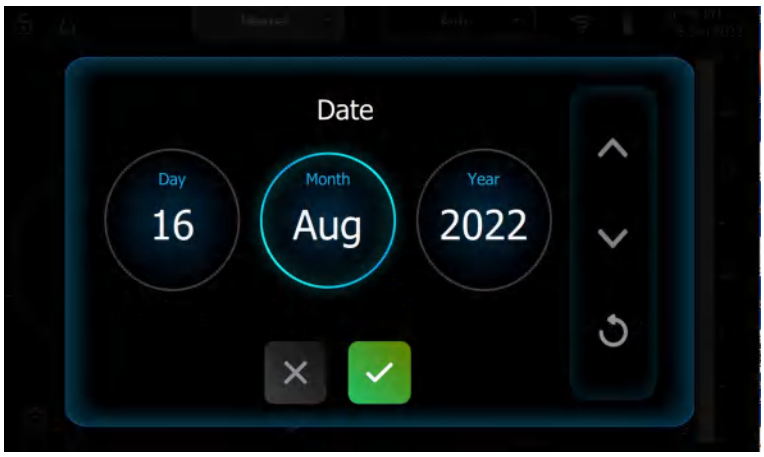
1. Press the Date and Time on the top menu bar.

2. Press Date

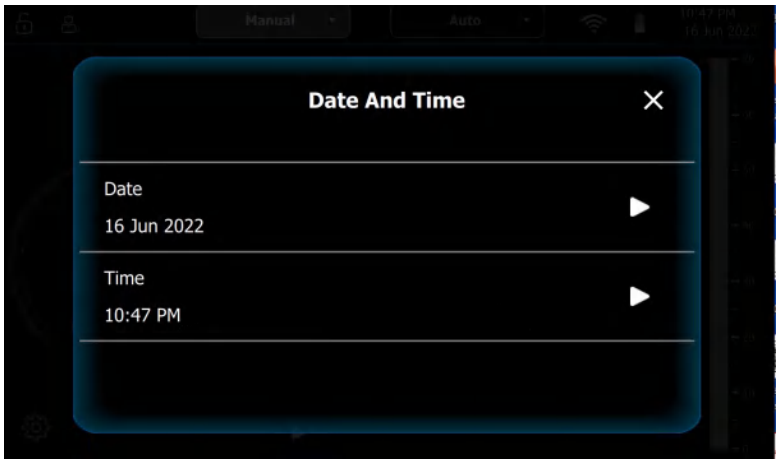


3. Select the appropriate day, month, and year by highlighting the parameter and using the arrow keys to adjust to the correct value.

4. Press the green checkmark to save the date.

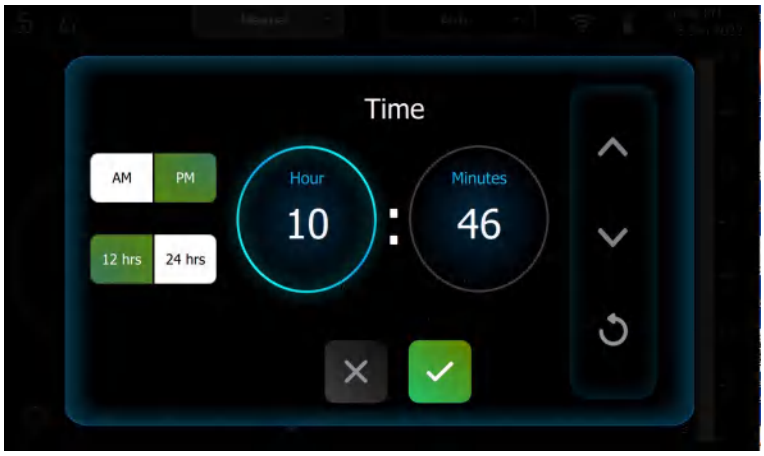


5. Press Time

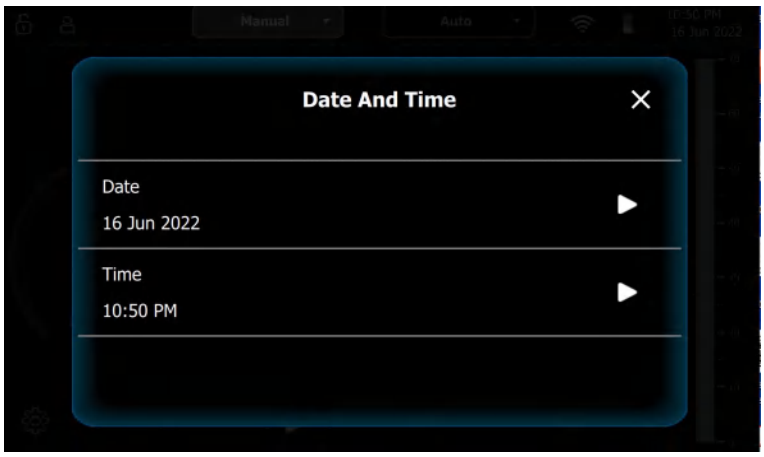


6. Select the appropriate time parameters including:
    a. AM or PM
    b. 12 hr vs 24 hr clock
    c. Hours and Minutes

7. Press the green checkmark to save the time.



8. Press the X on the top right to close the date and time window.

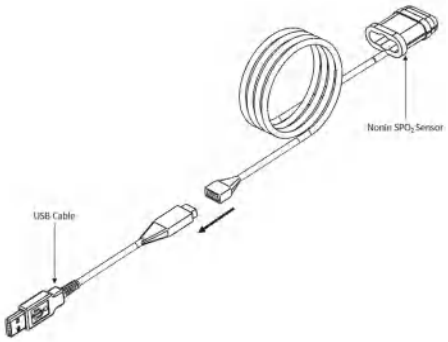


6.7 SpO2 Configuration

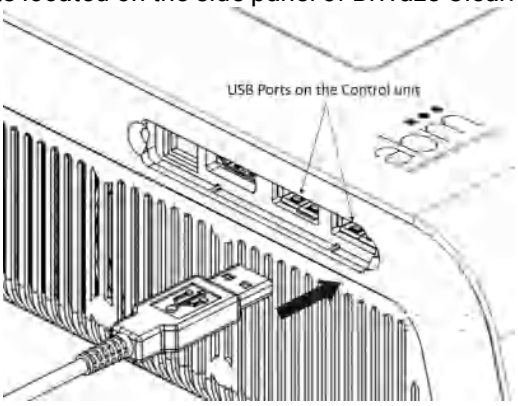
BiWaze Clear is validated with the Nonin SpO2 sensor with USB Connector. The information collected via the external sensor is displayed on the main screen during therapy.

To connect the Nonin SpO2 sensor to BiWaze Clear:

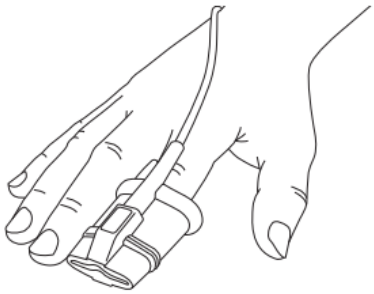
1. Connect the finger sensor cable to the USB controller cable.



2. Connect the USB controller cable to one of the two USB ports located on the side panel of BiWaze Clear.



3. Insert the patient's finger into the SpO2 sensor



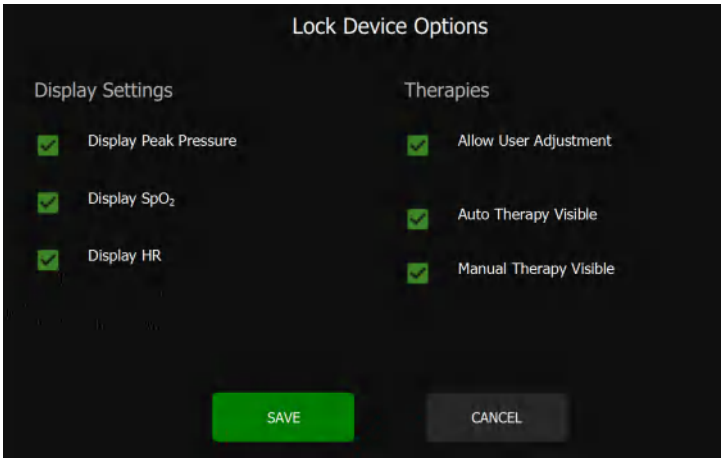
4. The oxygen and heart rate recorded by the external sensor will display on the main screen during therapy.

7. Locking and Unlocking Feature

7.1 Lock Feature

When the software is locked, display settings and therapy adjustment can be restricted. This mode is suitable for home users who are with minimal medical training and basic knowledge of the product. This mode is mainly intended for providing limited access to prevent risk of inappropriate therapy delivery.

Note: It is recommended to Lock the software when used in the home environment.

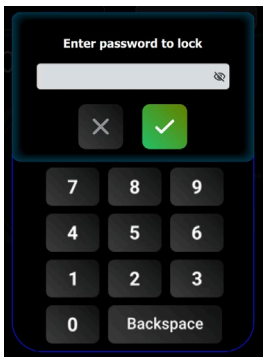


Option	Description
Display Peak Pressure	The peak pressure is displayed next to the manometer.
Display SpO2	The SpO2 level is displayed next to the manometer if the patient is using an approved external sensor and it is connected to the control unit.
Display HR	The heart rate is displayed next to the manometer if the patient is using an approved external sensor and it is connected to the control unit.
Allow User Adjustment	Users can adjust the pressure within the limit set in the Administrator section.
Auto Therapy Visible	Auto Therapy Mode can be visible or hidden from users.
Manual Therapy Visible	Manual Therapy Mode can be visible or hidden from users.

7.1.1 Locking

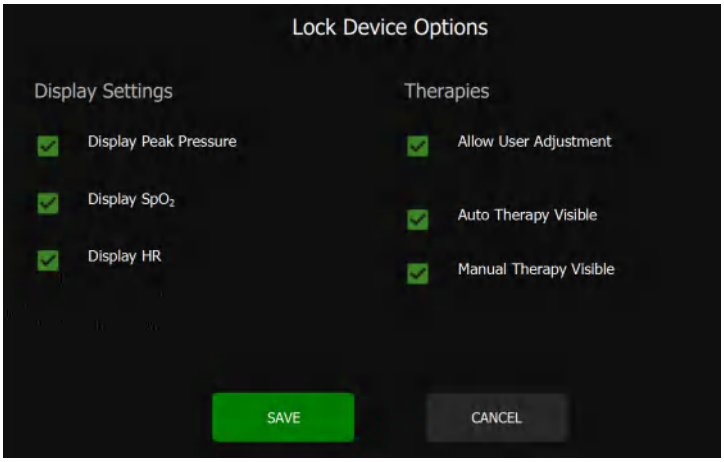
1. Press the grey padlock icon on the top left .
2. Enter the numeric password and press the check mark. The password is only available to trained healthcare professionals.

3. Edit the Lock Device Options by checking or unchecking the appropriate parameters. When a parameter is unchecked, it is not visible or Off. When a parameter is checked it will be visible or On when the system is locked.



4. Press SAVE.

Note: When the software is locked, therapies can't be edited unless Allow User Adjustment is enabled. This option allows the user to adjust pressures and time within the range set under the Administrator screens.



7.2 Unlock Feature

When the software is unlocked, all therapy settings are unrestricted to the user. This mode is primarily utilized by trained clinicians or advanced users with proper training. Users have complete access to adjust therapy settings based on the physiological needs of the patient.

7.2.1 Unlocking

1. Press the blue padlock icon on the top left .
2. Enter the numeric password and press the check mark. The password is only available to trained healthcare professionals.
3. The software will be unlocked and available to configure.

8. Cleaning and Maintenance

8.1 Cleaning the Control Unit

WARNING - Remove the power cord from the device and wall outlet before cleaning the control unit. The control unit's exterior surface should be cleaned before and after each patient use and more often if needed.

Unplug the control unit and clean the front panel and exterior of the enclosure (excluding Dual Lumen Breathing Circuit) as needed. You can also clean the power cable when it is not plugged in. Use one of the following cleaning agents:

- A clean cloth dampened with water and a mild detergent
- 70% Isopropyl alcohol or similar alcohol based towelettes used for medical devices with less than 70% Isopropyl alcohol
- 10% Chlorine bleach solution

Inspect the control unit and power cord for damage after cleaning. Replace any damaged parts. Allow the device to dry completely before plugging in the power cord.

8.2 Cleaning and Replacing the Air Inlet Filter

Under normal usage, you should clean the inlet air filter at least once every 1 month and replace it with a new one every six months.

Air inlet filter cleaning and replacing steps:

1. If the control unit is powered on, turn off the control unit.
2. Disconnect the power cable from the control unit.
3. Remove the air in-filter from the enclosure.
4. Examine the filter for cleanliness and integrity.
5. Wash the filter in warm water with a mild detergent.
6. Rinse thoroughly to remove all detergent residue.
7. Allow the filter to air dry completely before reinstalling it. If the filter is torn or damaged, replace it. Only filters from ABM Respiratory Care should be used as replacement filters.
8. Reinstall the filter.

8.3 Cleaning the Dual Lumen Breathing Circuit

- **WARNING** - Do not sterilize the breathing circuit.
- **WARNING** - Always use a new Dual Lumen Breathing Circuit including the Aerogen® Solo nebulizer when using BiWaze Clear on a new patient.
- **WARNING** - Replace the breathing circuit between patients to avoid cross infections.
- **WARNING** – All components of the Dual Lumen Breathing Circuit, including the Aerogen® Solo nebulizer are single patient use.
- **WARNING** – Aerogen® Solo nebulizer is not intended to be cleaned or sterilized.

8.3.1 Institutional (Hospital) Use

The Dual Lumen Breathing Circuit is for single patient use only. The coaxial tube, handset and patient interface should be washed thoroughly with liquid dishwashing soap and water or per facility protocol. These parts must completely air dry before reuse.

Note: Replace the bacterial / viral filter if it gets wet or clogged.
Note: The Dual Lumen Breathing Circuit is for a single patient use only and intended for 30 days of treatment or a maximum of 90 treatment sessions.

WARNING - Do not wash the bacterial/viral filter.

8.3.2 Home Use

After use, the breathing tube and patient interface should be washed thoroughly with liquid dishwashing soap and warm water. These parts must completely air dry before reuse.
Note: Replace the breathing circuit after 30 days or 90 therapy cycles, whichever comes first.

1. Disconnect all components of the single patient use circuit.
2. Wash the components (excluding the Bacterial / Viral Filter) in liquid dish-washing soap and warm water.
3. Rinse the components with clean water.
4. Examine the components for any remaining traces of soil. If the components are not visibly clean, repeat Step 2 and 3 again.
5. Let the component dry on a lint free towel completely prior to reuse.

WARNING -Do not wash the bacterial/viral filter.
Note: Replace the bacterial / viral filter if it gets wet or clogged.
Note: The Dual Lumen Breathing Circuit is for a single patient use only and intended for 30 days of treatment or a maximum of 90 treatment sessions.

8.4 Cleaning the Aerogen® Solo

The Aerogen® Solo Nebulizer is single patient use only and is not intended to be cleaned, disinfected or sterilized.

8.5 Storage and transportation

While not in use cover the patient port with the cap provided at the port. Power off the control unit and remove the power cable. Store in a dust free location outside the reach of children.
When in the home environment, use the carrying bag to transport or store the control unit. Do not place other baggage on top of the device.

8.6 Traveling with BiWaze Clear

It may be helpful to bring the user manual along to help security personnel understand the device.
If you are traveling to a country with a line voltage different than the one you are currently using, a different power cord or an international plug adaptor may be required to make your power cord compatible with the power outlets of the country to which you are traveling.

8.7 Preventive Maintenance

This device does not require preventive maintenance.

9. Accessories

9.1. Carrying Bag

A carrying bag is available for BiWaze Clear when used in the home environment. 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.

9.2 Mobile Cart

A mobile cart is available for BiWaze Clear in the hospital environment. The mobile cart has a mounting plate, a basket, and locking caster wheels. BiWaze Clear control unit is secured onto the mounting plate. The mobile cart is an optional accessory. The cart provides mobility in acute and outpatient facilities.

10. Informational Messages

This chapter describes the informational messages that may appear on-screen and troubleshoots some of the problems you may experience with your device and possible solutions to those problems.

The following type of informational messages may appear on-screen.

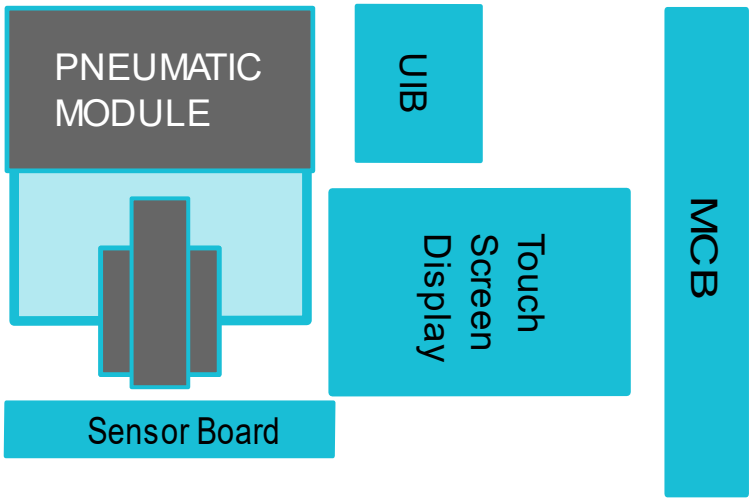
Message	Description
Therapy complete Information	Provides summary of the current therapy completion.
Error State Information	In case of any technical errors, the Error Message is displayed.

11. Technical Specifications

11.1 Theory of operations

BiWaze Clear is designed around a pneumatic assembly that controls positive as well as negative pressure and flow delivery to the patient. The main processor monitors sensors for pressure, flow and so on, and controls the blowers to meet treatment settings and make breathing comfortable for the user. A number of internal sensor readings are monitored to ensure that the BiWaze Clear functions correctly. Some of them are checked at power up, some at therapy start, and some are monitored continuously.
Main Control Board (MCB): This board has multiple processors including main processor for control of pressure and flow. This board controls the positive and negative flow control valves, blowers as well as monitors various temperatures and battery capacity. It also communicates with UI board and Sensor board.

UI Control Board (UIB): This board controls the user interface including the main touch screen LCD as well as USB, and HDMI ports. This board also provides wireless interfaces for Wi-Fi connectivity.
Sensor & Nebulizer Board: This board provides various pressure and flow sensors required to control as well as monitor the therapy parameters. This board also houses the connectors to peripherals like Nebulizer, USB and HDMI.
Pneumatic block: This block houses the blowers and valves to deliver air pressure and flow in both positive and negative direction. The pneumatic paths for positive and negative flow are independent.



11.1 Product Specification

OSC Therapy Parameter	Modes	Min	Max
Pressure	Manual & Auto	5 cmH_20	70 cmH_20
Nebulization	Manual & Auto	Disabled	Enabled
Frequency	Manual & Auto	Low	High
Duration	Auto	0:05min	30 min

PEP Therapy Parameter	Modes	Min	Max
Pressure	Manual & Auto	0 cmH_20	30 cmH_20
Nebulization	Manual & Auto	Disabled	Enabled
Duration	Auto	0:05min	30 min

NEB Therapy Parameter	Modes	Min	Max
Duration	Auto	0:05min	30 min

11.2 Environmental

	Operating	Storage
Temperature	40 F to 95 F (5 C to 35 C)	-4° F to 140° F (-25° C to 70° C)
Relative Humidity	15 to 90% (non-condensing)	10 to 90% (non-condensing)
Atmospheric Pressure	106 kPa to 70 kPa	106 kPa to 60 kPa

11.3 Physical

Dimensions	27.5 cm L x 23.5 cm W x 9.0 cm H (10.5" L x 9.2" W x 3.5" H)
Weight	3.8 kg (8.4 lbs.) (without battery) 4.1 kg (9.4 lbs.) (with battery installed)

11.4 Performance Specifications of the Aerogen® Solo

Flow Rate	> 0.2 mL/min (Average ~ 0.38 mL/min)
Particle Size	**As measured with the Andersen Cascade Impactor:** Specification Range: 1-5 µm Average Tested: 3.1 µm **As per EN 13544-1:** Aerosol Output rate: 0.30 mL/min Aerosol Output: 1.02 mL emitted of 2.0 mL dose Residual Volume: <0.1 mL for 3 mL dose

Performance may vary depending upon the type of drug and nebulizer used. For additional information contact Aerogen® Solo or drug supplier.
The temperature of the medication will not rise more than 10°C (18°F) above ambient during normal use.

Note: Above table shows the results of aerosol performance testing for the Aerogen® Solo using an 8-stage cascade impactor running at a continuous flow rate of 28.3 LPM. Indicated ranges correspond to confidence intervals with a confidence level of 95%.

	Albuterol Sulphate (1mg/ml)	Ipratropium (0.25mg/ml)	Budesonide (0.5mg/ml)
Particle size (µm)	2.90 - 3.23	3.07 - 3.42	3.45 - 3.79
Geometric Standard Deviation (GSD)	2.09 - 2.35	1.80 - 1.93	1.92 - 2.14
Emitted Dose (% of fill)	97.23 - 99.30	97.61 - 98.64	94.12 - 97.84
Respirable Dose (0.5 – 5.0 µm) (% of fill)	67.66 - 73.50	71.78 - 76.69	62.32 - 66.90
Coarse particle Dose (>4.7 µm) (% of fill)	27.00 - 31.11	23.62 - 28.21	32.31 - 36.12
Fine particle Dose (<4.7 µm) (% of fill)	66.33 - 72.07	68.58 - 73.84	59.36 - 64.17
Ultra-fine Particle Dose (<1.0 µm) (% of fill)	5.91 - 9.93	1.85 - 4.19	2.36 - 4.51

11.5 Physical Specifications of the Aerogen® Solo Nebulizer

Nebulizer Dimensions	67 mm H x 48 mm W x 25 mm D 2.6” H x 1.88” W x 1.1” D
Nebulizer Weight	13.5 g (0.5 oz) nebulizer and plug
Nebulizer Capacity	Maximum 6 mL

11.6 Orderable Part Numbers

Part Number	Product Name	Description
BK0368	BiWaze® Clear System – USA Acute Care	1 Control Unit, 2 Dual Lumen Breathing Circuit – Mouthpiece, Aerogen® solo power cable, User Manual, Acute Care Quick Reference Guide, Battery, USA Power Cord, Mobile Cart, Air Inlet Filter (3 pack)
BK0367	BiWaze® Clear System – USA Home Care	1 Control Unit, 2 Dual Lumen Breathing Circuit – Mouthpiece, Aerogen® solo power cable, User Manual, Home care Quick Reference Guide, Battery, USA Power Cord, Carrying Bag, Air Inlet Filter (3 pack)
BK0280	BiWaze® Clear Dual Lumen Breathing Circuit – Mouthpiece	Coaxial filter, Coaxial breathing tube, handset, Aerogen® Solo, Mouthpiece
BK0293	BiWaze® Clear Dual Lumen Breathing Circuit – Flexible Trach Adapter	Coaxial filter, Coaxial breathing tube, handset, Aerogen® Solo, Flex Trach Adapter
BK0258	BiWaze® Clear Dual Lumen Breathing Circuit – Adult Large Face Mask	Coaxial filter, Coaxial breathing tube, handset, Aerogen® Solo, Adult Large Face Mask
BK0287	BiWaze® Clear Dual Lumen Breathing Circuit – Adult Medium Face Mask	Coaxial filter, Coaxial breathing tube, handset, Aerogen® Solo, Adult Medium Face Mask

BK0289	BiWaze® Clear Dual Lumen Breathing Circuit – Adult Small Face Mask	Coaxial filter, Coaxial breathing tube, handset, Aerogen® Solo, Adult Small Face Mask
BK0291	BiWaze® Clear Dual Lumen Breathing Circuit – Adult Child Face Mask	Coaxial filter, Coaxial breathing tube, handset, Aerogen® Solo, Adult Child Face Mask
BC21095	Battery	Rechargeable battery
BK0388	Quick Reference Guide	Acute Care Quick Reference Guide
BK0386	Quick Reference Guide	Home Care Quick Reference Guide
BK0381	User Manual	Instructions of use for BiWaze Clear
BC20116	Power Cord	US Power Cord
BC22506	Mobile Cart (Acute Care Only)	Mobile Cart with basket, telescoping pole and locking caster wheels
BC21083	Carrying Bag	Carrying Bag for Home care environment
BC21274	Air Inlet Filter (Pack of 3)	Pack of 3 replaceable air inlet filters
BK0371	SPO2 pulse oximeter	Pulse oximeter
BK0373	SpO2 soft sensor small	SpO2 sensor small size
BK0372	SpO2 soft sensor medium	SpO2 sensor medium size
BK0374	SpO2 soft sensor large	SpO2 sensor large size

11.7 Standards Compliance

This device is designed to conform to the following standards:

- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for safety
- IEC 60601-1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62304: Medical device software — Software life cycle processes
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing (Biocompatibility)
- ISO 18562-1:2017 Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing within a Risk Management Process. ISO 14971: Application of Risk Management for Medical Devices

11.7. Device classifications

AC Voltage Source	100 to 240VAC, 50/60 Hz
AC Power Supply	Input: 100-240 V, 50/60 Hz 1.0-2.0A
Lithium-Ion Battery	Power: 90 Wh Capacity: 3400 mAh
Type of Protection Against Electric Shock	Class II
Degree of Protection Against Electric Shock	Type BF Applied Part
Patient applied part	Face mask and mouthpiece
Degree of Protection against Ingress	Exposure Protection, IP21
Mode of Operation:	Intermittent (30 mins ON – 15 mins OFF)

11.8 Wireless communication

Wi-Fi Specification	
Feature	**Dimension**
WLAN	IEEE Std 802.11b, 802.11g, and 802.11n with 20 MHz and 40 MHz SISO
Frequency	2412 MHz to 2462 MHz

Transmit Power	1Mbps: 17.4 dBm (Typ) 54 Mbps: 13.8 dBm (Typ) MCS7 (20MHz): 12.6 dBm (Typ) MCS7 (40MHz): 11.3 dBm (Typ)
Receive Sensitivity	1Mbps DSSS: -96.3 dBm (Typ) 54 Mbps OFDM: -74.9 dBm (Typ) MCS7 (20MHz): -72.4 dBm (Typ) MCS7 (40MHz): -67.0 dBm (Typ)
Security Authentication/Encryption	Wi-Fi-protected access (WPA and WPA2.0) and IEEE Std 802.11i (includes hardware-accelerated Advanced Encryption Standard [AES])

11.9 Control Accuracy

Parameter	Accuracy
Pressure	± 5 cmH2O
Time	± 0.5 seconds
Frequency	± 1Hz

Device performance and accuracy is specified at Temperature: 20-30° C; Humidity: 50% relative; Altitude: nominally 380 meters for typical patients.

11.10 Sound

The sound pressure of the device set at 30cmH2O in the PEP phase is less than 65 dBA at 1 meter.

11.11 Disposal

Dispose of this device and accessories in accordance with local regulations. This device and accessories should be disposed of separately, not as unsorted municipal waste. To dispose of your device and accessories, you should use the appropriate collection, reuse, and recycling systems available in your region. The use of these collection, reuse, and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment

11.12 Essential Performance

The Essential Performance of the BiWaze Clear is defined as follows:

- Therapy air pressure not to exceed 85 cmH2O.

12. EMC Information

WARNING - 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 BiWaze Clear System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

WARNING - The BiWaze Clear System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BiWaze Clear System should be observed to verify normal operation. If operation is not normal, the BiWaze Clear System or the other equipment should be moved.

WARNING - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

12.1 Electromagnetic Emissions

BiWaze Clear is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

12.2 Electromagnetic Immunity

BiWaze Clear is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains Not Applicable	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to line(s)	±1 kV line(s) to line(s) Not Applicable	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle at: 0^0, 45^0, 90^0 135^0, 180^0, 225^0 270^0 and 315^0 0% UT for 1 cycle 70% UT for 25/30 cycles, single phase at 0^0. 0% U_T for 250/300 cycles	0% UT for 0.5 cycle at: 0^0, 45^0, 90^0 135^0, 180^0, 225^0 270^0 and 315^0 0% UT for 1 cycle 70% UT for 25/30 cycles, single phase at 0^0. 0% U_T for 250/300 cycles	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical home or hospital environment.
NOTE: UT is the AC mains voltage prior to application of the test level.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	The BiWaze Clear system is suitable for the electromagnetic environment of typical homes or hospital settings.

Radiated RF IEC 61000-4-3	150 kHz to 80 MHz 6Vrms in ISM bands between 150KHZ to 80MHz 10 V/m 80 MHz to 2.7 GHz	6 Vrms 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2ÖP *d* = 1.2Ö*P* 80 MHz to 800 MHz *d* = 2.3Ö*P* 800 MHz to 2.7 GHz where *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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol.
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. **NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. 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, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.			

12.2.1 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device

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

Rated Maximum Power Output of Transmitter (Watts)	**Separation Distance According to Frequency of Transmitter (meters)**		
	150 kHz to 80 MHz outside ISM Bands d = 1.2ÖP	80 MHz to 800 MHz d = 1.2ÖP	800 MHz to 2.5GHz d = 2.3ÖP
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 meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter manufacturer. **Note 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

12.3 Electromagnetic Immunity to Wireless Communications Equipment

BiWaze Clear is intended for use in the electromagnetic environment specified below. The customer or user of the device should make sure is used in such an environment.		
Sides Tested	**Frequency (MHz)**	**Test Severity Level**
Left, Right	385	27V/m, 50%PM 18Hz
Left, Right	450	28V/m, FM±5kHz, 1kHz
Left, Right	710, 745, 780	9V/m, 50%PM, 217Hz
Left, Right	810, 870, 930	28V/m, 50%PM, 18Hz
Left, Right	1720, 1845, 1970, 2450	28V/m, 50%PM, 217Hz
Left, Right	5240, 5500, 5785	9V/m, 50%PM, 217Hz

12.4 Federal Communications Commission (FCC) Compliance Statement

FCC Part 15.19 Statement

BiWaze Clear complies with Part 15 of the FCC rules.
Operation is subject to the following two conditions:
(1) This device may not cause harmful interference
(2) This device must accept any interference received, including interference that may cause undesired operation.

FCC Part 15.105 Warning Statement

NOTE: This device has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on. The user is encouraged to try to correct the interference by one or more of the following measures:

- Re-orientate or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Part 15.21 Warning Statement

NOTE: Change or Modifications that are not expressly approved by the manufacturer could void the user's authority to operate the device.
This device should be operated with the minimum distance 20 cm between the device & your body.

FCC ID of Device:

FCC ID of BiWaze Clear is "**2ATX9-BK181**"
NOTE: The module must be used in strict accordance with the manufacturer's instructions as described in the user documentation that comes with the product.
To maintain compliance, the device must be used with specified BiWaze Clear accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

13. Troubleshooting

In there is an issue with BiWaze Clear, some of the issues are self-explanatory and relevant messages are displayed on screen to allow user to take necessary action to come out of the error condition. For other issues related to the control unit, it may require servicing from an ABM Respiratory Care authorized service center. Contact your health care/service provider for support.

Event Type	Description	Action
Red Strip with Error: High Temperature	The control unit temperature is high.	Check if the control unit is ventilated properly and not covered with cloth or other items. Ensure its placed on hard surface with space on all sides. Switch off the control unit and restart after 15 minutes of cool down.

		Move the control unit away from any sources of heat or hot ambient temperatures. Switch off the device and restart after 15 minutes of cool down.
		If problem persists, call your health care provider for servicing the device to replace the filters and functional check.
Control unit does not power up	Battery may be too low.	Connect the control unit to the power cable and check if the device powers on. If problem persists, call your health care provider for service.
Technical errors with an error code number on a Red strip on the LCD Screen and control unit shuts down after few seconds	Technical error related to temperatures or other high priority fault	Try rebooting the control unit and if problem persists, call your health care provider for service.
Technical errors with an error code number on a Red strip on the LCD Screen and control unit does not shut down. User cannot start the therapy.	Technical error related to subsystem malfunction	Try rebooting the control unit and if problem persists, call your health care provider for service.
Information with a self-explanatory message on the LCD screen in an Orange strip.	Informational messages	User can acknowledge and continue with therapy. Take action based on informational message if needed.
Control unit not performing as intended. Making abnormal sounds or therapy performance.	Control unit performance malfunction.	Ensure that you move away from any high electromagnetic or RF radiation sources like MR machines, power transformers etc.
		If problem persists, do not use the control unit and call your healthcare provider for the service.

The following types of error messages along with their error codes may appear on-screen in case of a malfunction.

Sr. No	Notification	Error Codes
1	Inspiratory Blower Error	1
2	Expiratory Blower Error	2
3	Insp. Pressure Sensor Error	4
4	Exp. Pressure Sensor Error	8
5	Insp. Flow Sensor Error	10
6	Exp. Flow Sensor Error	20
7	Barometric Pressure Sensor Error	40
8	Excess Pressure	80
9	High Delivered Air Temperature	100
10	High Battery Temperature	200
11	Positive Stepper Motor Error	400
12	Negative Stepper Motor Error	800
13	High MCB Temperature	1000
14	MCB Temperature Sensor Fail	2000
15	Delivered Air Temperature Sensor Fail	4000
16	Battery Temperature Sensor Fail	8000
17	Stepper Communication Error	10000
18	Pressure Sensor Mismatch	20000
19	Blower Calibration Error	40000
20	Flow Sensor Calibration Error	80000

21	High Leak Detected	100000
22	Mask Off Detected	200000
23	Low Battery Temperature	400000
24	Low MCB Temperature	800000
25	Low Patient Air Temperature	1000000
26	PMB and MCB Communication Error	2000000
27	Battery Charging Error	4000000
28	UIB and MCB Communication Error	8000000
29	Low Battery	10000000
30	Critical Low Battery	20000000
31	High Ambient Temperature Error	40000000
32	Stepper Value Slip Error	80000000

14. Limited Warranty

ABMRC LLC warrants that the BiWaze Clear System shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year from the date of sale by ABMRC, LLC to the dealer. If the product fails to perform in accordance with the product specifications, ABMRC, LLC, will repair or replace – at its option – the defective material or part. ABMRC, LLC will pay customary freight charges from ABMRC, LLC to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.
ABMRC, LLC disclaims all liability for economic loss, loss of profits, overhead, or consequential damages which may be claimed to arise from any sale or use of this product. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.
The warranty for accessories or consumables is as below;

Accessory/Consumable	Warranty Period
Battery	90 days
Carrying Bag	30 days
Mobile Cart	1 year

Other accessories and replacement parts, including, but not limited to, circuits, tubing, leak devices, exhaust valves, filters and fuses, are not covered under this warranty.
This warranty is given in lieu of all other express warranties. In addition, any implied warranties – including any warranty of merchantability or fitness for the particular purpose – are limited to one year. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.
To exercise your rights under this warranty, contact your local authorized ABMRC LLC dealer or your health care provider or contact ABM at: customer.service@abmrc.com

15. Service Instructions

If service or support is needed, use the following contact information for your country or region.

- In the United States of America:
  - Contact ABM Respiratory Care Customer Service at 877-ABM-RC01 (877-226-7201) or *customer.service@abmrc.com*.
- In Asia:
  - Contact your distributor or
  - a local ABM Respiratory Care representative via WhatsApp at +65 6428 6218 or *customer.service.asia@abmrc.com*.
- In Europe, the Middle East and Africa:
  - Contact your local distributor or
  - a local ABM Respiratory Care representative *customer.service.emea@abmrc.com*.

⚠ **CAUTION** -

- Do not remove the top cover or disassemble the device. The device should be serviced by authorized personnel only.

- Do not modify this equipment. No modification of this equipment is allowed by any unauthorized personnel.
- Replacement of consumables can be performed with standard tools only if required by an authorized service personnel.

Note: If a user and/or patient has a serious incident involving BiWaze Clear, immediately contact ABM Respiratory Care.

15.1 Expected service life

The service life for various subsystems is as follows:

Control Unit	5 Years
Power Cord	5 Years
Dual Lumen Breathing Circuit	30 days after unpacking
Aerogen® Solo	1 year
Carry Bag	1 year
Battery	1 year
Mobile Cart	3 years

15.2 FRU and Spare parts

There are no field replaceable spare parts orderable for service.

15.3 Planned Maintenance

There is no requirement for planned maintenance of the BiWaze Clear System.

15.4 Service: Cleaning and Maintenance

There is no field service applicable for the control unit. Any returns to the manufacturing shall be cleaned before shipping.

WARNING - Only authorized persons should service the BiWaze Clear System. Service by unauthorized persons could cause personal injury or equipment damage.

ABMRC LLC
860 Blue Gentian Road
Suite 200
Eagan, MN 55121
USA
www.abmrc.com

REF
BK181

URM
1463077491-381
BK0381
Rev: 5.0
Issue Date: Dec 2022

UI Software Version
Above 1.X.0