BiWaze® Cough SYSTEM

USER MANUAL

BC21084 Rev 14.0

abm RESPIRATORY CARE

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1. Introduction

The BiWaze® Cough device helps to clear bronchopulmonary secretions from the respiratory system by providing a therapy which mimics a cough. The therapy consists of three phases which mimic a cough; inhale, exhale, and pause phase.

The inhale phase is positive airway pressure to expand the lungs. Then the exhale phase is a sudden shift to negative pressure to pull the air out of the lungs. Finally, the pause phase provides a rest before the next inhale phase. BiWaze allows for positive pressure to be delivered during the pause phase to keep the airways open in between the inhale and exhale phases.

This User Manual is applicable for the product "BiWaze® Cough" intended for a patient or care provider user.

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

⚠ WARNING

Use BiWaze Cough only as directed by a physician or healthcare provider.
Use BiWaze Cough 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 Cough.
Ensure that the latest revision of User Manual is being used. Contact ABM Respiratory Care or authorized local distributor to enquire about the latest revision of the User Manual. Any User Manual, which is not the latest revision needs to be discarded.
Setup and configure BiWaze Cough 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.

1.1. Intended Use

This product is used for assisting patients to clear retained bronchopulmonary secretions by gradually applying positive pressure to the airway, then rapidly shifting to a negative pressure. This rapid shift in pressure, via a facemask, mouthpiece or an endotracheal or tracheostomy tube produces a high expiratory flow rate from the lungs, simulating a cough.

This device is designed for use on patients unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease. This device is intended for use in hospital, institutional setting or in home on adult patients and pediatric patients 3 years old and above.

1.2. Contraindications

BiWaze Cough is contraindicated in patients with the following pre-existing conditions:

- known susceptibility to pneumothorax or pneumo-mediastinum
- severe bullous lung disease
- recent barotrauma

1.3. General Warnings and Cautions

The following are general warnings and cautions. Further specific warnings, cautions and notes appear next to the relevant instructions in the manual.

⚠ WARNING

- A WARNING alerts you to possible injury.
- The operator should read and understand this entire manual before using the device.
- BiWaze Cough is a restricted medical device intended for use by qualified, trained personnel/ individual under the direction of a physician.
- BiWaze Cough is not intended to be operated by persons (including children) with reduced physical, sensory or mental capabilities without adequate supervision by a person responsible for the patient's safety.
- If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if the device is dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact your home care provider.
- Do not operate the system, or use any accessory, if you notice physical damage or signs of malfunction such as a damaged power cord, evidence of being submerged in water, or an unresponsive touchscreen.
- Therapy shall not be performed on a patient without a Bacterial/Viral (B/V) filter along the Breathing tube.

- Always use a new bacterial/ viral (B/V) filter when using the device on a new patient.
- Confirm all settings before each treatment.
- Soreness and/or pain in the chest from a pulled muscle may occur in patients using BiWaze Cough for the first time if the positive pressure used exceeds pressures which the patient normally receives during Positive Pressure Therapy. Such patients should start at a lower positive pressure during treatment, and gradually increase the positive pressure used based on patient tolerance and comfort.
- 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.
- Therapy should not be initiated while the device is in Carry Bag.
- Do not remove the top cover or disassemble the device as there are no serviceable parts inside. 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.
- Only ABM Respiratory Care supplied accessories and consumables like Power Cord, Breathing Circuits, Foot Switch, etc. should be used for optimum performance of the device.
- Keep the young children away from the power cable, breathing circuit and connectors to prevent any choking or strangulation.
- If connected, disconnect the foot pedal remote after use from the device to avoid tripping.

⚠ CAUTION

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

- Do not expose the device to excessive force, dropping or shaking.
- Keep the power cord and device away from any potential heat sources like room heater, hot iron, kettle steam etc.
- Shut down the device when not in use
- Make sure that all the air inlets at the side of the device are unobstructed. If the device is put 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.
- Do not operate the device while it's in the carrying case.
- Do not operate the device in direct sunlight for better visibility and avoid heating the LCD screen.
- 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.
- Do not operate the device in very dusty environment outside the room or in an environment with small fibers or airborne material which can clog the filters.
- 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.
- Disconnect the foot pedal and store it safely after user to avoid tripping on it.

Note: This product does not contain natural latex rubber.

2. BiWaze Product Overview

The BiWaze Cough includes the following components.

Product Package

- BiWaze Cough device
- Standard Breathing Circuit kit that includes a bacterial/viral filter, breathing tube, and patient interface (face mask, mouthpiece or flexible adapter for a trach)
- Patient Port Adapter
- Carrying Case
- AC Power Cord
- User Manual
- Air Inlet Filter

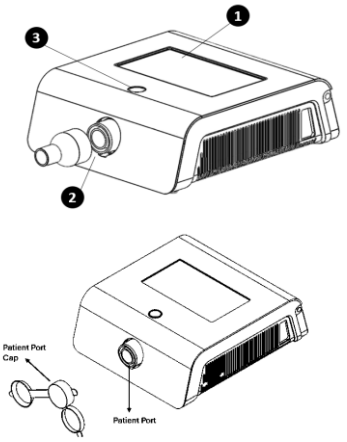
2.1. System Overview

BiWaze Cough helps patients in clearing excessively retained bronchopulmonary secretions in the lungs and upper airways. This is done by progressively applying positive pressure to the airway and then rapidly shifting to a significant negative pressure. This action replicates the effects of a natural cough and thereby helping in removal of secretions retained in the airways.

2.1.1. Main Control Interfaces

The items numbered in the illustration below are described in the table that follows.

Sl 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 logs.
2	Patient Port and Patient Port Adapter	The breathing circuit is connected to this port for therapy delivery through the patient port adapter.
3	Device Mode Button with LED	This LED light provides different color code lights. Green: Manual Mode Blue: Auto Mode Red: Error or shutdown mode The button within the LED light provides the ability to Start and Pause therapy.

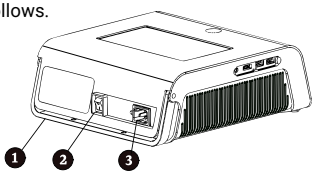


Note: Do not cover the patient port with the cap during start-up, while the device is switched on or in operation. Only use the cap to cover the patient port when the device is not in use.

2.1.2. Back Panel Interfaces

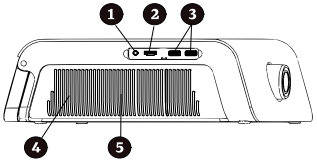
The items numbered in the illustration below are described in the table that follows.

Sl No	Item	Description
1	Handle	Handle to carry the device
2	Power source switch	Cuts off AC mains and battery power to the main processor
3	AC Power Inlet	AC power cord connection

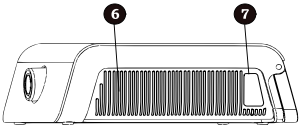


2.1.3. Side Panel Overview

The items numbered in the illustration below are described in the table that follows.



Device Left Side



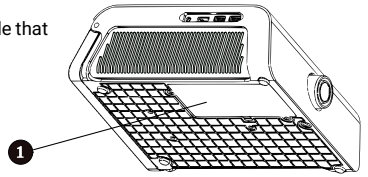
Device Right Side

Sl No	Item	Description
1	Foot Pedal port	Connection port for Foot Pedal
2	HDMI port	External HDMI display
3	USB ports	Connection for USB Flash drive
4	Air outlet	Outlet port for expiratory air
5	Power supply cooling Fan location	Cooling fan for the power supply
6	MCB Fan	Main control board fan
7	Air Inlet Filter	Inlet port for inspiratory air

⚠ **CAUTION:** Do not attach any unapproved devices or storage medium to any of the ports. Use only ABM Respiratory Care approved and supplied parts. Failure to do so may damage the system.

2.1.4. Bottom Panel Features

The items numbered in the illustration below are described in the table that follows.



Sl No	Item	Description
1	Battery housing	Internal battery is placed here

WARNING: Do not open the battery cover, only authorized service personnel can open and replace the battery. Do not try and use any other batteries, other than supplied by ABM Respiratory Care.

2.2. Symbols

The following symbols appear on this device.

Symbols	Definition
	AC Power
	Remote Control
	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
	Humidity Limitation
	Follow instructions for use
MD	Medical Device
REF	Catalogue Number
SN	Product serial number
Rx ONLY	Prescription use only
	Manufacturer*
	Stand-by

	CAUTION
	WARNING
	Not made with natural rubber latex
	Consult Instruction for use
	Unique Device Identifier
	Safe Working Load
	NRTL Marking

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

2.3. Traveling with the System

You should carry the user manual along with the BiWaze Cough System to help security personnel understand the purpose of 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 adapter may be required to make your power cord compatible with the power outlets of the country to which you are traveling.

2.4. How to Contact ABM Respiratory Care

For customers in USA, contact ABM Respiratory Care Customer Service; 877-ABM-RC01 (877-226-7201) or *customer.service@abmrc.com*.

For customers in Asia, contact ABM Respiratory Care Customer Service via WhatsApp at +65 6428 6218 or customer.service.asia@abmrc.com.

For customers in Europe, the Middle East and Africa, contact ABM Respiratory Care Customer Service via *customer.service.emea@abmrc.com*.

3. Therapy Modes and Features

3.1. Therapy Modes

Therapy	Description
Manual	Manual mode delivers therapy based on the Pause Pressure, Inhale and Exhale Pressure. The device delivers the set Inhale Pressure or Exhale Pressure for the amount of time that either the "+" or "-" button is pressed respectively. The device delivers Pause Pressure when neither button is pressed.
Auto	Auto mode delivers therapy based on the following prescription settings: Inhale Pressure, Inhale Time, Exhale Pressure, Exhale Time, Pause Pressure, Pause Time and Number of Cycles. Auto mode delivers pressure in the following sequence, repeating the sequence until the user pauses and exits the therapy, or the number of cycles count is reached: • Pause pressure for the duration of the Pause Time setting. • Positive pressure at the Inhale Pressure setting for the duration of the Inhale Time setting. • Negative pressure at the Exhale Pressure setting for the duration of the Exhale Time setting. When the **Inspiratory Trigger** feature is enabled, Auto mode delivers pressure in the following sequence, repeating the sequence until user pauses and ends the therapy, or the number of cycles count is reached: • Pause pressure until the device detects the next inspiratory effort or the pause phase times out after 30 seconds.

	• Positive pressure at the Inhale Pressure setting when the device detects the patient's effort to inhale for the duration of the Inhale Time setting. • Negative pressure at the Exhale Pressure setting for the duration of the Exhale Time setting. **Note:** The therapy is paused if the patient's inspiratory breath isn't detected. When **CoughCue** is enabled, Auto mode repeats the following three-phase cycle until the user pauses therapy or the programmed cycle count is reached: • Pause Phase – Maintains the programmed *Pause Pressure* for the set *Pause Time*. • Inspiratory Phase - Delivers positive pressure at the target *Insp Pressure* until either • inspiratory flow falls to the chosen CoughCue threshold (flow-based trigger), or • the target pressure is reached (pressure-based trigger). After the trigger, the device holds the pressure for the programmed *Inspiratory Hold Time* before switching to expiration. • Expiratory Phase - Applies negative pressure at the programmed *Exp Pressure* for the set *Exp Time*. **Note:** The system automatically transitions from inspiratory to expiratory phase after either 5 seconds or the combined inspiratory time + inspiratory-hold time, whichever occurs first.

3.2. Therapy Features

The device provides the following therapy features:

3.2.1. Inspiratory Trigger

An important characteristic of the device is its ability to trigger on the patient's inspiratory breath to help synchronize the therapy with the patient's natural breathing, so it is more comfortable for the patient.

The inspiratory trigger feature is available when the device is in Auto mode. The pressure delivery sequence is synchronized with the patient's effort to inhale.

When the inspiratory trigger setting is activated in Auto mode, the inspiratory breath will be delivered when the patient's inspiratory effort is detected. If the patient effort is not detected within 30 seconds, the therapy is automatically paused.

There are 10 levels of sensitivity that can be adjusted per the patient's level of effort. It is recommended to start at the setting of 1 (least sensitive) and as the patient's inhale becomes weaker, the sensitivity level can be adjusted incrementally. Level 10 is the most sensitive.

Note: When inspiratory trigger is enabled, the Pause Time setting is disabled, and the user cannot adjust the Pause Time setting.

3.2.2. CoughCue

Synchronizes the expiratory phase with the patient's natural breathing, enhancing comfort during therapy. The CoughCue feature is available only when the device is in Auto mode. The user can enable or disable this feature from the device settings screen. By default, it is turned off.

Users can choose between two CoughCue trigger types:

- **Flow-based Trigger:** Switches to expiration when inspiratory flow falls to either **50 %** or **0 %** of its peak.
- **Pressure-based Trigger:** Switches to expiration as soon as the programmed inspiratory pressure is reached.

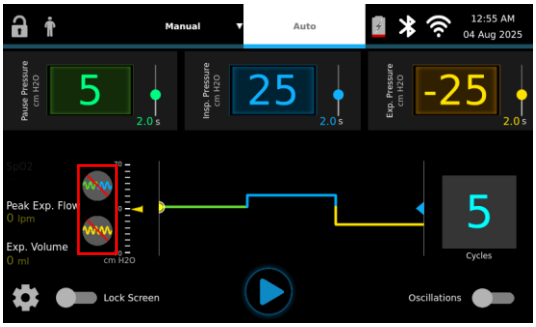
Inspiratory Hold Time – After a trigger is detected, the system can hold inspiratory pressure for **0–2 s** (adjustable in 0.1-s steps) to smooth the transition for patient comfort.

Note: The system automatically transitions from inspiratory to expiratory phase after either 5 seconds or the combined inspiratory time + inspiratory-hold time, whichever occurs first.

3.2.3. Oscillations

The Oscillation feature delivers an oscillatory therapy based on frequency and amplitude settings. Use of the oscillation feature enhances mobilization and improves bronchial drainage.

Users can customize this feature by independently enabling or disabling oscillations during different phases of the cough cycle. Oscillations can be applied during the pause and inhalation phases, limited to the exhalation phase, or applied throughout all phases of therapy, ensuring a personalized treatment experience.




Pause/Inspiratory Phase On


Pause/Inspiratory Phase Off


Expiratory Phase On


Expiratory Phase Off

When the Oscillation toggle is enabled, oscillations are applied to both the pause/inspiratory and expiratory phases. To limit oscillations to one phase, simply press the phase you wish to switch off.

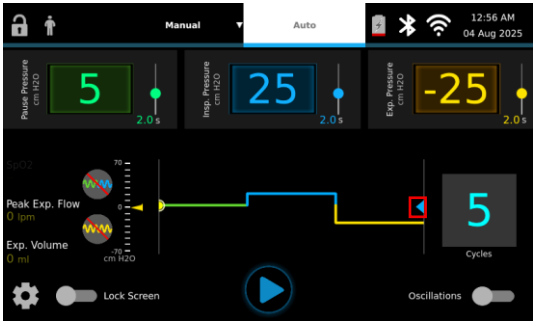
Note: The oscillations will be least apparent to the patient with lower amplitude and higher frequency settings.

Note: When inspiratory trigger is enabled, oscillations are automatically disabled for the Pause phase. When CoughCue is enabled, oscillations are automatically disabled for the Pause and Inspiratory phases.

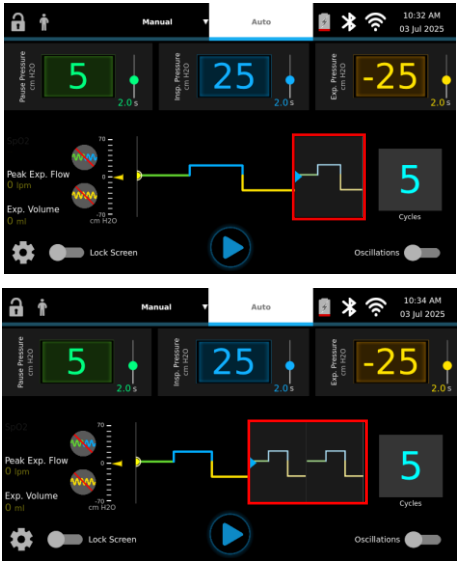
3.2.4. Look Ahead Display

The Look Ahead Display is accessible when the device is in Auto mode. When multiple cycles are programmed in the advanced therapy settings (see Section 6.7.2), users can preview the upcoming cycles while the current cycle is in progress.

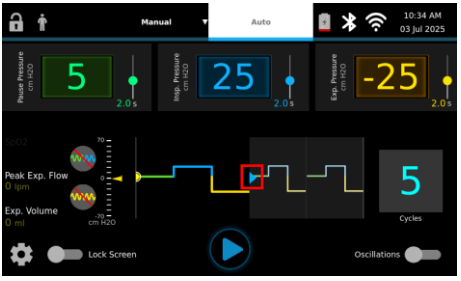
Clicking the highlighted arrow once will display the preview of the next cycle on the screen.



To view the previews for the next two cycles, double-click the displayed preview.



To close the Look Ahead Display press the blue arrow on the left of the display.



4. Therapy Setup

Review the following steps to prepare the device for the therapy.

Note: If the device was stored in temperature below 40 °F (5 °C) or above 95 °F (35 °C), allow the device to normalize for 15 minutes at room temperature 68 F (~20 °C) before using the device.

4.1. Position the Device Properly

Position the device on a firm, flat surface within arm's length of the patient or device operator. The device 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 device are not blocked. Air must flow freely around the device for the system to work properly.

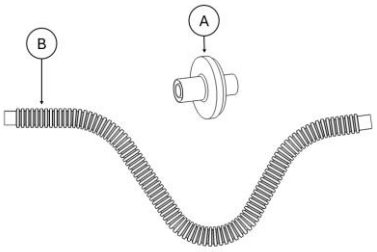
4.2. Breathing Circuit

BiWaze Cough offers two type breathing circuits:

(A) Standard Breathing circuit
(B) Dual Lumen Breathing circuit

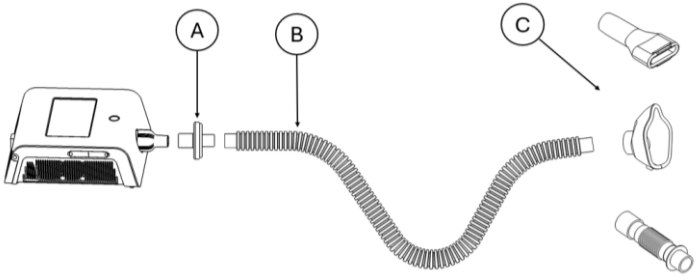
(A) Standard Breathing circuit

a. Standard Bacterial/Viral (B/V) filter
b. Standard 6 feet long, 22 mm diameter single tube



Assemble the standard breathing circuit

1. Ensure that standard 22mm patient port adapter is attached to the device
2. Connect the bacterial / viral filter (A) to the breathing tube (B)
3. Attach bacterial / viral filter to the patient port adapter
4. Attach one of the patient interfaces (C) (face mask, mouthpiece, or flexible trach adapter) to the breathing tube (B).



Note: The breathing tube diameter is 22mm and follows ISO-5356-1 standard. The B/V filter has a 99.9% filtration efficiency.

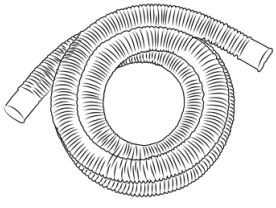
(B) BiWaze Cough Dual Lumen Breathing Circuit:

The Dual Lumen Breathing Circuit is an alternative breathing circuit designed to separate the inhaled air from the exhaled mucus and bacteria. This circuit can be used instead of the standard breathing circuit. This breathing circuit does not require the Patient Port Adapter to connect the Bacteria/Viral filter to the device. The coaxial B/V filter has a 99.9% filtration efficiency.

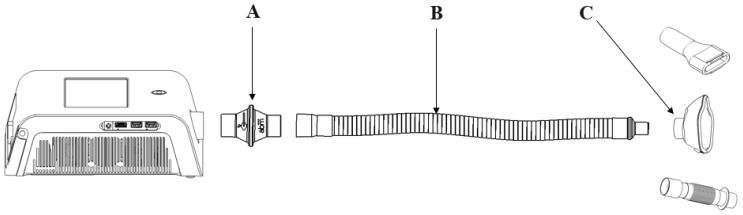
Note: Do not leave the oxygen port cap open in the coaxial bacterial/viral filter during therapy

a. Coaxial Bacterial/Viral filter

b. Coaxial breathing tube



Assemble the Dual Lumen breathing circuit



1. Attach coaxial bacterial /viral (B/V) filter (A) to the device.
2. Connect the coaxial bacterial/viral (B/V) filter (A) to the coaxial breathing tube (B).
3. Attach one of the patient interfaces (C) (face mask, mouthpiece, or flexible trach adapter) to the coaxial breathing tube (B). Use appropriate adapters between the breathing tube and patient interface if needed.

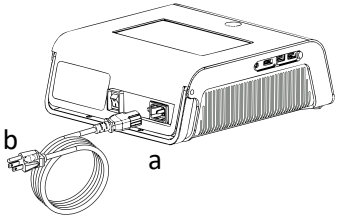
4.3. Supply Power to the Device

The device can operate on external AC power or built-in battery when charged.

4.3.1. Using AC Power

An AC power cord is included with the device.

a. Plug the socket end of the power cord into the AC inlet on the back of the device.
b. Plug the pronged end into an electrical outlet not connected to a wall switch.



Note: Ensure that all connections are secure.

4.3.2. Internal Battery

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

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

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.

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.

Disposal: Do not dispose the battery in landfill.

4.3.3. Device Power Source Indicators

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

4.3.4. AC Power Indicators

When AC power is applied to the device and the display is off, a red AC LED indicator on the Power On/Power Off switch illuminates. When AC power is applied and the display is on, a charging indicator icon appears on the battery symbol on top menu bar. The battery charging indicator icon disappears when the device is run on battery power.

4.3.5. Battery Level Indicators

When the battery is connected to the device, battery symbols will appear on-screen to indicate the battery status. The shading in the battery icon indicates the power remaining in the battery.

4.4. Setup Therapy Modes

Note: BiWaze Cough does not require any system pre-checks before use. Please follow your country guidelines/laws as applicable.

4.4.1. Manual Therapy Mode

1. Switch on the power at the back of the device.

Note: The device may take up to 30 seconds before the therapy screen is presented and device is ready for use. During this time the device is self-calibrating.

2. Confirm the therapy settings before starting therapy.
3. Assemble and attach the breathing circuit to the device. Press the therapy start button on the touch screen to begin therapy.
4. Press the **"+"** button on touch screen to deliver an inhale breath with one finger.
5. Quickly switch to pressing the **"–"** button with second finger simultaneously lifting the finger from the **"+"** button to begin the exhale breath.
6. The pause phase will engage if no buttons are pressed. Repeat the inhale and exhale steps above until the patient's secretions are cleared or as prescribed. After the therapy is completed, disconnect the breathing circuit from the device, and clear secretions that may have become visible in the mouth, throat, tracheostomy tube, or endotracheal tube.

4.4.2. Auto Therapy Mode

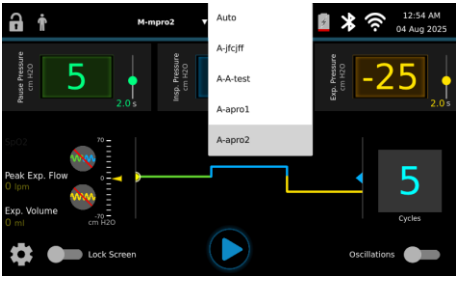
1. Switch on the power at the back of the device.
2. Confirm the therapy settings before starting therapy.
3. Assemble and attach the appropriate breathing circuit to the device. Press the start button on the touch screen to start therapy.
4. The device will automatically cycle from Pause, Inhale, and Exhale. The cycle will restart with Pause, Inhale, and Exhale until all the programmed cough cycles complete.
5. After the therapy is completed, disconnect the breathing circuit from the device, and clear secretions that may have become visible in the mouth, throat, tracheostomy tube, or endotracheal tube.

4.4.3. Therapy Profiles

When programming BiWaze Cough for a patient, up to 10 Therapy Profiles can defined under the Auto and/or Manual therapy modes. Therapy Profiles allow the user to quickly select a group of prescribed settings. The Therapy Profile names can be customized with any name up to 13 characters. The following settings are incldued as part of the therapy profile: See *Section 6.4 – Accessing the settings screen* for more information on how to save a therapy profile.

4.4.4. Selecting a profile

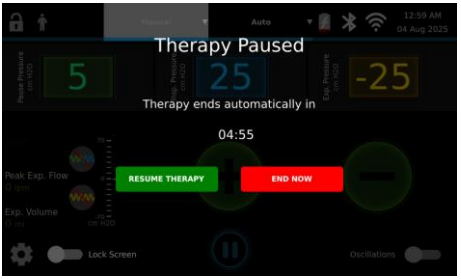
User can select available profiles under each mode (Auto/Manual) from the top ribbon menu bar.



5. Starting and stopping the therapy

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

- User can start the therapy by touching the "Start Therapy" Button on the main screen or by pressing the device mode LED button.
- User can pause the therapy by touching the "Pause Therapy" Button on main screen or by pressing the device mode LED button while therapy is ongoing.
- User can RESUME THERAPY or END NOW from the Therapy Paused screen.

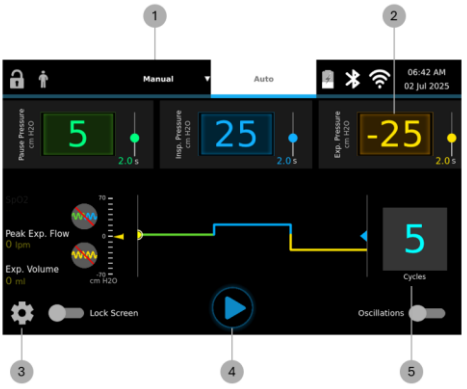


Note: If user does not resume or end the therapy while paused, the system automatically ends the therapy after the time expires.

6. Viewing and Changing Settings

6.1. Navigating the Menu Screens

1. Therapy Mode Selection (Manual and Auto)
2. Auto Therapy Pressure and Time Settings
3. Additional Therapy and Device Settings
4. Start /Pause Therapy
5. Number of Cycles



6.1.1. Timeout Periods

The following timeout events may occur on the device:

Auto Therapy Pause: Has a timeout period of 5 minutes. If the user pauses the therapy and doesn't resume it after 5 minutes the device ends the therapy and displays the "therapy complete" message.

Manual Mode Therapy Pause: Has timeout of 5 minutes if the user leaves the device untouched without shifting to positive or negative breath. The user can resume the therapy or after 5 minutes the device will end the therapy.

Manual mode + and -: If the user continues to touch + or – button for longer than 10 seconds the device will go into a Therapy Paused state.

Inspiratory Trigger Therapy Pause: In Auto mode, when the inspiratory trigger is enabled, if the patient's inspiratory effort is not detected by the device for 30 seconds, the device will go into a Therapy Paused state.

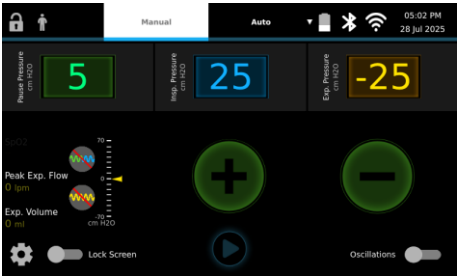
Confirmation Messages: Confirmation messages can only be removed by touch and have no auto timeout.

6.2. Manual Therapy Screen

When you switch on the power at the back of the device, the start screen appears momentarily with the manufacturer's logo.

The Manual Therapy screen displays the date and time, Wi-Fi and Bluetooth connection status, therapy mode menu, power source and battery indicator, optional Patient ID field, manual therapy settings and measurements.

1. Check if the device is in Unlocked or Locked status with / icon.
2. Change Therapy mode or select a Profile.
3. Check if the AC power charging with the icon on top of the battery icon.
4. Check the battery charge status.
5. Enable/Disable a Bluetooth connection
6. Enable/Disable Wi-Fi and connect to a network.
7. Change therapy pressure settings
8. Oscillations toggle
9. Phase Oscillations Selection

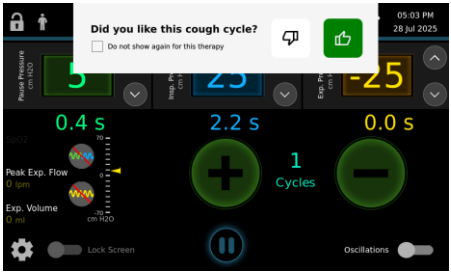


Note: Oscillations can be activated or deactivated at any time during therapy, without interrupting the session

10. Pressure manometer
11. Start/Pause the therapy
12. Deliver positive pressure using '+' button for inspiratory phase and negative pressure using '-' button for expiratory phase

Manual titration can be performed to determine the therapy settings which are comfortable for the patient. The pressure values for pause, inspiratory and expiratory phases can be adjusted in real time, when therapy is running. Along with the pressure values, the durations of each phase of therapy are also displayed on the screen.
After every therapy cycle, a pop-up will appear to ask for user feedback. There is also an option to hide this pop-up for the ongoing therapy.

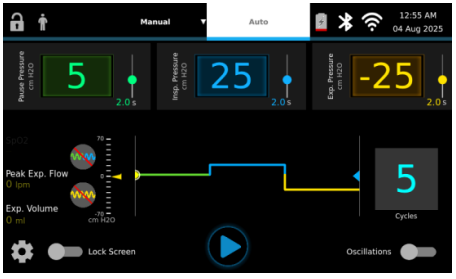
Note: Titration feedback can be enabled or disabled under device settings. See section 6.5 *Device Settings*.



6.3. Auto Therapy Screen

The Auto Therapy screen displays the date and time, Wi-Fi and Bluetooth connection status, therapy mode menu, power source and battery indicator, optional Patient ID field, auto therapy settings and measurements.

1. Check if the device is in Unlocked or Locked status with / icon.
2. Change Therapy mode or select a Profile.
3. Check if the AC power charging with the icon on top of the battery icon.
4. Check the battery charge status.
5. Enable/Disable a Bluetooth connection.
6. Enable/Disable Wi-Fi and connect to a network.
7. Change therapy pressure and time settings.
8. Oscillations toggle
9. Phase Oscillations Selection

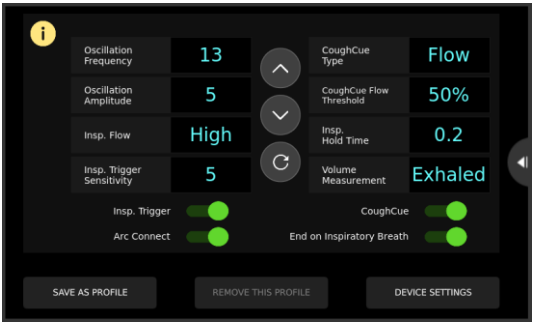


Note: Oscillations can be activated or deactivated at any time during therapy, without interrupting the session

10. Pressure manometer.
11. Start/Pause the therapy.

6.4. Accessing the Settings screen

The Therapy Settings screen appears after you touch the settings icon on bottom left corner of the screen.



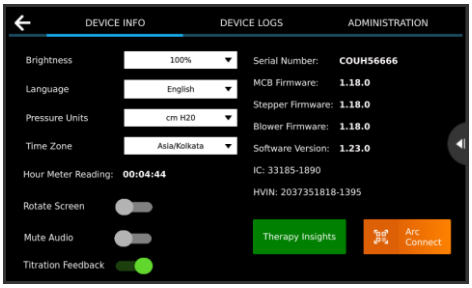
You can perform the following actions from the settings screen:

- Set oscillation frequency and amplitude
- Set inspiratory flow level
- Set inspiratory trigger sensitivity
- Save current settings as pre-set profile or remove a pre-set profile
- Enable/disable for Inspiratory Trigger
- Enable/disable for End on Inspiratory Breath
- Information Button to view descriptions of the features
- Access Device settings
- Enable/Disable for CoughCue
- Set CoughCue Type
- Set CoughCue Flow Threshold. This is only available when CoughCue Type is set as 'Flow'
- Set Inspiratory Hold Time
- Set the type of Volume Measurement to display on the therapy screen
- Enable/Disable Arc Connect

Setting	Description
Add/Remove Profiles	Save the current therapy settings as a preset profile, or delete the currently selected profile.
Inspiratory Trigger toggle	Switches the inspiratory trigger on or off (Auto mode only). When enabled, the device delivers inspiratory pressure only after it senses the patient's inhalation effort. If no effort is detected within the 30-second pause time, the inspiratory phase begins automatically. See "Inspiratory Trigger" in Section 3.2.1
End on Inspiratory breath toggle	Switches the end on inspiratory breath feature on or off (Auto mode only). Finishes the therapy with an inspiratory breath using the same settings as the last inspiratory phase programmed.
Inspiratory Trigger Sensitivity	Sets trigger sensitivity level from 1 to 10, with 10 being the most sensitive. It is recommended to start at 1 (least sensitive) and gradually increase sensitivity as needed. See "Inspiratory Trigger" in Section 3.2.1
Inspiratory Flow	Selects how quickly flow ramps to inspiratory pressure: Low, Medium, or High.
Oscillation Amplitude	Sets oscillation strength on a scale of 1 to 5 (5 = highest). See "Oscillations Control" in section 11.1.
Oscillation Frequency	Chooses oscillation frequency from 5 to 20 Hz in 1 Hz increments. See "Oscillations Control" in section 11.1
CoughCue Toggle	Enables CoughCue, allowing the system to initiate exhalation based on the selected trigger type—pressure or flow. See "CoughCue" in Section 3.2.2
CoughCue Type	Selects the exhalation trigger when CoughCue is active: Pressure threshold or Flow threshold. See "CoughCue" in Section 3.2.2
CoughCue Flow Threshold	When using flow-based CoughCue, exhalation is initiated when inspiratory flow drops to either 50% or 0%. See "CoughCue" in Section 3.2.2
Inspiratory Hold Time	Sets how long the device holds inspiratory pressure before triggering exhalation when CoughCue is enabled.
Volume Measurement	Select which volume the system calculates and displays: Inspiratory or Expiratory.
Arc Connect Toggle	Enables the system to transmit therapy data to the Arc Connect server when connected to Wi-Fi. See "Accessing the Device Settings Screen" in Section 6.5

6.5. Accessing the Device Settings Screen

You can access the Device Settings screen by following the settings icon > DEVICE SETTINGS button



You can perform the following actions from the settings screen:

- View the Serial number of the device
- View the firmware and software versions of the device
- Locate the IC and HVIN identifiers.
- See total therapy run time (Hour Meter Reading).
- Adjust screen brightness.
- Change the interface language.
- Set the device time zone.
- Open device logs.
- Access Administration menus.
- Rotate the display 180°.
- Mute audio alerts and therapy tones.
- Enable or disable Titration Feedback.
- Review Therapy Insights waveforms.
- Display the Arc Connect QR code for profile linking.

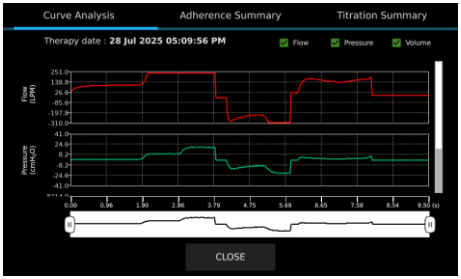
Setting	Description
Brightness	Adjust screen brightness to 10 %, 50 %, or 100 % (100 % is the brightest).
Language	Select preferred language from a dropdown list to display on the user interface
Pressure Units	Choose the pressure unit displayed on the screen: mbar, cmH_2O, or hPa.
Time Zone	Select desired time zone from a dropdown list
Hour Meter Reading	Displays the total therapy run time of the device in a HH:MM:SS format
Rotate Screen	Rotate the display by 180°
Mute Audio	Mute the audio for any notifications and therapy phase changes
Titration Feedback	Enable/disable the feedback ribbon popup during Manual mode therapy
Therapy Insights	View the details of the latest performed therapies. The information is separated into three sections: Curve Analysis, Adherence Summary and Titration Summary.
Arc Connect	Press to view a QR code that links the system to your profile in the Arc Connect app.

6.5.1. Therapy Insights

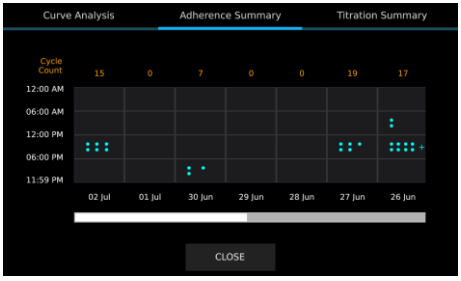
Press the **Therapy Insights** button to open the view; the information is organized into three sections:

1. **Curve Analysis**
   - Shows the flow, pressure, and volume waveforms from the most recent therapy session.
   - The therapy date and time appear above the waveforms.
   - Users can choose to view pressure, flow, or volume individually—or any combination of the three.
   - Scroll vertically to navigate when multiple graphs are displayed.
   - Drag the horizontal slider at the bottom to zoom in or out on the waveform(s).

Note: Leaks in the patient interface, tubing or accessories can alter the pressures, flow, and volume displayed by the system. The waveforms are not intended to be used as a diagnostic tool.



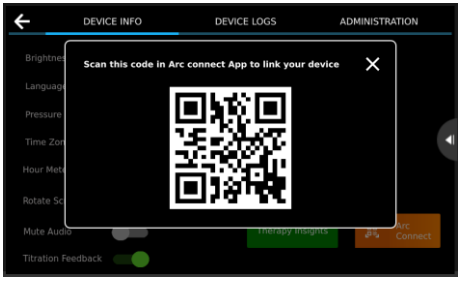
2. **Adherence Summary**
   - Shows one dot for every cough-therapy session completed each day, grouped by time blocks.
   - Swipe (or use the horizontal scroll bar) to review up to the last 14 days.
   - The daily cough cycle count appears for each date.



3. **Titration Summary**
   - Bar graph: Displays titration feedback for each cycle— ✓ marks "liked" cycles, ✗ marks "disliked" cycles.
   - Summary table: Aggregates only the liked cycles, listing the minimum, maximum, and average pressures for each phase, along with the average phase duration. The data presented enable clinicians to apply their clinical judgment in determining the most appropriate settings for each patient.

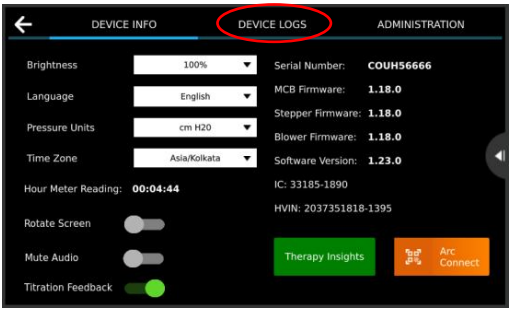
6.5.2. Arc Connect

Press **Arc Connect** to display a QR code on the device screen. Open the Arc Connect app on your phone and scan the code to link the system to your user profile.



6.5.3. Device Logs

The device logs are accessible by selecting the DEVICE LOGS tab.

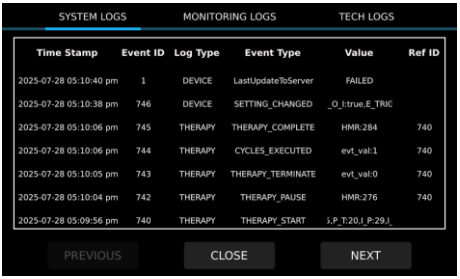


The device log separates the information into three sections:

Note: All log files in BiWaze Cough reflect an internal clock that is in UTC and is not changed by the date/time that is changeable on the main screen.

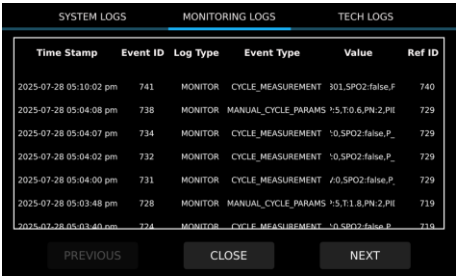
1. System logs

Displays system level events which have occurred in device. such as updates to WIFI settings or Date/time. The fields in this log include time of occurrence, type of event and value (e.g., Time, Date, WI-FI state etc.,).



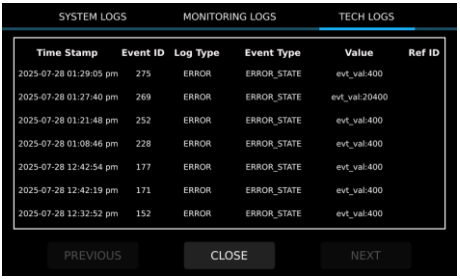
2. Monitoring logs

Displays the therapy cycles performed. The fields in this log include time of occurrence, type of event and cycle value (e.g., peak expiratory and expiratory volume etc.,).



3. Tech logs

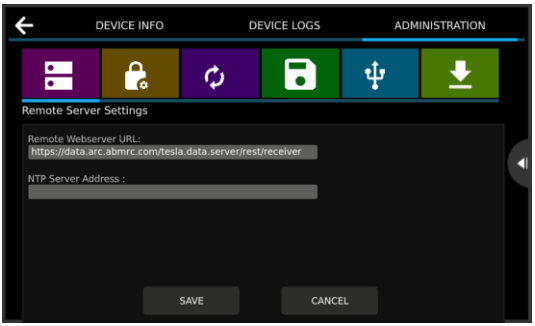
Displays errors which have occurred in device. The fields in this log include time of occurrence, type of event/Error and value (like error codes).



Note: To view the details of a log value, the user can press the Value field and a window will open to display the details. Also, the date is in YYYY-MM-DD format under Time Stamp field.

6.6. Accessing the Administration Settings

You can access the Administration settings by following the settings icon > DEVICE SETTINGS button > ADMINISTRATION tab.



Note: This screen is password protected, only trained service providers should access this screen.
You can perform following actions from the Device Administration screen:

- Download device logs to a USB disk
- Download device settings to a USB disk
- Upload/program a device with settings from a USB disk
- Configure Remote server for remote logging
- Configure lock limit adjustments
- Reset to default settings

Further details are provided in section 6.8.2

6.7. Modifying Patient Therapy Settings

6.7.1. Auto Therapy settings

From the Auto Therapy screen, the following settings may appear on-screen, depending on how the device is configured.

Note: When a device is Locked with a red padlock, the therapy pressures are not editable. There is an option to allow adjustments to therapy with a limit of <5 cmH2O and ± 2 seconds.

Setting	Description
Modes and Profiles	Allows you to quickly select a group of predefined prescription settings under each mode (Manual or Auto).
Oscillations Toggle	Allows you to Enable/Disable the oscillations. Oscillation creates the pressure pulses delivered to the patient based on Frequency and Amplitude settings.
Phase Oscillations Selection	Allows you to select how oscillations will be applied to the phases. Oscillations can be applied during the pause and inhalation phases, limited to the exhalation phase, or applied throughout all phases of therapy.
Inspiratory Pressure	Allows you to set the Inspiratory Pressure setting from 0 to 70 cmH2O in increments of 1. The Inspiratory Pressure is the pressure the patient receives while in the Inspiratory phase. User can adjust flow pattern for inspiratory phase from Advance Therapy Settings.
Inhale Time	Allows you to set the Inhale Time from 0.0 to 5.0 seconds in increments of 0.1. Inhale Time indicates how long the patient spends in the Inhale phase when in Auto mode. This setting is not available when Therapy Mode is set to Manual.
Exhale Pressure	Allows you to set the Exhale Pressure from 0 to -70 cmH2O in increments of 1. Exhale pressure is the pressure the patient receives while in the Exhale Phase.
Exhale Time	Allows you to set the Exhale Time from 0.0 to 5.0 seconds in increments of 0.1. Exhale Time indicates how long the patient spends in the Exhale Phase when in Auto mode. This setting is not available when the mode is set to Manual.
Pause Pressure	Allows you to set the Pause Pressure from 0 to 15 cmH2O in increments of 1. Exhale pressure is the pressure the patient receives while in the Pause phase of breath.
Pause Time	Allows you to set the Pause Time from 0.0 to 5.0 seconds in increments of 0.1. This setting is not available when the mode is set to Manual or when Inspiratory Trigger is enabled in Auto Mode (see Advanced Settings)
Number of Cycles	Allows you to set number of cycles the device will deliver automatically in Auto Mode. This setting also acts as cycle count down once therapy is started in Auto Mode. In Manual Mode this field displays count of breath cycles completed.

You can edit any of the three pressure settings by touching corresponding setting.

On touch you will be presented with following window

1,2,3 – Increment, decrement, reset the pressure setting

4,5 – Increment, decrement time setting

6 – Confirm the change

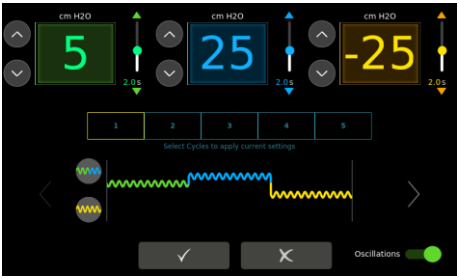
Note: The pressure and time settings are auto saved if the therapy was delivered with those settings.

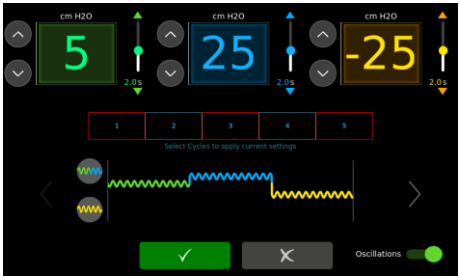
6.7.2. Auto Mode – Advanced Therapy Programming

BiWaze Cough allows advanced therapy programming with the creation of custom therapies for patient based upon their need. Each custom therapy can be saved as a pre-set profile. A custom therapy may have inhale breaths for the first few therapy cycles and end with a big inhale breath. A custom therapy may have inhale breaths in the middle of the standard cough therapy. The custom therapies allow healthcare providers the ability to provide therapy for each patient's specific need. The advanced therapy programming is only available to setup and edit if the device is Unlocked.

6.7.2.1. Add or Edit Advanced Therapy Programming

1. From the Auto Therapy screen, ensure the number of cycles you want the Advanced Therapy to have is displayed in the Cycle count box.
2. Perform a long press on the therapy waveform to be brought into the Advanced Therapy Programming screen.



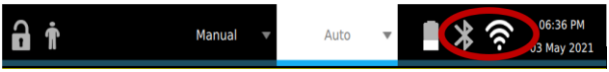


3. Select any breath cycle by touching the cycle number on the selection band. The selected cycle is highlighted in yellow on the selection bond.
4. Change the settings of selected cycle. The Pause, Inhale, and Exhale settings can have their pressure and time modified.
5. Press ✓ before selecting a different cycle to save the changes made.
6. Once a cycle is changed, it can be copied to other cycles to speed up programming. To copy, perform along press of a selected cycle in the selection band. The selected cycle turns “red” to highlight copy mode.
7. Once the “copy mode” is enabled user can select multiple cycles on the cycle selection band which will be highlighted in “red” to show selection.
8. Pressing ✓ will save the current settings to the selected cycles.
9. To close Advanced Therapy Programming, press ✕.

6.8. Viewing and Changing Device Settings

6.8.1. Network settings

Users can perform Bluetooth and Wi-Fi configuration from the main screen using the available icon on the top menu bar.

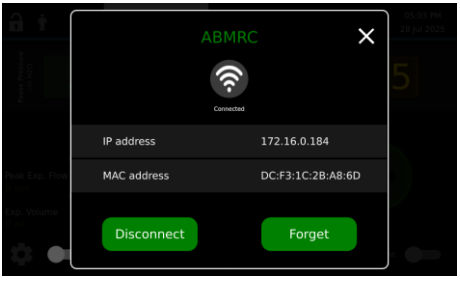


Bluetooth settings

- User can enable/disable the Bluetooth
- User can initiate the device to be open for pairing mode. Once selected the device stays in pairing mode for 5 minutes and then the pairing mode is switched off automatically.

Wi-Fi Settings

- User can enable/disable the Wi-Fi
- User can look for available networks and select one for connection
- Once Wi-Fi is connected, the IP address and MAC address is visible



WARNING: Connecting the device to public or unknown networks could result in unidentified risks.

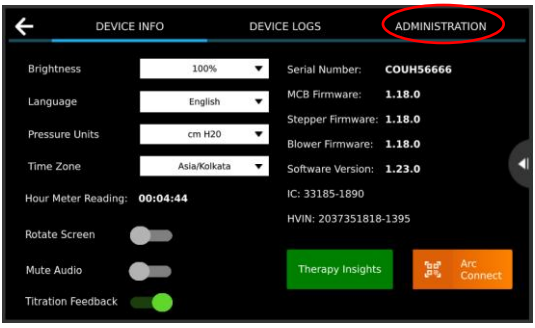
NOTE:

- If the network interfaces are connected to any unapproved systems user shall identify, analyze, evaluate and control any potential risks.
- Do not connect the device to unknown or public networks.
- Services like Bluetooth and Wi-Fi can be manually disabled by the user when not in use or if there are any safety or security concerns.

6.8.2. Administrative device settings

This screen is intended for use by trained service technicians. User can bring up administrative device settings from device settings menu by selecting “Administration” menu. User will be asked to enter admin password.

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



Following device settings are available for viewing and updating:

Setting	Description
Lock adjustment	Adjust the settings limits allowed by a user when in locked mode
Remote server address	Remote web server address

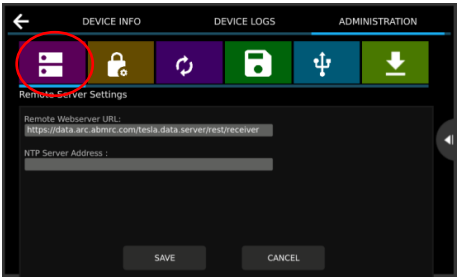
Download Therapy logs	Insert a USB disk in any of the two available slots in the device and download the therapy Logs.
Backup device Settings	Insert a USB disk in any of the two available slots in the device and download the device settings.
Restore Device Settings	Insert a USB disk in any of the two available slots in the device and upload the previously downloaded device settings.
Reset to default	Reset the device to default settings.

Detailed steps are given below sections:

6.8.2.1. 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.

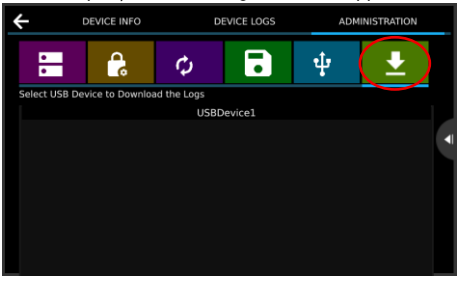


Note: A WI-FI connection is required to send data to Arc Connect.

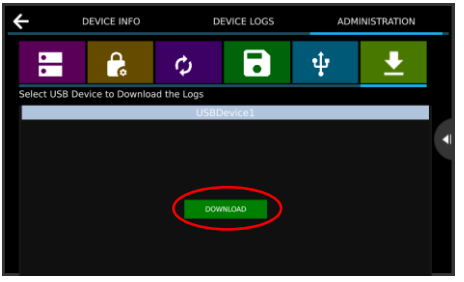
6.8.2.2. Download data logs

Data logs can be saved onto a USB drive in an encrypted format. The file can be decrypted in Arc Connect.

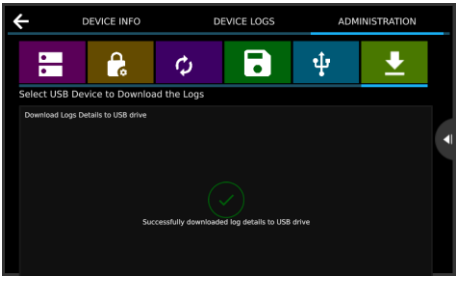
1. Select the download button as shown below and connect the USB drive (pen drive/thumb drive) to USB port (refer section 2.1.3 for USB port). The following screen will appear.



2. Select USBDevice1
3. Select DOWNLOAD



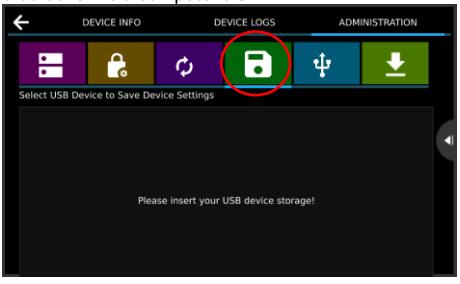
4. Once the download is complete, you'll see a notification stating the file was successfully downloaded. You can remove the USB thumb drive.



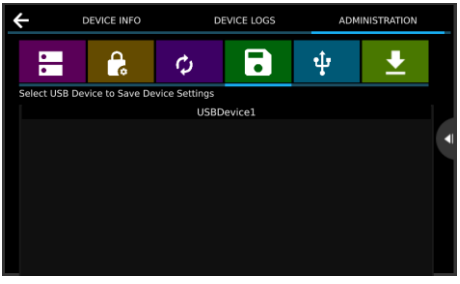
6.8.2.3. Download Settings

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

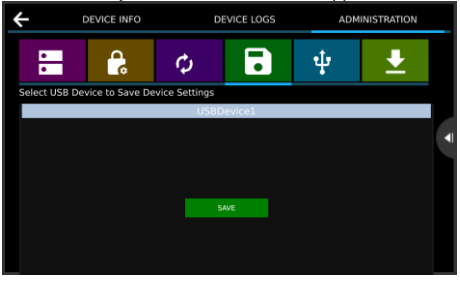
1. Press on the symbol that looks like a computer disk



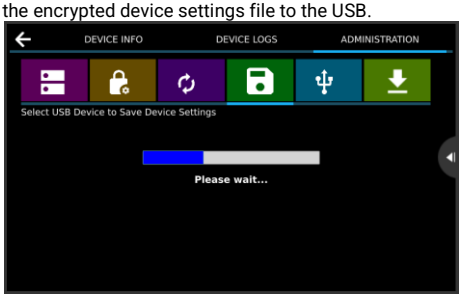
2. Insert a USB thumb drive in either of the two available slots in the control unit.



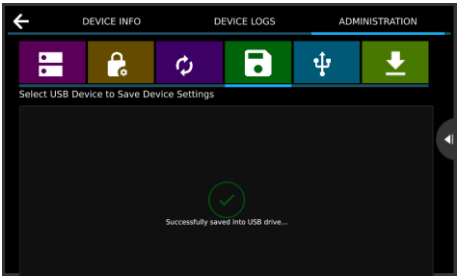
3. Once the software detects the USB, you will see USBDevice1 appear on the screen. Press on USBDevice1



4. Press SAVE to save the encrypted device settings file to the USB.



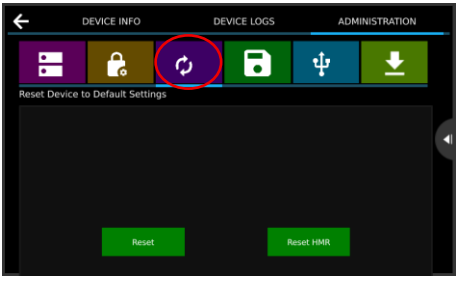
5. Once the download is complete, you'll see a notification stating the file was successfully downloaded. You can remove the USB thumb drive.



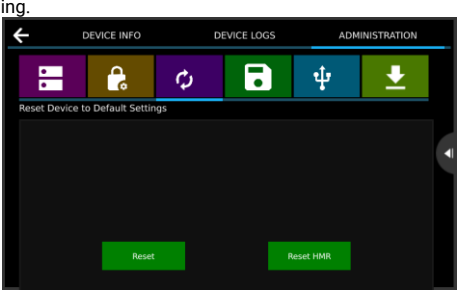
6.8.2.4. Reset Settings

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

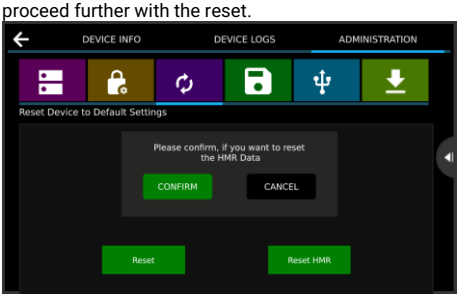
1. Press the tab with an arrow in a circle icon



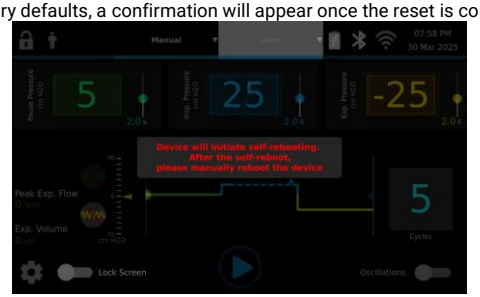
2. Press the Reset All button to reset all settings to the factory default or Reset HMR button to only reset the Hour Meter Reading.



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



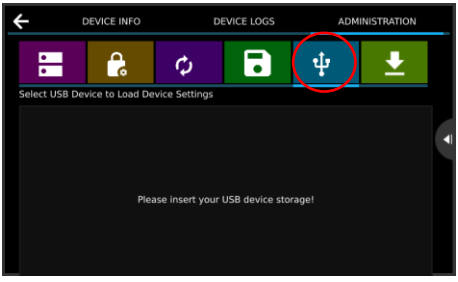
4. If you reset to factory defaults, a confirmation will appear once the reset is complete.



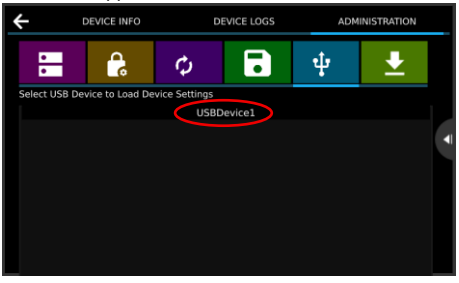
6.8.2.5. Restore Device Settings

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

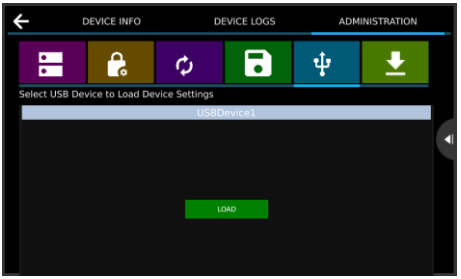
1. Select a tab with the USB icon.



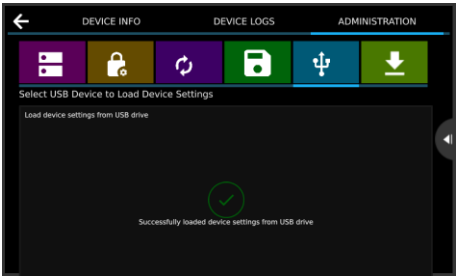
2. Insert a USB thumb drive in either of the two available slots in the control unit. Once the software detects the USB, you will see USBDevice1 appear on the screen.



3. Select the USBDevice1 and press LOAD to upload previously saved BiWaze Cough settings.



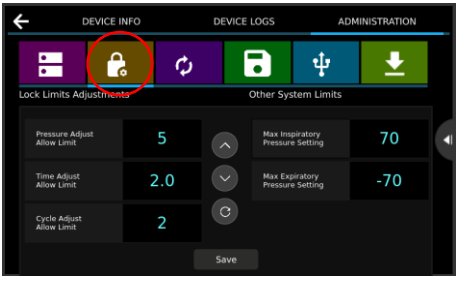
4. Once the upload is complete, you'll see a notification stating the file was successfully loaded. You can remove the USB thumb drive.



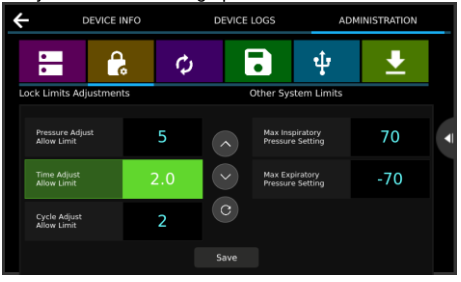
6.8.2.6. Lock Limit Adjustments and Other System Limits

This tab allows you to set adjustment limits for Pressure, Time and Cycles when the system is in Lock mode. You can also set maximum allowable limits on inspiratory and expiratory pressure. This is applicable in both lock and unlock modes.

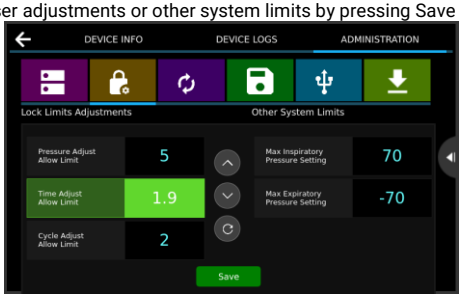
1. Select a tab with the Lock icon as shown below.



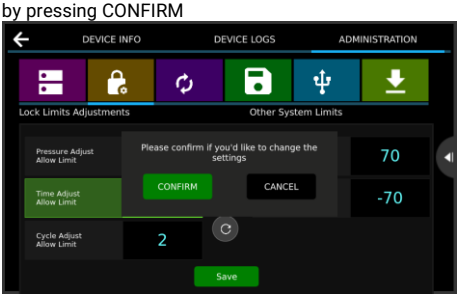
2. Select the setting and adjust the values using up and down arrows.



3. Save the allowed user adjustments or other system limits by pressing Save



4. Confirm the changes by pressing CONFIRM



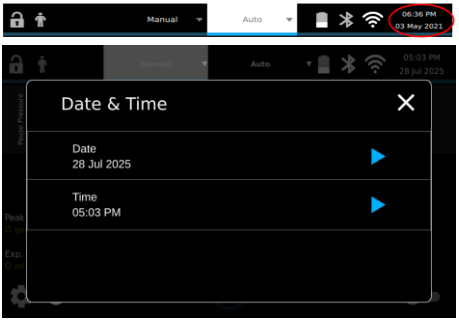
6.8.3. Date and time

BiWaze Cough allows users to either sync the date and time with the current location by connecting to a WI-FI network or manually set the date and time (when not connected to Wi-Fi). The date and time set on the device is not reflected in the internal device logs which is set to Universal Time (UTC).

Note: BiWaze Cough will automatically sync the date/time when connected to WIFI so the manually set date/time will be overwritten.

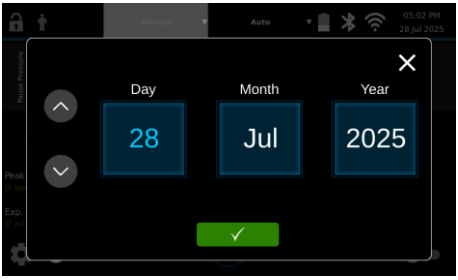
To manually set the date:

1. Press on the date on the top right corner (as shown below)



2. Press the blue arrow next to Date
3. Use the arrow keys to increase or decrease the number

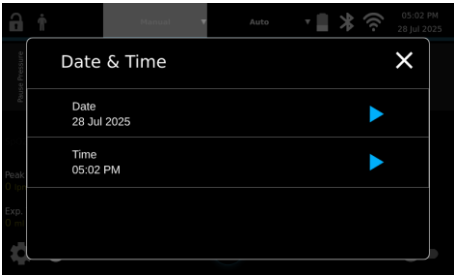
4. Press the ✓ to save and close the date settings



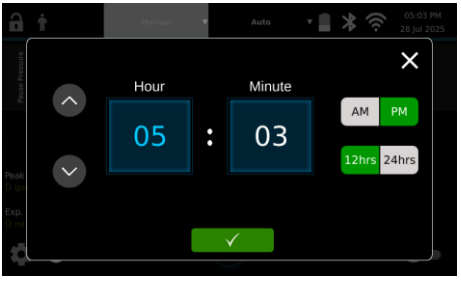
To manually set the time:

1. Press on the time on the top right corner (as shown below)

2. Press the blue arrow next to Time



3. Select either Hour or Minute by pressing the number.
4. Use the arrow keys to increase or decrease the time
5. Select either 12 hour or 24-hour clock. If a 12-hour clock is selected, choose AM or PM
6. Press the ✓ to save and close the time settings



7. Locking and Unlocking the device

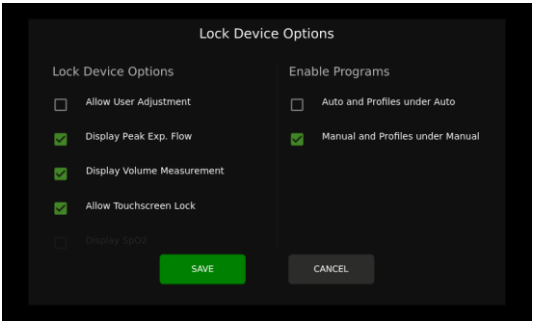
The device is recommended to be Locked for home users. The information related to access and passwords are available to home care providers.

The lock menu is available on top left corner of the screen. The icon shows when the device is locked and when the device is unlocked. Touching the same icon starts the unlock/lock process.

7.1. Locking options

The BiWaze Cough therapy options can be locked with limited flexibility for the home user. After a password is entered, a screen with the following options will appear.

- Allow User Adjustments
- Display Peak Exp. Flow
- Display Volume Measurement
- Allow Touchscreen Lock
- Enable (show) Auto and Profiles under Auto
- Enable (show) Manual and Profiles under Manual



When BiWaze Cough is locked and allow user adjustments is disabled, the user is unable to edit the programmed therapy or the therapy settings, except for the inspiratory trigger, inspiratory trigger sensitivity, CoughCue, CoughCue Type, CoughCue Flow Threshold, and Inspiratory Hold Time.

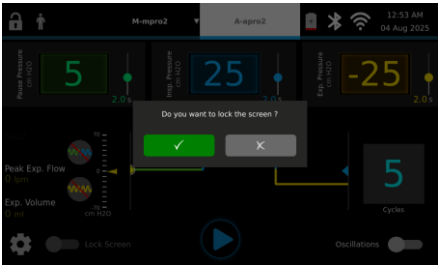
The Allow User Adjustment option allows the following settings can be adjusted when the lock is enabled:

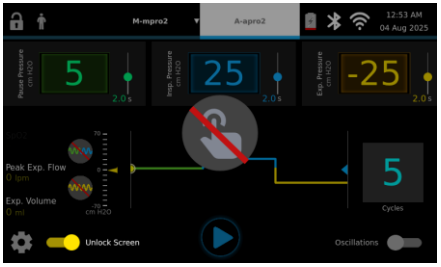
- Oscillations (on/off)
- Oscillation frequency (increase or decrease)
- Oscillation amplitude (reduce only)
- Flow (increase or decrease)
- Pressure (based upon limit settings up to 5 cmH2O in the Administration screen)
- Time (based upon limit settings up to 2 seconds in the Administration screen)

- Cycle (based upon setting in the Administration screen)
- End on Insp Breath (on/off)

7.2. Touchscreen Lock

The system includes a touchscreen-lock feature that prevents unintended touches or accidental setting changes. The screen can be locked instantly, no password required, so activation is quick and easy. Once the lock is enabled and confirmed, all touch input is disabled until the screen is unlocked.
Note: The touchscreen lock cannot be enabled while therapy is running.





8. Cleaning and Maintenance

8.1. Cleaning the Device

⚠ **CAUTION:** Remove the main power cord from the device and wall outlet before cleaning the device.

The device's exterior surface should be cleaned before and after each patient use and more often if needed.

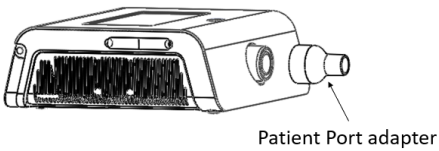
Unplug the device and clean the front panel and exterior of the enclosure (excluding Breathing Circuit) as needed using one of the following cleaning agents:

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

Inspect the device and tubing for damage after cleaning. Replace any damaged parts. Allow the device to dry completely before plugging in the power cord. Repeat this process if the BiWaze Cough System is used with a new patient or per facility protocol.

8.2. Cleaning the patient port adapter

After removing the Patient port adapter from the device, the patient port adapter should be washed thoroughly with mild dishwashing detergent and warm clean water or per facility protocol. Place the patient port adapter on a lint free towelette to air dry before reuse.
Repeat this process for each therapy, if the BiWaze Cough System is used with a new patient, or per facility protocol.


Patient Port adapter

8.3. 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:

- If the device is operating, stop the airflow. Disconnect the device from the power source.
- Remove the filter from the enclosure. Refer *Section 2.1.3 Side Panel Overview* for air inlet filter placement.
- Examine the filter for cleanliness and integrity.
- Wash the filter in warm water with a mild dishwashing detergent. Rinse thoroughly to remove all detergent residue.
- Place the filter on a lint free towelette to air dry before reinstalling it. If the filter is torn or damaged, replace it. Only filters from ABM Respiratory Care should be used as replacement filters.
- Reinstall the filter.

8.4. Cleaning the Breathing Circuit

- **WARNING** - Do not sterilize the breathing circuit. Always use a new bacterial/viral (B/V) filter when using the device on a new patient.
- **WARNING** - Replace the breathing circuit between patients to avoid cross infections.
- **WARNING** – All components of the Breathing Circuit are single patient use.

8.4.1. Cleaning the Standard Breathing circuit

8.4.1.1. Institutional (Hospital) Use

Breathing Circuit: Breathing Tube, Patient Interface, and Connectors:
The disposable breathing circuit is for single patient use only. The breathing tube and patient interface should be hand washed thoroughly with mild dishwashing detergent and warm clean water or per facility protocol. Place these parts on a lint free towelette to air dry completely before reuse.

Note: Replace the breathing circuit after 30 days or 90 treatment sessions, whichever comes first

Bacterial/Viral Filter:
If the device is to be used by more than one patient, the Bacterial/Viral (B/V) filter must be replaced to prevent cross contamination.

For a single patient use, the filter, which protects the device from entraining foreign material from the patient, can be left in place if it is not blocked by sputum or trapped moisture.

Note: Do not try to wash the Bacterial/Viral (B/V) filter.

Note: For a single patient replace the breathing circuit after 30 days or 90 treatments sessions whichever comes first.

8.4.1.2. Home (Individual) Use

Breathing Circuit: Breathing Tube, Patient Interface, and Connectors:
After use, the breathing tube and patient interface should be hand washed thoroughly with mild dishwashing detergent and warm clean water. Place these parts on a lint free towelette to air dry completely before reuse.

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

Bacterial/Viral Filter:
The filter, which protects the device from entraining foreign material from the patient, can be left in place if it is not blocked by sputum or trapped moisture.

Note: Do not try to wash the Bacterial/Viral (B/V) filter.
Note: Replace the filter if it gets wet or clogged.

8.4.2. Cleaning the Dual Lumen Breathing Circuit

8.4.2.1. Institutional (Hospital) Use

Breathing Circuit: Breathing Tube, Patient Interface, and Connectors:
The disposable Dual Lumen Breathing Circuit is for single patient-use only. The coaxial tube and patient interface should be hand washed thoroughly with mild dishwashing detergent and warm clean water or per facility protocol. Place the washed components on a lint free towelette to air dry completely before reuse.

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

WARNING - Do not wash the coaxial bacterial/viral filter.

8.4.2.2. Home Use

After use, the breathing tube and patient interface should be hand washed thoroughly with mild dishwashing detergent and warm clean water. Place the washed items on a lint free towelette to air dry completely before reuse.

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

1. Disconnect all components of the single patient-use circuit.
2. Wash the components (excluding the coaxial Bacterial / Viral Filter) in mild dishwashing detergent and warm clean water.

3. Rinse the components with warm 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 coaxial 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 or 90 treatment sessions, whichever comes first.

8.5. Storage and transportation

While not in use cover the patient port with the cap provided at the port. Switch off the device and remove the power cable. Store in a dust free location outside the reach of children.

While transporting use the carry bag provided with the device. While travelling in airplane do not check in the device, carry it in cabin. Do not place other baggage on top of the device.

8.6. Preventive Maintenance

This device does not require routine servicing.

9. Accessories

There are several accessories available for BiWaze Cough. When using the accessories, always follow the instructions included with them.

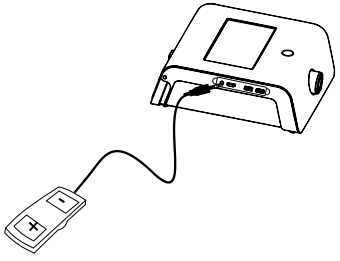
9.1. Foot Pedal

You can use the Foot Pedal (BC20120) to deliver therapy in Manual Mode. The Foot Pedal can be connected to the Remote-Control Connector on the side of BiWaze Cough. See *Section 2.1.3* for port connection details.

Note: Therapy must be started from the main screen before the foot pedal can be used.

CAUTION: Remove the Foot pedal from the device after use and store it safely to avoid entanglement or tripping.

Note: The Foot Pedal is an optional accessory and is not essential for functionality of the device. Once therapy is started in Manual mode , the foot pedal can be used as optional remote to apply manual mode therapy by initiating inhale (+ press), exhale (- press) and pause phase (no press).



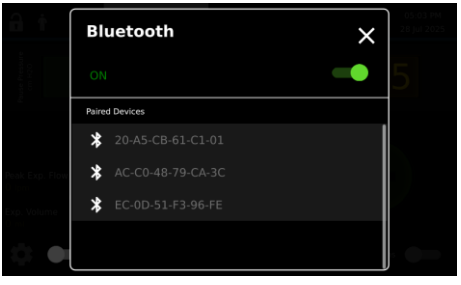
9.2. BiWaze® Cough Remote App

You can use BiWaze® Cough Remote App as remote control to start and stop therapy as well as deliver therapy in Manual Mode.

9.2.1. Pairing the BiWaze® Cough Remote App to the device

BiWaze® Cough Remote App must be paired with the device before it can be used. You can turn on secure pairing from the Bluetooth menu on the device by enabling the toggle on the device. The paired devices will be shown under the 'Paired Devices' section.

Bluetooth pairing is performed securely using a passkey, which must be confirmed on both the app and the device.

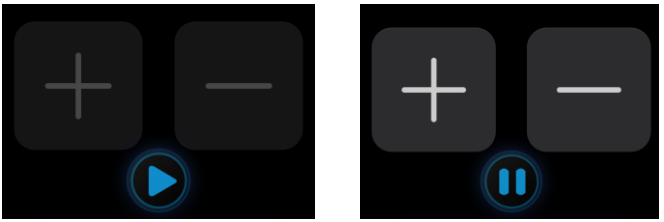


9.2.2. Connecting the BiWaze® Cough Remote App to the device

1. Ensure that Bluetooth is enabled on both the device and the mobile phone. To pair the device with the mobile phone, press the Bluetooth pair button on the app to start searching nearby devices. Select the correct BiWaze Cough serial number.
2. A Bluetooth Pairing Request pop-up will appear to confirm the secure pass key on the device and the mobile phone.
3. Once the user confirms the pass keys on both the device and the mobile phone, the main screen will show status as 'Connected' and the current therapy mode from BiWaze Cough system.

Auto Mode: User can start, pause and resume the therapy from BiWaze® Cough RemoteApp.

Manual Mode: User can initiate Inhale (+), Exhale (-) and Pause (No touch) phases from the app. See section 4.4.1 for details on Manual Mode Therapy.



Note: The screens shown in this section are for illustration purpose only. The actual screen might vary.

9.3. Carrying Bag

A carrying bag (BC21083) is available for BiWaze Cough device. 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.

9.4. BiWaze Mobile Cart

A Mobile Cart (BC22506) is available for BiWaze Cough to be used in an acute care setting. The cart has a mounting plate, a basket, and a stand. The cart is an optional accessory and can be used to provide 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.

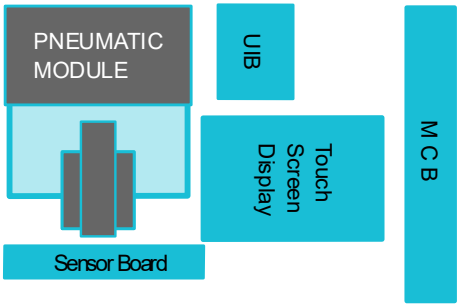
The following type of informational messages may appear on-screen.

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 Cough 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 Cough functions correctly. Some of them are checked at power up, some at therapy start, and some are monitored continuously.



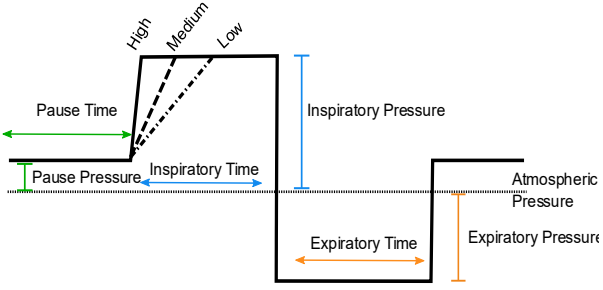
Main Control Board (MCB): This board has multiple processors including main processor for control of pressure and flow. This board controls the positive and negative flow control valves, blowers as well as monitors various temperatures and battery capacity. It also communicates with UI board and Sensor board.

UI Control Board (UIB): This board controls the user interface including the main touch screen LCD as well as USB, HDMI and Foot Pedal ports. This board also provides wireless interfaces for Wi-Fi and Bluetooth connectivity.

Sensor 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 USB and other ports.

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.

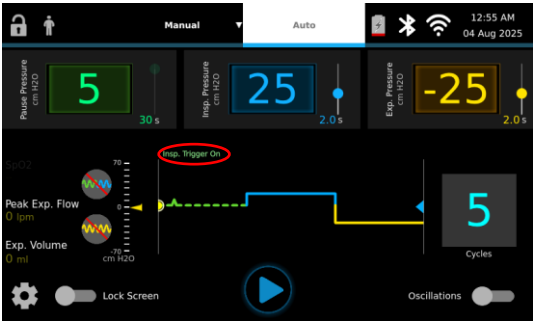
Basic MI-E / Cough Therapy: Single basic Cough cycle comprises of applying a pause pressure followed by an Inspiratory Pressure and suddenly switching to a negative pressure (Expiratory phase). A cough therapy treatment may have multiple such cycles (usually 5-7 cycles) with pauses in between.



In **Auto Mode** the changes in the pressure are triggered by time settings for pause, inspiratory and expiratory time.

Inspiratory Trigger: If the inspiratory trigger is enabled in advanced settings menu the pause phase is extended till the device detects patient inhale effort and applies the Inspiratory pressures when patient effort is detected. The inspiratory trigger sensitivity can be set in the range 1-10 with 10 being most sensitive.

The trigger works with detection of flow change created by the patient effort. Inspiratory flow is monitored during the pause phase (every 16ms) when Inspiratory trigger is enabled. The total patient effort detected is compared with predetermined thresholds. A trigger is raised whenever the effort detected exceeds these thresholds.



The therapy screen shows the text that trigger is on and allows 30 secs timeout in pause phase to detect patient effort. If patient effort is not detected in that time frame the treatment is paused.

CoughCue:
CoughCue synchronizes the device's expiratory phase with the patient's natural breathing, designed to promote a more comfortable and stronger cough. It does this by detecting the point at which the lungs are full—identified either by a drop in inspiratory flow or by a pressure plateau—and then switching to exhalation. Two trigger modes are available:

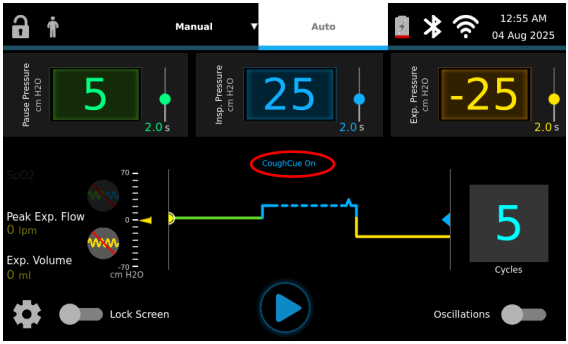
1. **Flow Based Trigger**
   - Detection: When inspiratory flow peaks and then falls, the device begins tracking the decline.
   - Threshold: The clinician selects a trigger threshold of 50 % or 0 % of the peak inspiratory flow. Once the flow drops to the chosen threshold, the expiratory phase starts.
   - Result: Aligning with diaphragm movement maximizes peak expiratory flow, helping generate a more forceful cough.
   - Inspiratory Hold: An optional inspiratory-hold time (0–2 s in 0.1 s steps) can be added after the trigger to allow full lung expansion.

2. **Pressure Based Trigger**
   - Detection: The device monitors airway pressure; when it stabilizes at the set inspiratory pressure (the pressure plateau), it interprets this as full lung inflation.
   - Action: Upon reaching the plateau, the device switches to expiration.
   - Inspiratory Hold: The same adjustable inspiratory-hold setting (0–2 s, 0.1 s increments) lets you fine-tune comfort and lung recruitment.

The inspiratory hold time setting defines how long the device maintains the inspiratory phase after detecting the chosen trigger for exhalation. It is adjustable from 0 to 2 seconds in increments of 0.1 seconds, allowing clinicians to balance lung expansion with patient comfort.

Note: The system automatically transitions from inspiratory to expiratory phase after either 5 seconds or the combined inspiratory time + inspiratory-hold time, whichever occurs first.

Setting	Values	Description
CoughCue Trigger Type	Flow, Pressure	Chooses whether the device detects the end of inspiration by a drop in flow or by a pressure plateau, then switches to exsufflation.
CoughCue Flow Trigger Threshold	50%, 0%	Starts exsufflation when inspiratory flow falls to the selected percentage of its peak value.
Insp Hold time	0 to 2 seconds (Increments of 0.1 seconds)	How long the device maintains inspiratory pressure after the trigger before moving to exsufflation.



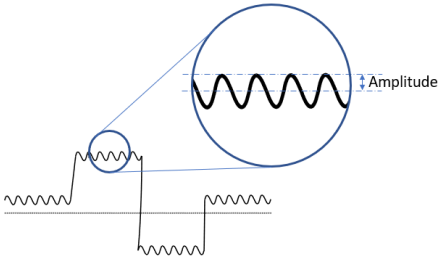
Inspiratory Flow: While the expiratory switching is desired to be fast and at high flow to simulate cough, the inspiratory flow may be controlled to a comfortable level by selecting the flow between low, medium and high.

The High Flow setting applies maximum flow to target the Inspiratory pressure as fast as possible providing maximum peak volumetric flow based on set pause and inspiratory pressure settings.

At Medium setting, the flow is controlled in such a way that the peak volumetric flow observed during Inspiratory phase is within 70% to 40% of that observed when High setting is applied.

At Low setting, the flow during Inspiratory phase is controlled in such a way that the peak volumetric flow observed during Inspiratory phase is within 40% to 10% of that observed when High setting is applied.

Oscillations Control: BiWaze Cough allows 5-20 Hz frequency oscillations on applied pressure to facilitate secretions mobilization. Once enabled the oscillation amplitude can be set at 1-5 levels with 1 as the lowest amplitude.



Note: When oscillations are active, the mean pressure may vary depending on the set pressure and frequency:

- For set pressures below 50 cmH_2O, the mean pressure may vary by up to ±7 cmH_2O.
- For set pressures of 50 cmH_2O or higher, the variation may be up to ±15 cmH_2O.

The mean-to-peak amplitude varies based on the set pressure, airway resistance, and lung compliance. The expected amplitude range for different amplitude settings are provided below:

Amplitude vs. Mean-to-Peak Range

Amplitude Setting	Mean-to-Peak Range (Inhale Pressure < 50 cmH_2O)	Mean-to-Peak Range (Inhale Pressure ≥ 50 cmH_2O)
1	2 to 10 cmH_2O	6 to 21 cmH_2O
2	2 to 11 cmH_2O	9 to 25 cmH_2O
3	3 to 13 cmH_2O	9 to 27 cmH_2O
4	3 to 14 cmH_2O	11 to 28 cmH_2O
5	4 to 15 cmH_2O	15 to 30 cmH_2O

Amplitude values and their tolerance may vary by up to 5%, depending on the set pressure, frequency, airway resistance, and lung compliance.

Device performance has been validated using a QuickLung test lung with 5 $cmH_2O/L/s$ airway resistance and 20 ml/cmH_2O compliance (Restrictive Lung Setting with 1L lung).

11.2 Part Numbers

Catalog Number	Description	Contents
BC20113	BiWaze Cough System - USA	BiWaze Cough Control Unit Patient Port Adapter Carry Bag Standard Breathing Circuit with Face Mask - Adult Medium User Manual – English US BiWaze Cough Lock Feature Instructions BiWaze Cough Patient Guide US Power Cord Air Inlet Filter (3 pack)
BC23633	BiWaze Cough System – SGP	BiWaze Cough Control Unit Patient Port Adapter Carry Bag Standard Breathing Circuit with Face Mask - Adult Medium User Manual – English US BiWaze Cough Lock Feature Instructions BiWaze Cough Patient Guide US Power Cord UK Power Cord Air Inlet Filter (3 pack)
BC20120	Foot Pedal	Foot Pedal with cable assembly
BC21274	Air Inlet Filter (Pack of 3)	Air Inlet Filter (Pack of 3)
BC21095	Battery - Lithium Ion	Lithium-Ion Rechargeable Battery
BC22496	Patient Port Adapter	Adapter for connecting standard breathing circuit to the patient port
BC21084	User Manual Eng USA	User Manual (English US)
BC23575	BiWaze Cough Patient Guide	Patient Guide (English US)
BC23891	BiWaze Cough Acute Care QRG	Quick Reference Guide for Acute Care (English US)
BC23787	BiWaze Cough User Manual - Spanish	User Manual (Spanish)
BC22506	BiWaze Mobile Cart	Mobile Cart with a mounting plate for BiWaze Cough with a telescoping pole, 5 caster wheels (3 locking) and a basket
BC20116	Power Cord – USA	Power Cord for USA
BC24343	Hospital Power Cable	Hospital grade Power Cord for USA and Canada
BC21405	Power Cord – UK/SGP	Power Cord for Singapore
BC21083	Carrying Bag	Carrying Bag with Handle
BC21086	Breathing Circuit - Standard - Face Mask - Infant	Corrugated Tube (22mm), Bacteria/Viral Filter, Face Mask Infant
BC21087	Breathing Circuit - Standard - Face Mask - Child	Corrugated Tube (22mm), Bacteria/Viral Filter, Face Mask Child
BC21088	Breathing Circuit - Standard - Face Mask - Adult Small	Corrugated Tube (22mm), Bacteria/Viral Filter, Face Mask Adult Small
BC21089	Breathing Circuit - Standard - Face Mask - Adult Medium	Corrugated Tube (22mm), Bacteria/Viral Filter, Face Mask Adult Medium
BC21273	Breathing Circuit - Standard - Face Mask - Adult Large	Corrugated Tube (22mm), Bacteria/Viral Filter, Face Mask Adult Large
BC21092	Breathing Circuit - Standard - Mouthpiece	Corrugated Tube (22mm), Bacteria/Viral Filter, Mouthpiece
BC21090	Breathing Circuit - Standard - Trach	Corrugated Tube (22mm), Bacteria/Viral Filter, Flexible Trach Adapter
BC23387	BiWaze Cough Dual Lumen Breathing Circuit - Mouthpiece	Coaxial Breathing Tube, Coaxial B/V Filter Mouthpiece
BC23394	BiWaze Cough Dual Lumen Breathing Circuit - Trach	Coaxial Breathing Tube, Coaxial B/V Filter Flexible Trach Adapter
BC23400	BiWaze Cough Dual Lumen Breathing Circuit - Face Mask Child	Coaxial Breathing Tube, Coaxial B/V Filter Face Mask Child

BC23406	BiWaze Cough Dual Lumen Breathing Circuit - Face Mask Adult Small	Coaxial Breathing Tube, Coaxial B/V Filter Face Mask Adult Small
BC23412	BiWaze Cough Dual Lumen Breathing Circuit - Face Mask Adult Medium	Coaxial Breathing Tube, Coaxial B/V Filter Face Mask Adult Medium
BC23418	BiWaze Cough Dual Lumen Breathing Circuit - Face Mask Adult Large	Coaxial Breathing Tube, Coaxial B/V Filter Face Mask Adult Large
BC20121	BiWaze Cough Remote Control App - Android	BiWaze Cough Mobile App for Android
BC20122	BiWaze Cough Remote Control App - Apple	BiWaze Cough Mobile App for iOS

11.3 Product Specification

Therapy Parameter	Specification
Inspiratory Pressure	0 to 70 cmH2O
Inspiratory Time	0 to 5 seconds
Expiratory Pressure	0 to -70 cmH2O
Expiratory Time	0 to 5 seconds
Pause Pressure	0 to 15 cmH2O
Pause Time	0 to 5 seconds
Oscillation Frequency	5 to 20 Hz
Oscillation Amplitude	1 to 5 level
Cycles	1 - 20 number of cycles

11.4 Environmental

	Operating	Storage
Temperature	41 °F to 95 °F (5 °C to 35 °C)	-4 °F to 140 °F (-20 °C to 60 °C)
Relative Humidity	15 to 95% (non-condensing)	15 to 95% (non-condensing)
Atmospheric Pressure	101 kPa to 77 kPa	105 kPa to 65 kPa

11.5 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)

11.6 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
- EC 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
- IEC 62366-1: Medical devices — Part 1: Application of usability engineering to medical devices
- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing (Biocompatibility)
- 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, 2.0 A-1.0A
Lithium-Ion Battery	Power: 90.65 Wh Capacity: 3500 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

Bluetooth Specification	
Feature	**Dimension**
Bluetooth Compliance	Bluetooth 4.2 Secure Connection Compliant and CSA2 Support
Frequency	2.4 to 2.48 GHz
Transmit Power	GFSK: 11.7 dBm (Typ)
Receive Sensitivity	GFSK: -92.2 dBm (Typ)
Modulation	Frequency Shift Keying Frequency hopping spectrum
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 Displayed Parameter Accuracy

Parameter	Accuracy	Resolution	Range*
Pressure	> of ± 5 cmH2O or 10% of reading	1 cmH2O	-70 to 70 cmH2O
Peak Expiratory Flow	> of ± 15 lpm or 15% of reading	1 lpm	0-500 lpm
Expired/Inspired Volume	± (25 ml +15 % of reading) for peak flows greater than or equal to 20 lpm	1 ml	50-2000 ml

Accuracies stated in this manual are based on specific environmental conditions. For stated accuracy, the environmental conditions are Temperature: 20-30° C; Humidity: 50% relative; Altitude: nominally 380 meters.
*This range will only apply when the system is in closed loop state.

11.10 Control Accuracy

Parameter	Range	Accuracy
Pressure	-70 to 70 cmH2O	± 5 cmH2O*
Inhale Time	0-5 seconds	± (10% of setting + 0.1 second)
Exhale Time	0-5 seconds	± (10% of setting + 0.1 second)
Pause Time	0-5 seconds	± (10% of setting + 0.1 second)
Frequency	5-20 Hz	± (10% of setting)
Amplitude	1-5	N/A

*The ±5 cmH_2O pressure accuracy applies only when oscillations are disabled.
Device performance and accuracy is specified at Temperature: 20-30° C; Humidity: 50% relative; Altitude: nominally 380 meters for typical patients.

11.11 Sound

The sound pressure of the device set at -40 cmH2O/+40 cmH_2O in the Pause phase is less than 60 dBA at 1 meter.

11.12 Disposal

Dispose of this device, breathing circuit and accessories in accordance with local regulations. This device, breathing circuit and accessories should be disposed of separately, not as unsorted municipal waste. To dispose of your device, breathing circuit and accessories, you should use appropriate collection and recycling

systems available in your region. The use of these collection and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment.

11.13 Essential Performance

The Essential Performance of the BiWaze Cough Device is defined as follows:

- Inhale Pressure not to exceed 85 cmH_2O for 1 minute
- Exhale Pressure not to exceed -75 cmH_2O for 5 secs
- Duration of inhale phase in Auto Mode within ± (10% of the setting + 0.5 seconds)
- Duration of exhale phase in Auto Mode within ± (10% of the setting + 0.5 seconds)
- All breath phases with times > 0 occurring in proper order in Auto Mode

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 Cough System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The BiWaze Cough System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BiWaze Cough System should be observed to verify normal operation. If operation is not normal, the BiWaze Cough System or the other equipment should be moved.
- 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 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

This device 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 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device 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.			

12.3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

This device 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
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6Vrms in ISM bands between 150KHZ to 80MHz 10 V/m 80 MHz to 2.7 GHz	3 Vrms	The BiWaze Cough is suitable for the electromagnetic environment of typical homes or hospital settings. 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: $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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.

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

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5GHz $d = 2.3\sqrt{P}$
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.

12.5 Guidance and Manufacturer's Declaration - Electromagnetic Immunity to Wireless Communications Equipment

The device is intended for use in the electromagnetic environment specified below. The customer or user of the device should make sure it 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

12.6 Federal Communications Commission (FCC) Radiation Exposure Statement

FCC Part 15.19 Statement BiWaze Cough 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 BiWaze Cough is "2ATX9-1395".

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

To maintain compliance, the device must be used with specified BiWaze Cough accessories supplied or designated for this product. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

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. Modifications not expressly approved by manufacturer could void your authority to operate the equipment.

NOTE: The device is also registered under Infocomm Media Development Authority (IMDA), Singapore. The compliance label shows the license details.

Complies with
IMDA Standards
[DB107612]

12.7 Industry Canada (IC) Compliance Statement

This Device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.
(2) This device must accept any interference, including interference that may cause undesired operation of the device.

IC ID of BiWaze Cough is "33185-1890"

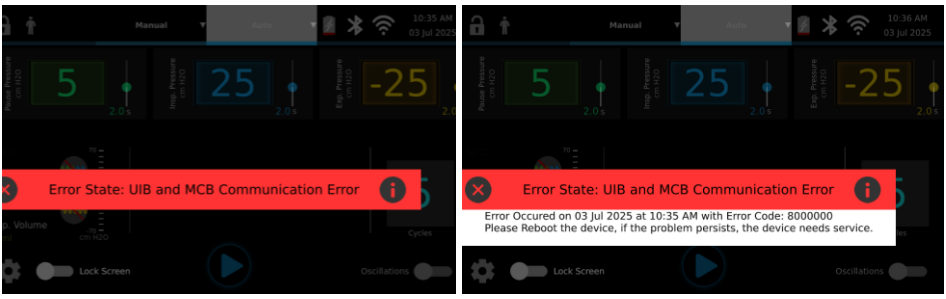
Warning Statements:

- This equipment complies with radio frequency exposure limits set forth by Industry Cananda for an uncontrolled environment.
- This equipment should be installed and operated with a minimum distance of 20 cm between the device and the user or bystanders.

13. Troubleshooting

In case the BiWaze Cough device user runs into any device related issues, error messages will pop up on the screen. On the clicking the button, the error details will be displayed on the screen. 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 device problems user may require servicing the device from ABM Respiratory Care authorized service center. Please get in touch with your health care provider for such service needs. Refer to *Section 2.4* for contact details.

Example: Error Message and details when information icon is pressed on the Error Message



Event Type	Description	Action
Device shows a Red Strip with Error: High Temperature	The device temperature is high.	Check if the device is ventilated properly and not covered with cloth or other items. Ensure it's placed on hard surface with space on all sides. Switch off the device and restart after 15 minutes of cool down.
		Move the device 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.
Device does not power up	Battery may be too low.	Connect the device to mains power and check if the device powers up. 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 device shuts down after few seconds	Technical error related to temperatures or other high priority fault	Try rebooting the device and if the 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 device does not shut down. User cannot start the therapy.	Technical error related to subsystem malfunction	Try rebooting the device and if the 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.
Device not performing as intended. Making abnormal sounds or therapy performance.	Device 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 device 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 device malfunction.

Sl. No.	Error Message	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	Low Battery Temperature	400000
22	Low MCB Temperature	800000
23	Low Patient Air Temperature	1000000
24	PMB and MCB Communication Error	2000000
25	Battery Charging Error	4000000
26	UIB and MCB Communication Error	8000000
27	Low Battery	10000000
28	Critical Low Battery	20000000
29	High Ambient Temperature Error	40000000
30	Stepper Value Slip Error	80000000

Note: In case of above Error code or any other issue/ Error code, restart the device. If the error persists, contact ABM Respiratory Care (refer section 2.4 for contact details).

14. Limited Warranty

ABMRC, LLC warrants that the BiWaze Cough 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
Foot Pedal	90 days

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 dealer or contact ABM Respiratory Care. For contact details, refer to Section 2.4.

15. Service Instructions

To have your device serviced, contact your provider. Refer to *Section 2.4* to contact ABM Respiratory Care Customer Service.

⚠ **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.

15.1 Expected Service Life

The service life for various subsystems is as follows:

Main Device	5 Years
Power Cord	5 Years
Breathing circuit kit	30 days after unpacking or 90 treatment sessions
Carry Bag	2 years
Battery	1 year
Device 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 this device.

15.4 Service: Cleaning and Maintenance

There is no field service applicable for the device. Any returns to the manufacturer shall be cleaned before shipping.

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