PRTN-2037351818-1888 1.0

BiWaze Cough

User Reference Manual

UI Software version 1.x

Accessing Unlock Mode

WARNING

The information on this page is ONLY for home care providers. Remove this page from the manual before giving the manual to the patient.

Lock & Unlock Modes

The device has operation modes as follows;

Unlock Mode: In this mode, all therapy setting/controls are unrestricted to the user. This mode is primarily used by clinicians or advanced users with extensive training and relevant respiratory knowledge. The users can have full access to adjust therapy settings based on the patient's physiological needs.

Lock Mode: In this mode, majority of the therapy settings are restricted/locked. Users cannot change the therapy air parameters beyond a preset range. However, users can choose different therapy settings using pre-saved profiles. This mode is suitable for home users who are with minimal medical training and basic knowledge of the product. This mode is mainly intended for providing limited access to prevent risk of inappropriate therapy delivery.

When the device is in Lock Mode, use the following steps to enter Unlock Mode:
From the Standby screen, select the lock symbol from left corner of top menu bar and enter the following password <11012018>

Note: ABM recommends that home care providers set the device back to Lock Mode before returning it to the patient so patients cannot change their prescription settings.

Table of Contents

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 exhale phase is a sudden shift to negative pressure to pull the air out of lungs. Finally, the pause phase provides positive pressure which keeps the airways open in between the inhale and exhale phases.

This User Guide is applicable for product "BiWaze Cough" (Model "BiWaze Cough") indented for a patient or care provider user.

⚠ WARNING

- Use the BiWaze Cough device only as directed by a physician or healthcare provider.
- Use the BiWaze Cough device 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 the BiWaze Cough device.
- Install and configure the BiWaze Cough device 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, 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 up.

1.2 Contraindications

The BiWaze Cough device 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 instruction in the manual.

WARNING

A **warning** alerts you to possible injury.

- The operator should read and understand this entire manual before using the device.
- The BiWaze Cough device is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.
- The BiWaze Cough device 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 or the power supply are dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, discontinue use and contact your home care provider.
- Device shall not be operated on a patient without a Bacterial/Viral (B/V) filter along the Breathing Circuit.
- Always use a new bacterial filter when using the device on a new patient.
- Always check time and pressure settings before each treatment.
- Soreness and/or pain in the chest from a pulled muscle may occur in patients using the 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 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 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, patient breathing tubes 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 its 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 young 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 environ with small fibers or airborne material which can clog the filters.
- Main Device has 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.

2 BiWaze Product Overview

The BiWaze Cough system may include the following components. Some components are optional accessories that may not be packaged with the device.

Product Package

- BiWaze Cough Device
- Standard Patient Circuit Adaptor, Standard Patient Circuit, bacterial filter, 6 ft (1.83 m) flexible tubing, and a Patient interface.
- Carrying Case
- AC Power Cord
- User Reference Manual

Accessories

- Foot Pedal
- Various Patient Interface Accessories (Mask sizes, trach adapters, mouthpiece interface)
- BiWaze Coaxial Patient Circuit Tubing

2.1 System Overview

The 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.

The therapy air is delivered through a Breathing Circuit which generally consists of

corrugated breathing tubes (standard and custom types), B/V filter, end adapters, and with either the mouthpiece, face mask or an adapter to a tracheostomy or endotracheal tube as the final patient interface.

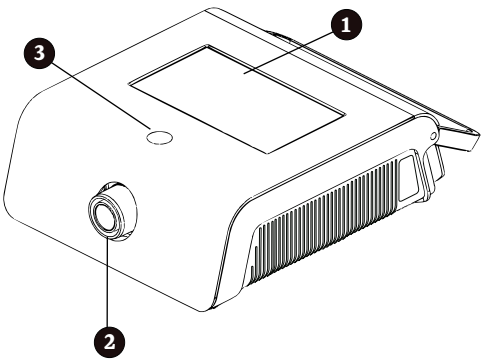
2.1.1 Expected service life

The service life for various subsystems is as follows:

Main Device	5 Years
Breathing Tube Adaptors and power cords	5 Years
Patient Breathing tubes	30 days after unpacking
Carry Bag	2 years
Batteries	1 year

2.1.2 Main Control Interfaces

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

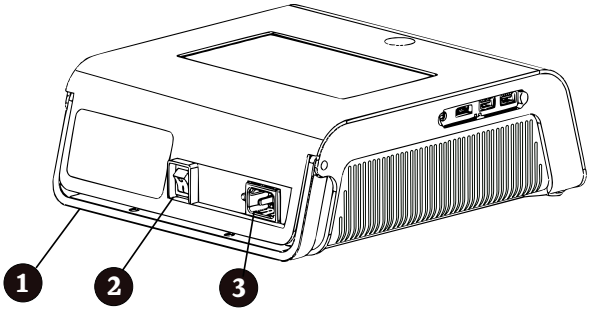


1	Touch Screen	The Touch screen allows you to view settings, system status information, real-time patient data, and logs. You can also modify settings from the touch screen.
2	Patient Port	Patient circuit tubing is connected to this port on the device

3	Device Mode LED Light	This LED light provides different color code lights. Green: Manual Mode Blue: Auto Mode Red: Error or shutdown Mode

2.1.3 Back Panel Interfaces

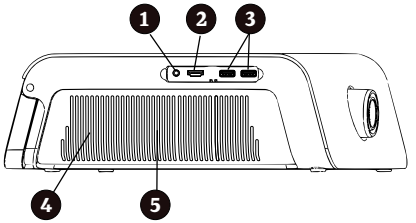
The items numbered in the illustration below are described in the table that follows.



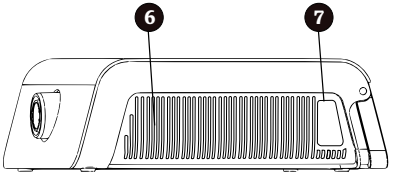
	Item	Description
1	Handle	Handle to carry the device
2	Power source cut off switch	Cuts off AC mains and Batter power to main processor.
3	AC Power Inlet	Connect the AC power cord here.

2.1.4 Side Panel Overview

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



Device Left Side



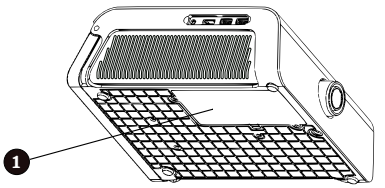
Device Right Side

Item		Description
1	Foot Pedal port	Connection port for Foot Pedal
2	HDMI port	External HDMI display can be connected here
3	USB ports	USB memory sticks and SPo2 connectors are connected here
4	Air outlet	This is the outlet port for expiratory air
5	Power supply cooling Fan location	Cooling fan is located here
6	MCB Fan	Fan with main control board
7	Air Inlet Filter	This is the inlet port for inspiratory air

⚠ CAUTION: Don't not attach any unapproved devices or storage medium to any of the ports. Use only ABM approved and supplied parts. Failure to do may damage the system.

2.1.5 Bottom Panel Features

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



Item		Description
1	Battery housing	Internal battery is placed here

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

2.2 Symbols

The following symbols appear on this device.

	Consult accompanying instructions for use
	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.
	Environment requirements for storage and shipping
	Refer to instruction manual

	Date of Manufacture
	Catalogue Number
	Authorized representative in European community
	Product serial number
	FCC marking
	Prescription device
	Manufacturer
	CE Marking
	Caution
	Warning

2.3 Traveling with the System

It may be helpful to bring this manual along with you to help security personnel understand the device.

If you are traveling to a country with a line voltage different than the one you are currently using, a different power cord or an international plug adaptor may be required to make your power cord compatible with the power outlets of the country to which you are traveling.

2.4 How to Contact ABM Respiratory Care

To have your device serviced, contact ABM Customer Service department at +1 843 830 2233 or info@abmrespiratorycare.com. The device does not have any serviceable parts while in use.

3 Therapy Modes and Features

3.1 Therapy Modes

Therapy Mode	Description
Manual	Manual mode delivers therapy based on the Pause Pressure Inhale Pressure and Exhale Pressure prescription settings. The device delivers the set Inhale Pressure for the amount of time that the "+" button is pressed. The device delivers the set Exhale Pressure for the amount of time that the "-" is pressed and delivers Pause Pressure when neither button are pressed Therapy starts in the Pause Phase when activated in Manual mode.
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 & exits the therapy, or the number of cycles count is reached:

	1. Positive pressure at the Inhale Pressure setting for the duration of the Inhale Time setting. 2. Negative pressure at the Exhale Pressure setting for the duration of the Exhale Time setting. 3. Pause pressure for the duration of the Pause Time setting. When the **Inspiratory Trigger** feature is enabled, Auto mode delivers pressure in the following sequence, repeating the sequence until user pauses & exits the therapy or the number of cycles count is reached: 1. 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. 2. Negative pressure at the Exhale Pressure setting for the duration of the Exhale Time setting. 3. Pause pressure until the device detects the next inspiratory Effort or Pause phase timeout of 30 secs. Note: The device goes in standby mode and therapy is paused when there is a breath phase time out.

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 inspiration to help synchronize the therapy with 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, therapy starts in the Pause phase until patient effort is detected or the Pause phase times out after 30 seconds and device goes in standby mode.

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

3.2.2 Oscillations

The Oscillation therapy feature delivers an oscillatory therapy based on Frequency and Amplitude settings. Use of the oscillation feature enhances mobilization and improves bronchial drainage. The oscillations will be least apparent to the patient with lower amplitude and higher frequency settings.

If the Oscillation setting is enabled, the user can choose to apply the vibrations along with oscillations. Vibrations are low amplitude 20Hz oscillations which are super imposed on standard oscillations. The Frequency and Amplitude settings of oscillations can be changed as needed.

4 Therapy Setup

Follow the following steps to prepare the device for the therapy.
Note: If the device was stored in temperature below 5 °C or above 35 °C, allow the device to normalize for 15 minutes at room temperature (~20 °C) before using the device.

4.1 Position the Device Properly

Position the device on a firm, flat surface within arm's length reach of the patient or device operator. The device should be placed below elbow level for 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.

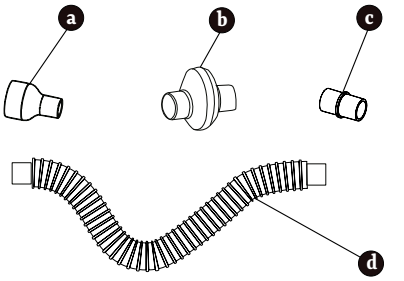
4.2 Assemble the Patient circuit

BiWaze Cough System offers two patient circuit types.

4.2.1 Standard Patient Circuit kit

Standard Patient Circuit kit comprise of:

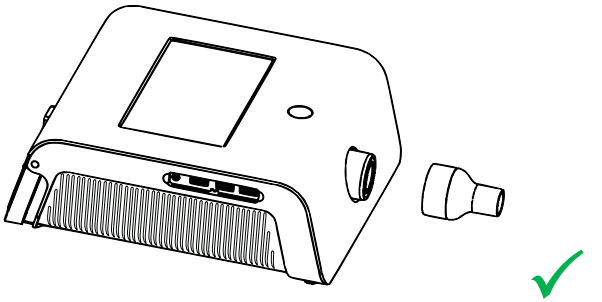
a. Standard patient circuit adaptor for "Standard Tube to Device" connection
b. Standard bacterial filter
c. Optional 22mm "tube to patient interface" connector.
d. Standard 6 feet long, 22 mm diameter single tube



Setting Standard Patient circuit for Therapy

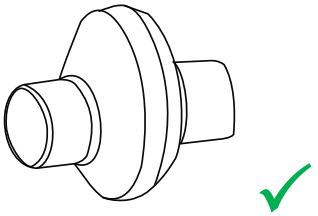
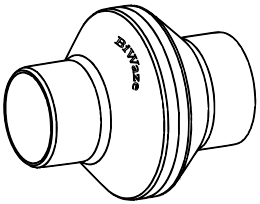
Step 1. Identify the Patient circuit Kit: If the patient circuit tube is a single tube without any tube inside the outer tube, its standard patient circuit tube.

Step 2. Ensure that standard 22mm single port adaptor is attached to the device. Attach one if needed.



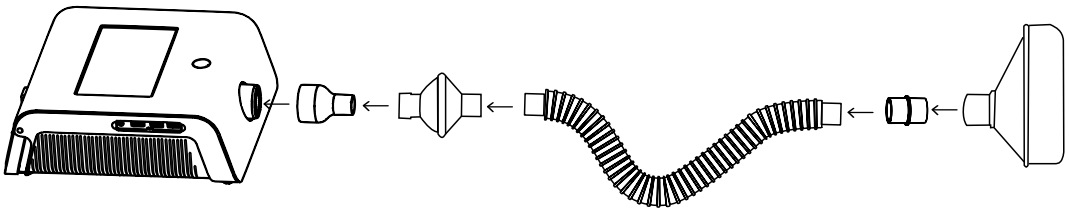
Step 3. Take a standard bacterial filter and attach it to the device.

Please note: The BiWaze custom filter has word "BiWaze" on it while standard filter does not.

Standard bacterial filter	BiWaze special bacterial filter
	

Step 4. Attach the patient circuit tube to the bacterial filter

Step 5. Attach the patient interface (mask or mouth piece) to other end of the tube. Use appropriate adaptors between tube and patient interface if needed.

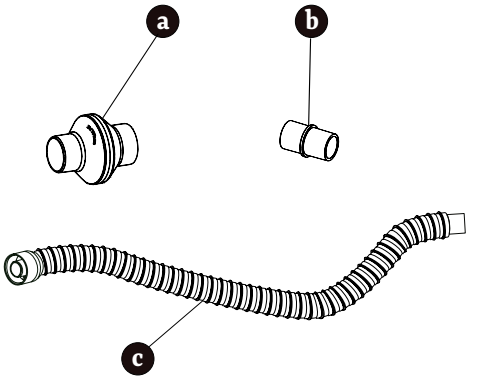


4.2.2 BiWaze Custom Patient Circuit

BiWaze Cough device comes with an optional "BiWaze custom patient circuit kit" with dual channel for superior hygiene. This kit comprises of:

Custom Patient Circuit kit comprise of:

a. BiWaze Special Bacterial filter
b. Optional 22mm "tube to patient interface" connector.
c. 6 feet long, coaxial tube

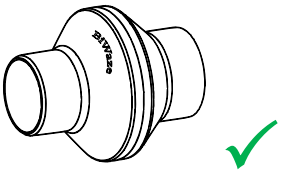


Setting BiWaze special Patient circuit for Therapy

Step 1. Identify the Patient circuit Kit: If the patient circuit tube is a dual coaxial with tube inside the outer tube, its BiWaze special patient circuit tube.

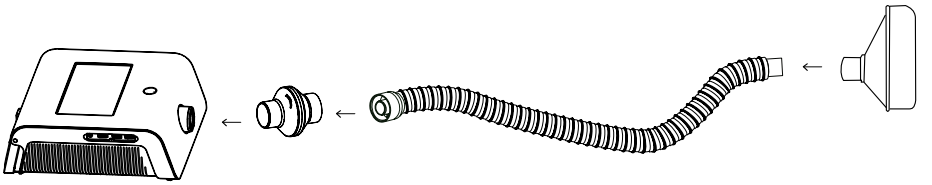
Step 2. Ensure that No adaptor is attached to the device and coaxial port is visible.

Step 3. Take a BiWaze special bacterial filter and attach it to device



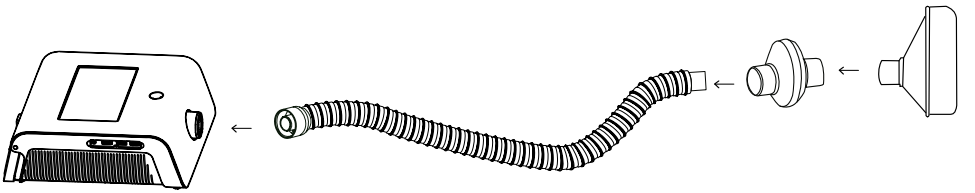
Step 4. Attach the BiWaze coaxial patient circuit tube to the bacterial filter

Step 5. Attach the patient interface (mask or mouth piece) to other end of the tube. Use appropriate adaptors between tube and patient interface if needed.



Refer to the instructions included with the patient circuit for more information.

Note: BiWaze Coaxial Patient circuit can also be used with any standard Filter at patient end with appropriate connector.



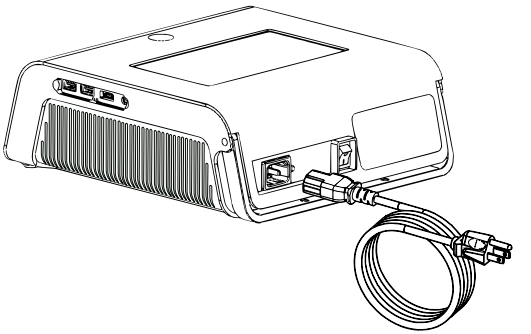
4.3 Supply Power to the Device

The device can operate on external AC power and built in Batteries when charged.

4.3.1 Using AC Power

An AC power cord is included with the device.

1. Plug the socket end of the power cord into the AC inlet on the back of the device.
2. Plug the pronged end into an electrical outlet not connected to a wall switch.
3. Ensure that all connections are secure.



4.3.2 Internal Battery

ABM offers an internal Lithium-ion battery pack for the device. Please contact your sales support or health care provider for battery replacement.
Internal Battery can power the device with active therapies for up to 1 hour* on full charge or equivalent to four 15 minutes therapies.
*subjected to default settings, the actual run time can vary depending on age of the battery, settings and actual active therapy time.

The user can call health care provider to replace the batteries or continue to use the device on AC mains.
The internal batteries can charge simultaneously while the device is operating on the AC mains power and switches to Battery power source when AC mains is disconnected.

Disposal: Do not dispose the batteries 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.

4.3.3.1 AC Power Indicators

When AC power is applied to the device and the display is off, the red AC LED indicator on the Power On/Power Off button lights. When AC power is applied and the display is on, the charging indicator  on the battery symbol on top menu ribbon appears. The Battery charging indicator turns off when the device is run on battery power.

4.3.3.2 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

4.4.1 Manual Therapy Mode

If Manual mode is selected, complete the following steps (see section 4.4.4 for information on accessing therapy modes and profiles):

1. Attach the appropriate patient interface to the device.
2. Press the Power On/Power Off button at the back of the device to turn the device on and enter Standby.
   Note: The device may take up to 30 seconds before the main therapy screen is presented and device is ready for use.
3. Check your settings before starting therapy.
4. Attach the appropriate patient interface to the patient.
5. Press the therapy start button on the touch screen to start therapy.
6. Press the "**+**" button on touch screen to insufflate with one finger
7. Rapidly touch the **"–"** button with second finger simultaneously lifting the finger from the "**+**" button to exsufflate.
8. Leave the touch screen without touching any button in the Pause phase for a few seconds, or shift immediately to the positive pressure phase for another cough cycle, depending on the patient's preference
9. Go through as many cough cycles as determined by the clinician, until the patient is comfortable.

10. After the therapy is completed, disconnect the patient from the device, and clear secretions that may have become visible in the mouth, throat, tracheostomy tube, or endotracheal tube.
11. Repeat as advised by your clinician.

4.4.2 Auto Therapy Mode

If Auto mode is selected on the main screen, complete the following steps (see section 4.4.4 for information on accessing modes and profiles):

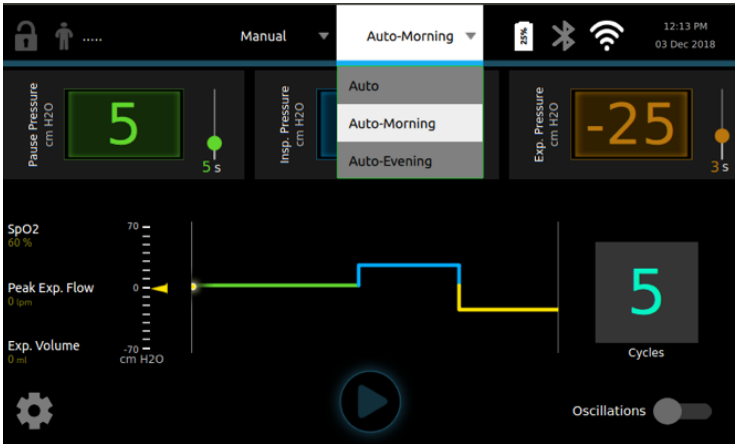
1. Attach the appropriate patient interface to the device.
2. Press the Power On/Power Off button at the back to turn the device on.
3. Check your settings before starting therapy.
4. Attach the appropriate patient interface to the patient.
5. Press the Therapy start button on the touch screen to start therapy.
6. The device will automatically cycle from Inhale (positive) to Exhale (negative) to Pause phase and back to Inhale.
7. After the therapy is completed, disconnect the patient from the device, and clear secretions that may have become visible in the mouth, throat, tracheostomy tube, or endotracheal tube.
8. Repeat as advised by your clinician.

4.4.3 Preset Profiles Settings

When setting the device up for the patient, the health care professional can define up to three Profile settings under each Mode. Profiles allow the user to quickly select a group of prescribed settings to apply therapy. See Section 6.3 - Advanced settings for more information on how to save the Profile settings.

4.4.4 Selecting a profile

User can select available profiles under each mode (Auto/Manual) from the top ribbon Mode/Profiles drop downs.



5 Starting and stopping the therapy

⚠ Caution: Ensure that the Patient circuit and the patient port are dry before using the device on the patient.

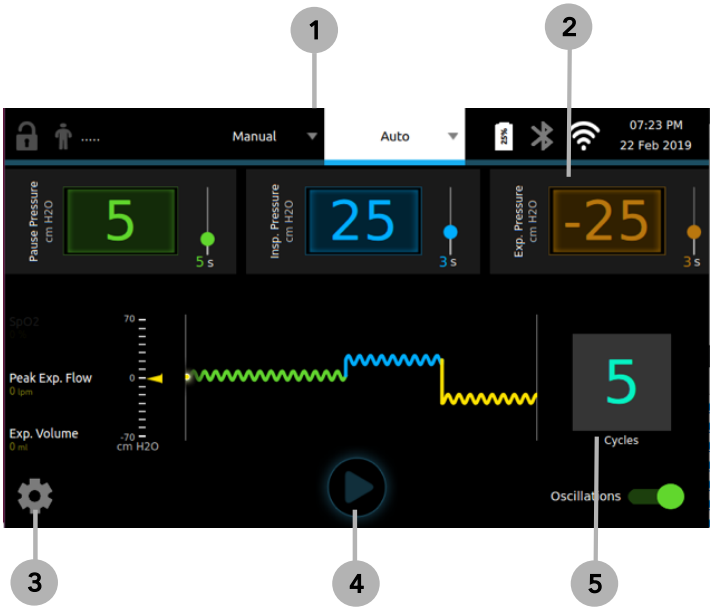
- User can start the therapy by touching the "Start Therapy" Button on the main screen.
- User can pause the therapy by touching the "Pause Therapy" Button on main screen while therapy is ongoing.
- User can terminate or resume the therapy from the Pause Therapy screen.

Note: If user does not resume or terminate the therapy from Paused state, the system automatically terminates the therapy after timeout.

6 Viewing and Changing Settings

6.1 Navigating the Menu Screens

Navigation for all the menu screens is through main touchscreen.



1. Mode Selection
2. Main Pressure and Time Settings
3. Advanced Settings
4. Start Therapy/Pause Therapy
5. Number of Cycles Setting

6.1.1 Timeout Periods

The following timeout events may occur on the device:

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 goes into standby mode and displays "therapy complete" message.

Manual Mode Pause Phase touch: Has timeout of 5 minutes if the user leaves the device untouched without shifting to positive or negative breath phase. The device goes into standby mode.

Manual mode + and - Phase touch: Has timeout period of 10 seconds, if the user continues to touch + or – button for longer than 10 seconds. The device goes into standby mode.

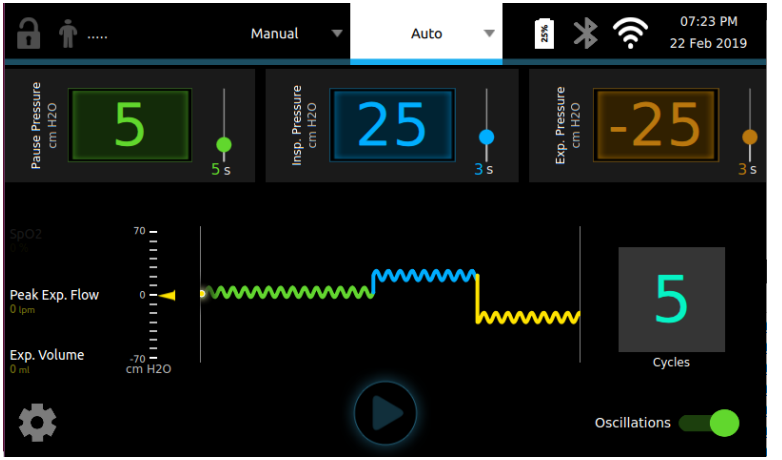
Confirmation Messages: Confirmation messages can only be removed by touch and have no auto timeout.

6.2 Accessing the Main Therapy Screen

When you press the Power Switch at the back of the device, the Startup screen appears momentarily with Device logo.

The Main Therapy screen then appears, as shown here. It displays the date and time, network connection status, therapy mode menu, power source and battery indicator, optional Patient ID field, main settings and measurements.

You can perform the following actions from the Main Therapy screen when the device is in standby mode:

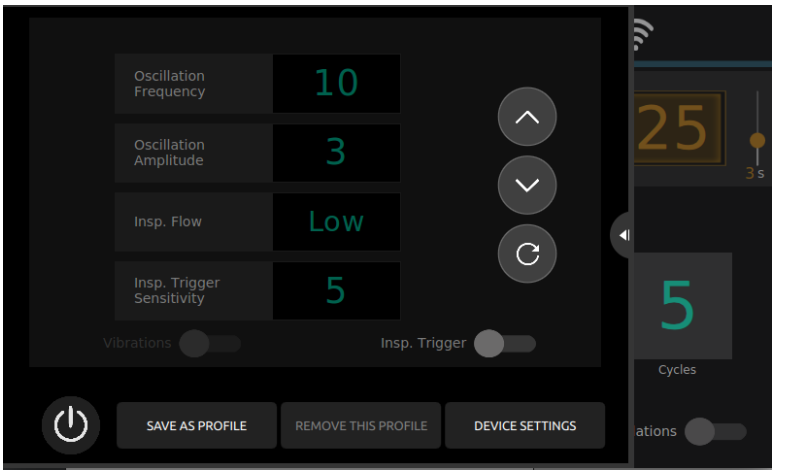


1. Check if the device is in Locked on Unlocked Operation Model. Lock or Unlock the device settings with / menu
2. Check currently selected Therapy Mode and Profile which is highlighted.
3. Change Therapy mode or preset Profile from Therapy mode Menu
4. Check if the main AC power is available with charging symbol on top of battery symbol
5. Check the battery charge status
6. Enable/Disable the Bluetooth
7. Enable/Disable Wi-Fi and select network
8. Change Main therapy pressure and time settings
9. Enable/Disable the Oscillations

   Note: Oscillations can be toggled even while therapy is ongoing.
10. Monitor pressure manometer and breath phase during therapy
11. Start/Pause the therapy

6.3 Accessing the Advanced Settings Screen

The Advanced Settings screen appears after you touch the settings icon on bottom left corner of main screen when the device is in standby mode.

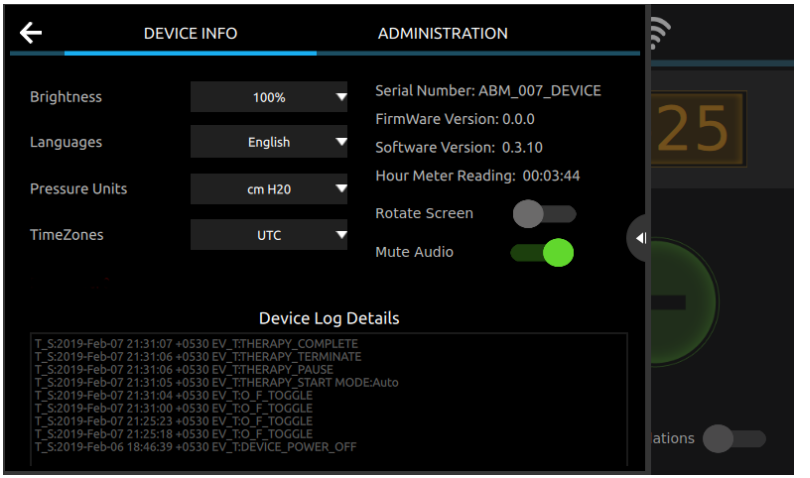


You can perform the following actions from the Advanced settings screen:

- Set oscillation frequency and amplitude
- Set vibration on and off
- Set inspiratory trigger sensitivity
- Set inspiratory flow level
- Save current settings as preset profile or remove a preset profile
- Access Device settings
- Power off the device safely

6.4 Accessing the Device Settings Screen

You can access the Device Settings screen from the main therapy screen by following Advanced settings icon ⚙ > "Device Settings" tab



You can perform the following actions from the Device settings screen:

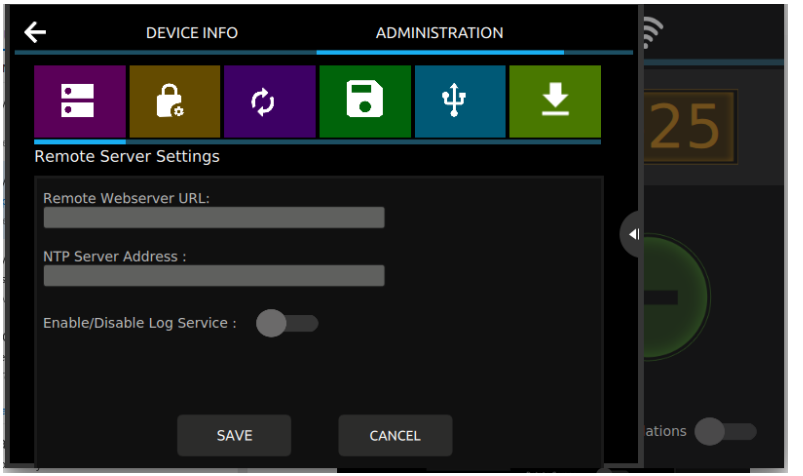
- Check the serial number of the device
- Check firmware and software versions of the device
- Change Date time/ time zones
- Check device logs

- Set device display brightness
- Select device language
- Access Device Administration menu

6.5 Accessing the Device Administration Settings Screen

You can access the Device Administration Settings screen from the main therapy screen by following Advanced settings icon > "Device Settings" tab > "Administration"

Note: this screen is password protected, please get in touch with your clinician for any changes needed on the device administration settings.



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

6.6 Modifying Patient Therapy Settings

6.6.1 Main Therapy settings

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

Note: When the device is completely locked the users can only select available profiles (presets) enabled by HCP, but not adjust any of the settings.

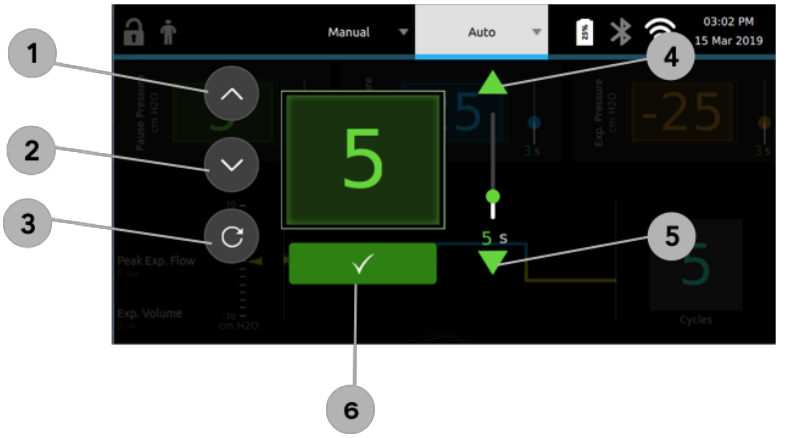
Note: HCP may lock the device with some adjustment allowed by end user, the range of settings that can be changed in that mode is small (<5cm and ± 2 secs) and depends on configuration done by HCP

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. (see advanced therapy settings)
Inspiratory Pressure	Allows you to set the Inspiratory Pressure setting from 0 to 70 cmH2O in increments of 1. The Inhale Pressure is the pressure the patient receives while in the Inhale 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 0.5. 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 0.5. 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 30 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 30.0 seconds in increments of 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 select any of the three pressure setting 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 on main screen get auto saved for next reboot if the therapy was delivered with those settings.

6.6.2 Advanced Therapy settings

Following therapy settings are available when the user touches the Advanced Settings icon at the bottom left corner of the main screen.

Setting	Description
Add/Remove Profiles	Allows you to save currently selected settings as profile as presets for quick select. User can also remove currently selected profile from this screen.
Inspiratory Trigger toggle	Allows you to Enable/Disable the inspiratory trigger. If the inspiratory trigger is on, the pause time setting is over ridden as the device trigger inspiratory phase from pause phase of breath only when it detects an inspiratory effort.
Inspiratory Trigger Sensitivity	Allows you to choose between sensitivity in range of 1-10 with 10 being most sensitive. User can update this setting to adjust sensitivity of trigger.
Inspiratory Flow	This setting allows user to select between low, medium and high inspiratory flow. For patient comfort its recommended to use "Low" flow setting for inspiratory phase of breath.
Oscillation Amplitude	Allows user to set the oscillation amplitude in range from 1 to 5 with 5 being higher amplitude. Refer to Section: Oscillation Feature for details
Oscillation Frequency	Allows user to select frequency of oscillation in range of 5-20Hz with increments of 1

Vibration toggle	If this option is available in the Device Model. Allows you to super impose low amplitude 20 Hz oscillations over and above the set Oscillation frequency and amplitude.

6.6.3 Oscillation feature

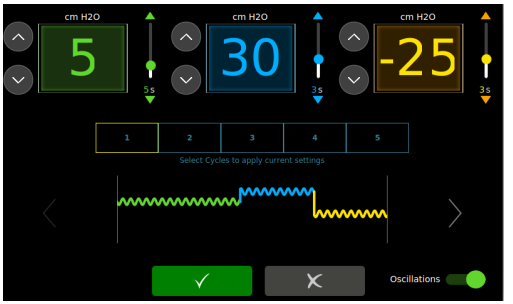
BiWaze Cough device provides oscillation feature during all phases of a breath cycle. The user can enable/disable the oscillations with toggle button on the main screen.

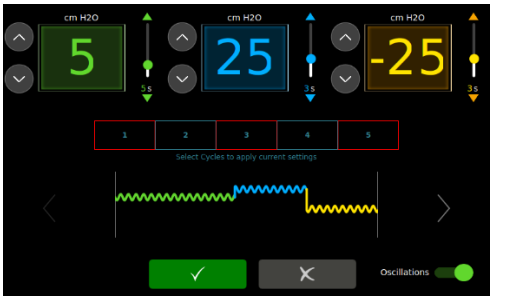
The user can also change the Frequency of oscillations in 5-20 Hz Range amplitude in levels 1-5.

6.6.4 Auto Mode – Advanced Cough Cycle Customization

BiWaze Cough Therapy device allows advanced customization of Cough Cycles for advanced users. Example: to program last n cycles with only positive pressure to increase patient comfort. This setting is available only in Unlocked Operation Mode.

Once user has programmed the Auto mode therapy settings from main screen including number of Cough breath cycles. User can initiate advanced Cough Cycle customization by performing a "long touch" on the wave form area and user is presented with following screen.





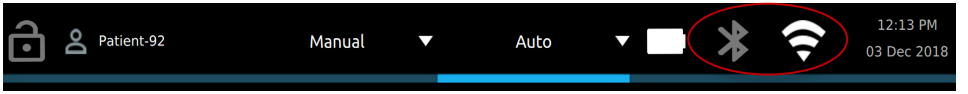
Once the user is in Advance Cycle Customization mode user can

1. Select any breath cycle by touching the cycle number on the selection band. The selected cycle is highlighted in **yellow** on the selection bond.
2. Change the settings of selected cycle only.
   Note: user needs to press ✓ before selecting next or different cycle else the changes are not saved.
3. Once a cycle is selected and user has changed the settings of that cycle. User can choose to copy the same settings to other cycles by entering **copy mode**. Copy mode is enabled by long press of a selected cycle in the selection band. The selected cycle turns "**red**" to highlight **copy mode**.
4. 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.
5. Pressing ✓ will save the current settings to the selected cycles.

6.7 Viewing and Changing Device Settings

6.7.1 Network settings

User can perform blue tooth and Wi-Fi configuration from the main screen using the available icon on the top ribbon.



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. Only paired devices can connect to the device using ABM mobile app.

Wi-Fi Settings

- User can enable/disable the Wi-Fi
- User can look for available networks and select them for connection

Warning :

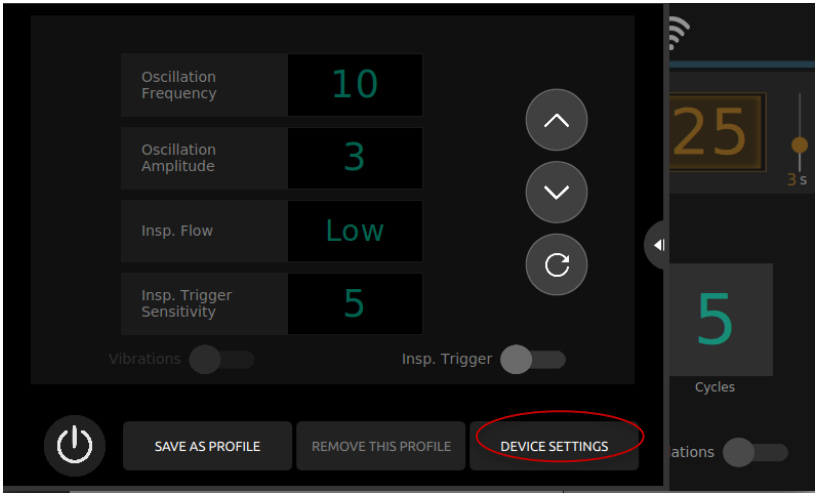
Connecting the device to public or unknown networks could result in previously unidentified risks.

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

6.7.2 Device settings

User can bring up standard device settings from Advanced Settings menu followed by selection of Device Settings button.

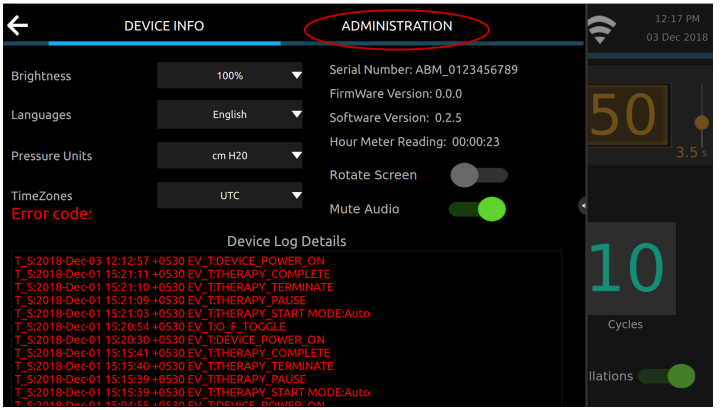


Following device settings are available for viewing and updating.

Setting	Description
Language	Select the language in which the software will appear (English, French, German, etc.)
Pressure Units	Select the pressure units that display on-screen. You can choose either cmH_2O or hPa. All pressure units that appear on-screen display in the unit of measure selected here.
LCD Brightness	Select the brightness of the screen backlight from 1-10, with 1 being the dimmest setting and 10 being the brightest.
Time Zone	Select the time zone for the date/Time
HMR reading	This displays the total time the patient receives therapy.
Therapy logs	User can browse therapy logs in the log view panel on this screen.

6.7.3 Administrative device settings

This screen is intended for use by HCP or clinical staff. User can bring up administrative device settings from device settings menu by selecting "Administration" menu. User will be asked to enter admin password.



Following device settings are available for viewing and updating.

Setting	Description
Lock adjustment	Admin user can change settings limits allowed in locked mode
Remote server address	Update remote web server address here, the therapy logs are uploaded to this server. Update HL7 ftp server address here if available.
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.

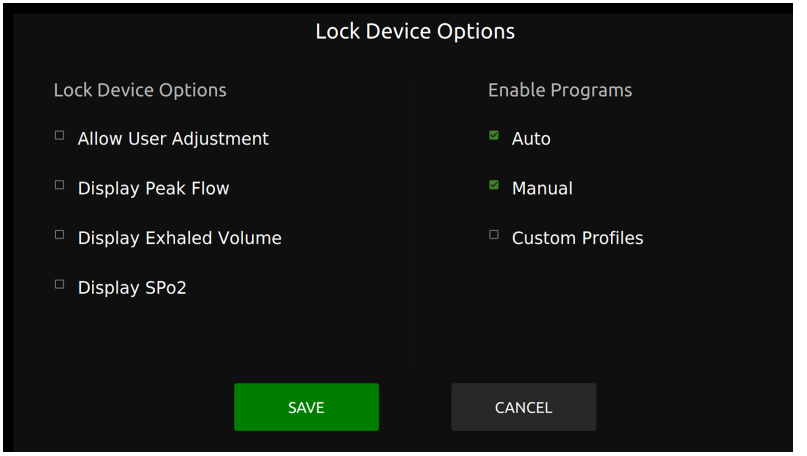
7 Locking and Unlocking the device

The device is recommended to be in the Locked Operation Mode 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

BiWaze Cough device menus can be locked with limited flexibility to the home user. After the administrative password is entered the user is presented with following options before the lock operation is complete.

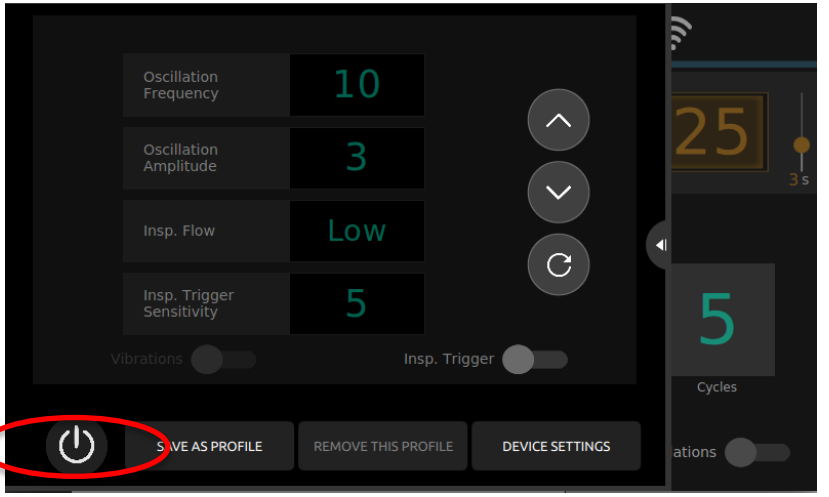


From these options the user can

- Select Modes and Profiles available to home user.
- Select if user is allowed to adjust pressure and time with in set limits (default 5cm for pressures, 2 secs for breath phase

8 Safe Shutdown and Power off

Initiate safe shutdown: Bring up Advanced Settings Panel using icon ⚙ at the bottom left corner of the main screen. Touch the power on off button.



Once the screen has shutdown, the led in front turns red. You may now switch off the device with power button at the back of the device.

9 Cleaning and Maintenance

9.1 Cleaning the Device

⚠ **Caution**: Remove the main power chord 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 as needed using one of the following cleaning agents:

- A clean cloth dampened with water and a mild detergent
- 70% Isopropyl alcohol
- DisCide Towelettes

- 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.

9.2 Cleaning and Replacing the Air Inlet Filter

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

- If the device is operating, stop the airflow. Disconnect the device from the power source.
- Remove the filter from the enclosure.
- Examine the filter for cleanliness and integrity.
- Wash the filter in warm water with a mild detergent. Rinse thoroughly to remove all detergent residue.
- Allow the filter to air dry completely before reinstalling it. If the filter is torn or damaged, replace it. Only ABM-supplied filters should be used as replacement filters.
- Reinstall the filter.

9.3 Cleaning the Patient Circuit

WARNING: Do not sterilize the patient circuit. Always use a new bacterial filter when using the device on a new patient.

9.3.1 Institutional (Hospital) Use

Patient Circuit: Breathing Hose, Patient Interface and Adapters:

If the device is to be used by more than one patient, the circuit must be replaced.

Bacteria Filter:

If the device is to be used by more than one patient, the bacterial filter must be replaced to prevent cross contamination. Do not try to wash the bacterial filter.

Note: For a single patient replace the circuit after 30 days or 90 therapy cycles whichever comes first.

9.3.2 Home (Individual) Use

Patient Circuit: Breathing Hose, Patient Interface and Adapters:

After use, the breathing hose and patient interface should be washed thoroughly with liquid dishwashing soap and water. These parts must completely air dry before reuse.

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

Bacteria Filter:

The filter, which protects the device from entraining foreign material from the patient, can be left in place as long as it is not blocked by sputum or trapped moisture. Do not try to wash the bacterial filter.

Note: Replace the filter after 30 days or if it gets wet or clogged.

9.4 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.

9.5 Preventive Maintenance

This device does not require routine servicing. Only service personnel who are trained and certified by ABM are authorized to service the device.
The instructions for service are captured in BiWaze Cough service manual. ABM will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist to repair those parts of that are designated by as repairable by service personnel.

10 Accessories

There are several accessories available for BiWaze Cough device. Contact your home care provider for additional information. When using the accessories, always follow the instructions included with them.

10.1 Patient Circuits

BiWaze Cough System offers two patient circuit types.

- Standard Patient Circuit kit : PRTN-2037351818-20123
- BiWaze Custom Patient Circuit kit : PRTN-2037351818-20124

Please refer to **section 4.2** for details on Patient Circuit Accessory Options.

10.2 USB Disk

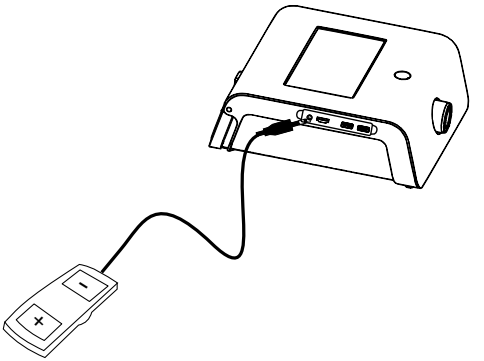
The system comes with an USB storage disk (PRTN-2037351818-20158) to take backup of logs and information as well as device settings for institutional users.
Note: USB disk is an optional accessory and is not essential for functionality of the device
Note: Use only USB storage disks available from ABM.

10.3 Foot Pedal

You can use the Foot Pedal (PRTN-2037351818-20120) to deliver therapy in Manual Mode. The Foot Pedal can be connected to the Remote-Control Connector on the side of the BiWaze Cough device. See Section **2.1.4** for port connection details.

Note: Therapy has to 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.



Once therapy is started in Manual mode from the main device. The foot pedal can be used as optional remote to apply manual mode therapy by initiating inhale (+ press), exhale (- press) and pause phase (no exhale) using foot pedal.

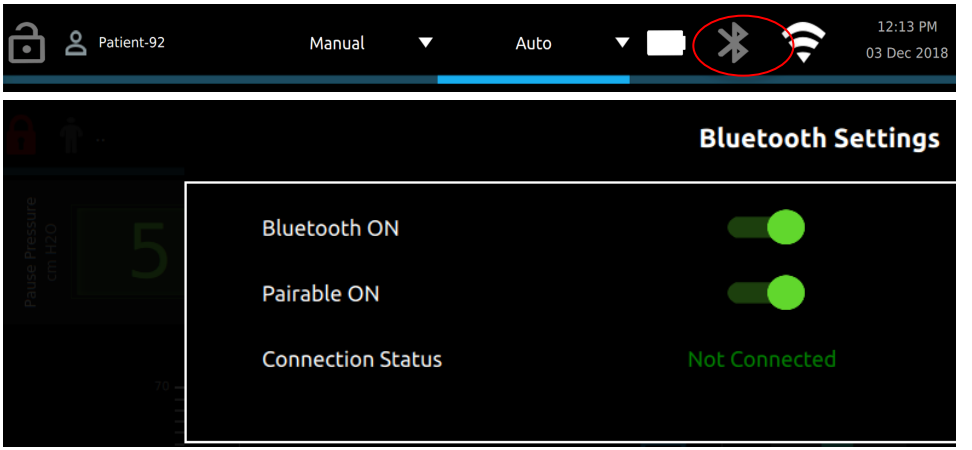
10.4 BiWaze Mobile App

You can use BiWaze Mobile app (IOS: PRTN-2037351818-20122 , Android :PRTN-2037351818-20121)as remote control to start stop therapy as well as deliver therapy

in Manual Model. For more information about availability of mobile app please contact your sales support or health care provider.

10.4.1 Pairing the mobile app to the device

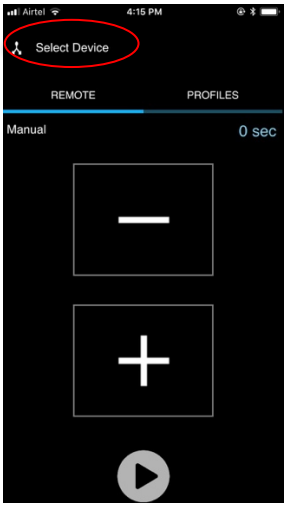
Mobile app has to be paired with the device before it can be used. You can turn on the pairing from the Bluetooth menu on the device by enabling the "Pairable ON" toggle on the device. After this step, you can follow the steps in next section for connecting the app to the device.

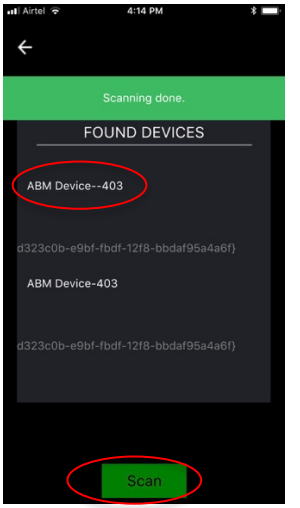


Note: For security purpose the Pairable ON toggle is tuned OFF automatically after 5 minutes after enabling manually. **You have to follow this step only for the first time** you are connecting your mobile app to the device.

10.4.2 Connecting the mobile app to the device

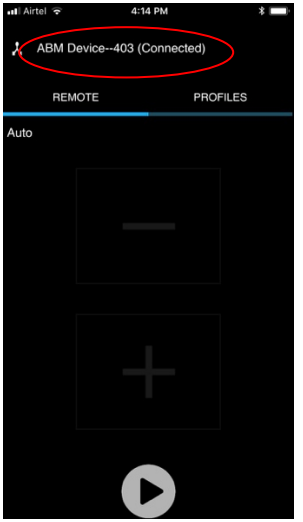
1. Ensure that Bluetooth is enabled on both the BiWaze Cough device and the mobile device. Connect to the app to the BiWaze Cough device.

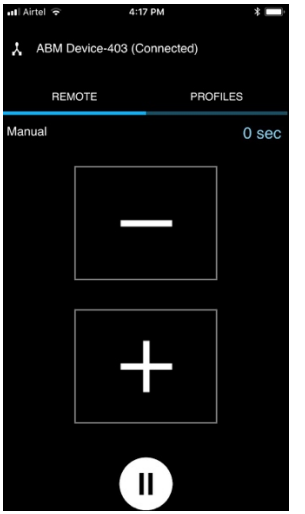




Please note that the ABM devices will appear with name "ABM Device –" <last 4 digits of serial number>

2. Once connected the main screen will show status as connected and the current mode from BiWaze.





Auto Mode: User can start, pause and resume the therapy from Mobile App

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

10.5 Carrying Bag

A carrying bag (PRTN-2037351818-1435) 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.

11 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.

11.1 Informational Messages

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

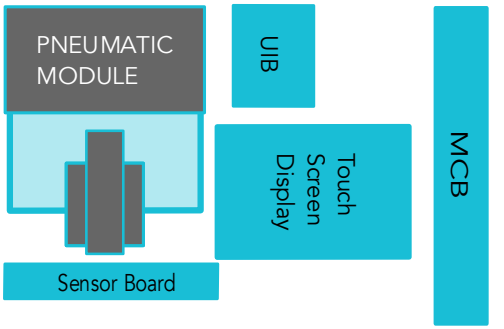
Message	Description
Therapy complete Information	Provides summary of the current therapy completion.
Error State Information	In case of any technical errors, the Error Message is displayed.

12 Technical Specifications

12.1 Theory of operations

BiWaze Cough is designed around a pneumatic assembly which 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 treatment start, and some are monitored continuously.



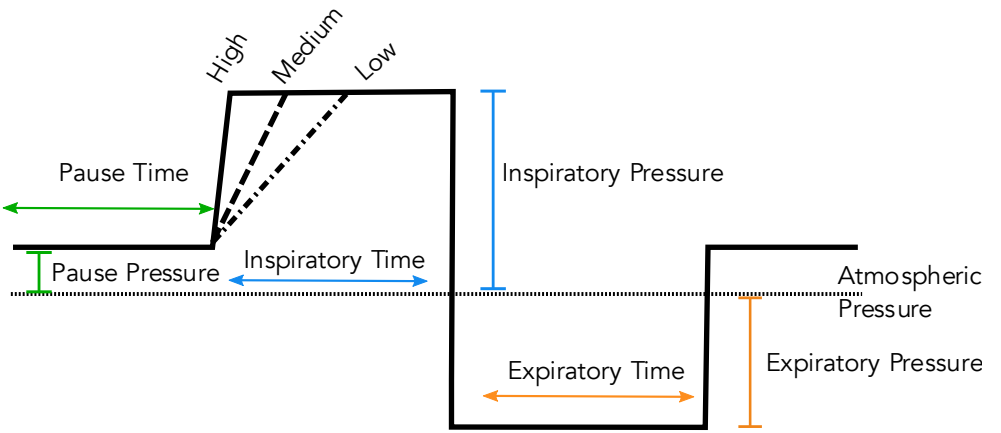
Main Control Board (MCB): This board has multiple processors including main processor for control of pressure and flow. This board controls the positive and negative flow control valves, blowers as well as monitors various temperatures and battery capacity. It also communicates with UI board and Sensor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

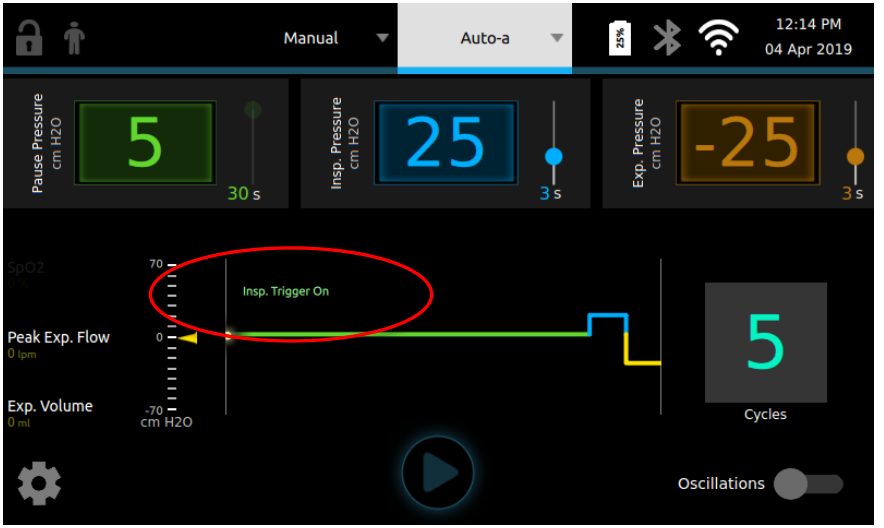
Basic MI-E / Cough Therapy: Single basic Cough cycle comprises of applying a pause pressure followed by an Inspiratory Pressure and suddenly switching to a negative pressure (Expiratory phase). A cough therapy treatment may have multiple such cycles (usually 5-7 cycles) with pauses in between.



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 pressure and flow change created by the patient effort. Both Inspiratory flow and pressure are 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.

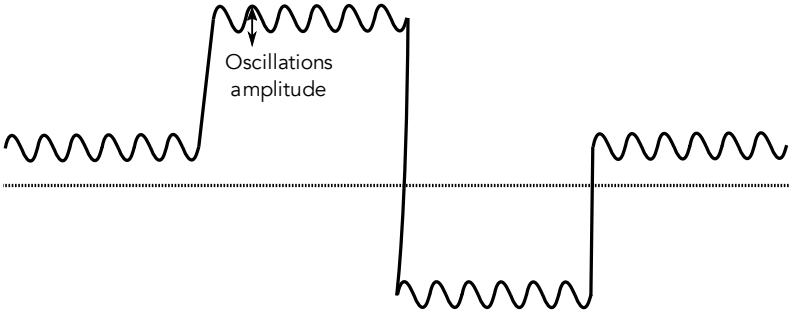
Inspiratory Flow: While the expiratory switching is desired to be fast and at high flow to simulate cough, the inspiratory flow may be controlled to a comfortable level by selecting the flow between low, medium and high.

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.

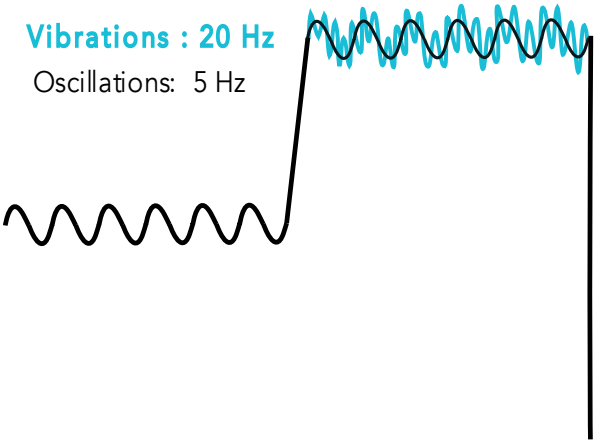
Oscillations Control: BiWaze Cough device allows 5-20 Hz frequency oscillations on applied pressure to facilitate secretions mobilization. Once enabled the oscillation amplitude can be set at 1-5 levels with 1 as the lowest amplitude.



Note: The mean pressure may vary by up to 25% when the oscillations are on depending on the frequency and set pressure.

Vibrations Control: If enabled BiWaze cough device can apply a constant 20 Hz, level 1 amplitude oscillation superimposed on the set oscillation.

Example:



12.2 Environmental

	Operating	Storage
Temperature	5° C to 35° C	-20° C to 60° C
Relative Humidity	15 to 95% (non-condensing)	15 to 95% (non-condensing)
Atmospheric Pressure	101 kPa to 77 kPa (approximately 0-2286 meters)	N/A

12.3 Physical

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

12.4 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

- ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing (Biocompatibility)
- ISO 13485: 2016: Medical Devices Quality Management Systems
- ISO 14971:2012 : Application of Risk Management for Medical Devices

12.5 Device classifications

AC Voltage Source	100 to 240VAC, 50/60 Hz
AC Power Supply	Input: 100-240 V, 50/60 Hz 1.0-2.0A IEC 60601-1 & IEC 60601-1-2 certified
Lithium Ion Battery	Power: 88 Whr Capacity: 3200 mAh IEC 62133-2 certified
Type of Protection Against Electric Shock	Class II
Classification According to Directive 93/42/EEC	Class IIa
Degree of Protection Against Electric Shock	Type BF Applied Part
Patient applied part	Face mask and mouth piece
Degree of Protection against Ingress	Exposure Protection, IP21
Mode of Operation:	Intermittent (30 mins ON – 15 mins OFF)

12.6 Wireless communication

Feature	Dimension
Bluetooth Specification	
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	
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])

12.7 Displayed Parameter Accuracy

Parameter	Accuracy	Resolution	Range
Pressure	> of ± 5 cmH_2O or 10% of reading	1 cmH_2O	-70 to 70 cmH_2O
Peak Cough Flow (PCF)	> of ± 15 lpm or 15%	1 lpm	0-500 lpm
Exhaled Tidal Volume (Vte)	± (25 +0.15 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.

12.8 Control Accuracy

Parameter	Range	Accuracy
Pressure	-70 to 70 cmH_2O	± 5 cmH_2O
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	1-20 Hz	± (10% of setting)
Amplitude	1-10 cmH_2O	± 5 cmH_2O

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

12.9 Sound

The sound pressure of the device set at -40 cmH2O/+40 cmH2O in the Pause phase is less than 65 dBA at 1 meter.

12.10 Disposal

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

12.11 Essential Performance

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

- Inhale Pressure not to exceed 85 cmH2O for 1 minute
- Exhale Pressure not to exceed -75 cmH2O 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

13 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.

13.1 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	

13.2 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% U_T for 0.5 cycle at: 0^0, 45^0, 90^0 135^0, 180^0, 225^0 270^0 and 315^0. 0% U_T for 1 cycle 70% U_T for 25/30 cycles, single phase at 0^0. 0% U_T for 250/300 cycles	0% U_T for 0.5 cycle at: 0^0, 45^0, 90^0 135^0, 180^0, 225^0 270^0 and 315^0. 0% U_T for 1 cycle 70% U_T 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: U_T is the AC mains voltage prior to application of the test level.			

13.3 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	3 Vrms 150 kHz to 80 MHz	3 Vrms	The BiWaze 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

Radiated RF IEC 61000-4-3	6Vrms in ISM bands between 150KHZ to 80MHz 10 V/m 80 MHz to 2.7 GHz		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.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, 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.
b. Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

13.4 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.			

13.5 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 is used in such an environment.			
Sides Tested	Frequency (MHz)	Test Severity Level	Test Distance (m)
Front, back, left, right	385	27V/m, 50%PM 18Hz	0.3
Front, back, left, right	450	28V/m, FM±5kHz, 1kHz	0.3

Front, back, left, right	710	9V/m, 50%PM, 217Hz	0.3
Front, back, left, right	745	9V/m, 50%PM, 217Hz	0.3
Front, back, left, right	780	9V/m, 50%PM, 217Hz	0.3
Front, back, left, right	810	28V/m, 50%PM, 18Hz	0.3
Front, back, left, right	870	28V/m, 50%PM, 18Hz	0.3
Front, back, left, right	930	28V/m, 50%PM, 18Hz	0.3
Front, back, left, right	1720	28V/m, 50%PM, 217Hz	0.3
Front, back, left, right	1845	28V/m, 50%PM, 217Hz	0.3
Front, back, left, right	1970	28V/m, 50%PM, 217Hz	0.3
Front, back, left, right	2450	28V/m, 50%PM, 217Hz	0.3
Front, back, left, right	5240	9V/m, 50%PM, 217Hz	0.3
Front, back, left, right	5500	9V/m, 50%PM, 217Hz	0.3
Front, back, left, right	5785	9V/m, 50%PM, 217Hz	0.3

13.6 Federal Communications Commission (FCC) Radiation Exposure Statement

This device complies with Part 15 of the FCC rules. This equipment operates with a distance of 14 mm between the radiator and the touch screen LCD or user interface. The FCC ID for this device is FCC ID:**2ATX9-1395**

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.

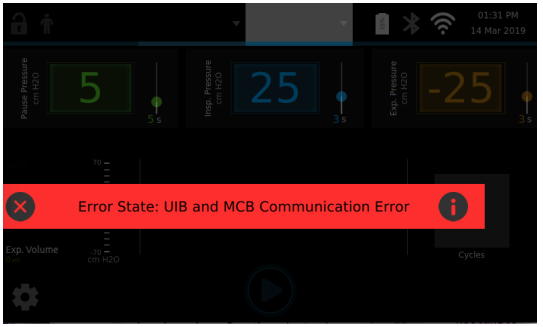
NOTE:

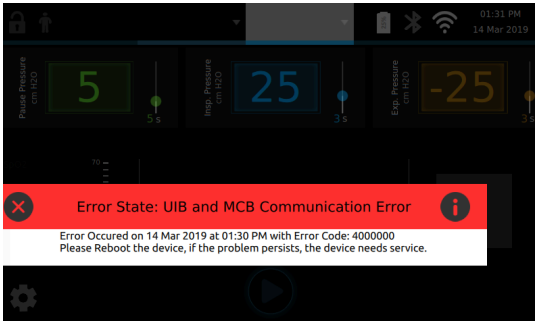
The module must be used in strict accordance with the manufacturer's instructions as described in the user documentation that comes with the product. Modifications not expressly approved by manufacturer could void your authority to operate the equipment.

14 Trouble Shooting

In case the BiWaze Cough device user runs into any device related issues, 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 authorized service center. Please get in touch with your health care provider for such service needs.

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 its 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 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 problem persists, call your health care provider for service.
Information with a self-explanatory message on the	Informational messages	User can acknowledge and continue with therapy. Take

LCD screen in an Orange strip.		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.

15 Limited Warranty

Advanced Bio Machines Pte Ltd (ABM) warrants that the BiWaze Cough Therapy system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year from the date of sale by ABM to the dealer. If the product fails to perform in accordance with the product specifications, ABM, will repair or replace – at its option – the defective material or part. ABM will pay customary freight charges from ABM. 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.

ABM 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.

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 ABM dealer or your health care provider or contact ABM at: info@abmrespiratorycare.com

16 Service Instructions

There are no service instructions for the device in the field. The device needs to be sent back to the manufacturer. Please get in touch with you provider for details.

⚠ Caution

- Do not remove the top cover or disassemble the device as there 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.

16.1 FRU and Spare parts

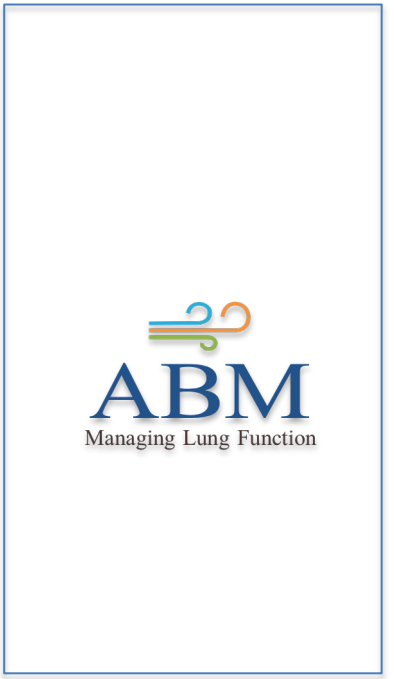
There are no field replaceable spare parts orderable for service.

16.2 Planned Maintenance

There is no requirement for planned maintenance of this device.

16.3 Service Cleaning and Maintenance

There is no field service applicable for the device. Any returns to the manufacturing shall be cleaned and maintained as per manufacturing site work instructions.



ABMRC, LLC
239 Fairchild St.
Charleston, SC 29492
USA

Porta Medical UG.
Holstenstrasse 64a
23701 Eutin
Germany

EC REP

REF PRTN-2037351818-1395

Model : BiWaze Cough
FCC ID: 2ATX9-1395