BiWaze® Cough SYSTEM

Frequently Asked Questions

Control Unit & Battery

1 What is the purpose of the BiWaze Cough system?
The BiWaze Cough system is designed to help patients with weakened respiratory muscles who cannot cough effectively on their own. It mimics a natural cough by delivering a deep inhalation followed immediately by a strong exhalation. This therapy is commonly used for patients who have difficulty clearing airway secretions due to neuromuscular disorders, spinal cord injuries, or severe fatigue related to lung disease.

2 Who can use BiWaze Cough?
The BiWaze Cough system is intended for pediatric through adult patients and can be used in both home and hospital care settings.

3 How much does the control unit weigh?
The BiWaze Cough control unit weighs 9.4 lb (4.1 kg), including its standard internal battery. Each system comes with a battery included.

4 What are the dimensions for control unit?
The BiWaze Cough control unit dimensions are 10”5 L x 9.2” W x 3.5” H (27.5cm L x 23.5cm W x 9.0cm H).

5 How many therapies can one battery charge deliver?
On a full charge, the internal battery can support up to 2 hours of therapy. The battery can recharge while the system operates on AC power and will automatically switch to battery power if AC power is disconnected.

6 What are the specifications of the BiWaze Cough battery?
BiWaze Cough uses a proprietary lithium-ion battery with a capacity of 3,400 mAh. It maintains at least 80% of its original capacity for approximately 400 charge cycles and requires about 4.5 hours to recharge fully from 0% to 100%.

7 Can BiWaze Cough be taken on a plane?
BiWaze Cough can be carried on a plane. Since the system contains a lithium-ion battery, it must be transported in carry-on luggage and not checked baggage. Please note that therapy cannot be performed while in flight.

8 What patient interfaces are available to use with BiWaze Cough?
The single-patient-use breathing circuit can be used with several interfaces, including face masks (various sizes), a mouthpiece, and a tracheostomy or endotracheal tube adapter.

9 What are the safe operating temperatures for BiWaze Cough?
The safe operating temperatures are 41°F to 95°F (5° to 35°C) and storage range is -13°F to 158°F (-25°C to 70°C). If the device has been in an environment outside of the safe operating range, do not use it immediately. Instead, move it to a location within the safe range and allow the device to adjust to that temperature internally before turning it on.

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10 Can any breathing circuit be used by the BiWaze Cough System?

Yes. Any 22 mm ISO ID/OD breathing tube, filter, and patient interface can be used with the BiWaze Cough system when paired with the patient port adapter. ABM Respiratory Care offers breathing circuit kits that include various sizes of face masks, a mouthpiece, or a flexible tracheostomy adapter.

11 What is the difference between the touchscreen lock and the device lock?

The touchscreen lock prevents accidental setting changes while the system is being moved, such as during transport within a hospital. When the touchscreen is locked, therapy cannot be started. The device lock prevents any changes to programmed therapy settings while the device is in use.

12 Can BiWaze Cough be locked so patients are unable to edit the programmed therapy?

Yes. The BiWaze Cough system includes a locking feature that prevents users in the home from changing programmed therapy settings. The password to lock and unlock the device is provided in the Locking Feature insert included with the user manual for all new BiWaze Cough systems.

13 What is needed when traveling to a different country?

If traveling to a country with a different line voltage, you will need a country-specific power cord or an international plug adapter.

14 What is the password used to access the lock screen?

Each new BiWaze Cough system includes "Lock Feature Instructions," which provide the code needed to lock or unlock the device.

15 What to do if BiWaze Cough doesn't reach peak pressure?

- Review the therapy settings:
  - If the Flow option is set to Low, change it to High.
  - If peak pressure is then reached but the patient finds the flow too strong, reduce the Flow option to Medium.
  - If at Low or Medium flow, the patient is comfortable but peak pressure is still not reached, slightly increase the I-Time to allow more time for pressure to build.
- Check the entire circuit for a leak (from patient to device):
  - Ensure all parts of the circuit are assembled correctly and fit together tightly.
  - Inspect for cracks or holes in the circuit.
- Address specific leak points in patient interface:
  - Face mask: Apply firm steady pressure to ensure a seal; confirm the mask size is correct so it seals tightly around the nose and mouth.
  - Mouthpiece: Instruct the patient to form a tight seal; if they cannot, switch to a mask.
  - Tracheostomy adapter: Verify correct size and ensure all connections are secure.

16 What languages are available in the BiWaze Cough System?

The languages available include: English, Spanish, French, Italian, German, Portuguese, Norwegian, Danish, Finnish, Russian, Polish, Swedish, and Dutch.

Therapy Questions

17 What is the difference between Automatic and Manual therapy mode?

In Manual mode, the clinician controls each inhale and exhale phase by pressing and holding the buttons for the desired duration of each phase.
In Auto mode, the system delivers therapy automatically according to pre-programmed prescription settings, which may include Inhale Pressure, Inhale Time, Exhale Pressure, Exhale Time, Pause Pressure, Pause Time, and Number of Cycles.

18 What position should the patient be in to receive therapy?

For optimal therapy delivery, the patient's head should be elevated to a 30-degree angle or higher, unless otherwise directed by a healthcare provider.

19 How many therapy cycles are typical for a treatment?

Follow the physician orders for the number of cycles. If no cycle direction is provided, it is common to do a therapy of 3 to 5 cycles (for children) or 4 to 6 cycles (for adults).

20 What are the device setting options?

Inspiratory Pressure = 0 to 70 cmH_2O
Inspiratory Time = 0 to 5 seconds
Expiratory Pressure = 0 to -70 cmH_2O
Expiratory Time = 0 to 5 seconds
Pause Pressure = 0 to 15 cmH_2O
Pause Time = 0 to 5 seconds
Oscillation Frequency = 5 to 20 Hz
Oscillation Amplitude = 1 to 5 level
Cycle count = 1 to 20

21 How can I set auto therapy to end on an inspiratory breath?

The Insp Breath toggle to enable and disable the feature is found under the administrative screen. By default this patient comfort feature is disabled. This feature allows the auto therapy to end on the programmed inspiratory breath pressure, leaving the patient's lungs full of air after therapy is complete. Even if enabled, this feature will not activate on therapies customized through advanced programming.

22 How does BiWaze Cough apply oscillations?

BiWaze Cough allows 5-20 Hz frequency oscillations on applied pressure to facilitate secretion mobilization. Once enabled the oscillation amplitude can be set at 1-5 levels with 1 as the lowest amplitude. When oscillations are active, the mean pressure may vary depending on the set pressure and frequency:

- For set pressure below 50 cmH20, the mean pressure may vary by up to 7 cmH20.
- For set pressure of 50 cmH20 or higher, the variation may be up to 15 cmH20.

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

Amplitude Setting	Mean to Peak Range (Inhale pressure < 50)	Mean to Peak Range (Inhale pressure > 50)
1	2 to 10 cmH20	6 to 21 cmH20
2	2 to 11 cmH20	9 to 25 cmH20
3	3 to 13 cmH20	9 to 27 cmH20
4	3 to 14 cmH20	11 to 28 cmH20
5	4 to 15 cmH20	15 to 30 cmH20

23 How does the inhalation trigger work?

The inhalation trigger is a feature which allows the device to try to synchronize with the patient's natural breathing. The inhalation therapy is "triggered" when the patient's breath effort is detected. The trigger is based on the detection of pressure and flow changes in the system. The algorithm

aggregates the last 4 values of pressure and flow every 20 milliseconds and compares it to the selected level of sensitivity (levels range from 1 to 10 with 10 being the most sensitive).

The system waits to detect the inhalation effort of the patient in a window of 30 seconds, in the case when no trigger is detected, the system goes into pause state.

24 How is the peak cough flow calculated?

During each exhalation phase, the system measures flow continuously and records the highest value as the peak cough flow. Any sudden spikes in the expiratory flow signal are disregarded to ensure the displayed value reflects the actual peak flow.

25 What are the most common PAP on Pause settings?

The typical pressure used during the pause phase is 5 to 8 cmH_20. This is a comfort setting and should be adjusted per patient preference.

26 What patient conditions should use this therapy?

Patient conditions usually covered by insurance includes:

Amyotrophic lateral sclerosis (ALS)	Multiple sclerosis
Progressive bulbar palsy	Spinal cord injury (SCI)
Muscular dystrophy	Motor neuron disease
Spinal muscular atrophy (SMA)	Quadriplegia

27 Why do oscillations not work on the pause phase when the inspiratory trigger is on?

When the inspiratory trigger is enabled, the system must detect the patient's natural inhalation effort. Oscillations are temporarily disabled during the pause phase to avoid interfering with this detection.

Maintenance

30 How often should the inlet filter be changed?
Under normal usage, the inlet air filter should be cleaned at least once every month and replace it with a new filter every six months. The inlet air filters are offered by ABM Respiratory Care in packs of three.

31 How often should the BiWaze Cough be serviced or have preventative maintenance?
The BiWaze Cough System doesn't require any routine or preventative maintenance.

32 How often should the single patient use breathing circuit be replaced?
A new single patient use breathing circuit should be used after 90 treatments or 30 days.

33 Does BiWaze Cough need to be calibrated?
The device does not need to be calibrated as it performs a self-calibration each time the device started during the Power-On Self-Test.

Connectivity & Data

34 Does BiWaze Cough store usage data?
Yes. The BiWaze Cough system records therapy usage data, including therapy settings and operational history, which can be reviewed on the device or exported to a USB in an encrypted file.

35 How can the exported encrypted file be decrypted?
A decryption tool is available on the Arc Connect website, https://arcconnect.abmrc.com/

36 Can BiWaze Cough integrate with an EMR / EHR?
BiWaze Cough does not directly integrate with EMR/EHR systems. However, data can be exported to Arc Connect where a PDF can be created and manually uploaded into other systems.

37 How secure is the data transmission?
Data transmitted via Wi-Fi to Arc Connect is encrypted using secure protocols.

38 What the Wi-Fi used for on BiWaze Cough?
Wi-Fi is used to send therapy usage data to Arc Connect and to synchronize the date and time. No other internet communication is permitted.

39 What devices connect to BiWaze Cough via Bluetooth?
BiWaze Cough has an app that connects to the device via Bluetooth. The BiWaze Cough Remote app provides a remote control to control the cough therapy without touching the device, thus allowing the caregiver to focus more on the patient.

Troubleshooting

40 **What should I do if the device has an error?**
The red circle indicates an error that prevents therapy. Follow the on-screen instructions or refer to the error code list. Contact customer support if the issue persists.

41 **Where can I find the reasons behind an error code?**
Error code descriptions and corrective actions are listed in the troubleshooting section of the User Manual.

Service & Support

42 **Is training requiredbefore using BiWaze Cough?**
Yes. Users should receive training from a qualified healthcare provider or MEC before using the system.

43 **Where can I find replacement parts and accessories?**
Replacement parts, such as breathing circuits, filters, and accessories, can be purchased through MEC, 1300 632 633 or www.mec.com.au

44 **Who do I contact for assistance with BiWaze Cough?**
Contact: MEC, 1300 632 633 or www.mec.com.au

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For further information about this product or a service, visit our webpage:
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