

Device Questions

1 **How much does the device weigh?**

The device weighs 9 lbs. which includes the internal battery. A battery is included with each device.

2 **How many therapies can one battery charge deliver?**

The internal battery on a full charge can support 20 default therapies on one charge (default therapy is 5 cycles of +/- 25 cm H₂O for 2 seconds). The battery can charge simultaneously while the device is operating on AC power and switches to the battery when AC power is disconnected.

3 **What are the specifications of the BiWaze battery?**

BiWaze Cough has a proprietary lithium ion battery with a capacity of 3,400 mAh and will go 400 cycles before it drops to 80% capacity. The battery takes 4 hours and 15 minutes to go from 0% to 100% charge.

4 **Does the battery have a memory effect?**

Unlike well-known nickel-cadmium and nickel-metal-hydrate batteries that will gradually lose usable capacity if recharged after only being partially discharged, the lithium-ion battery used in BiWaze Cough doesn't have the memory effect.

5 **What are the safe operating temperatures for the device when it is running?**

The safe operating temperatures are 40° to 95°F (5° to 35°C). If the device is in a location which exceeds this temperature range, do not use the device. Bring the device into a location within the safe temperature range, wait for the device to reach the safe temperature range internally before powering on the device.

6 **What patient interfaces are available to use for therapy?**

The patient interfaces available for the single patient use breathing circuit include a face mask (various sizes), mouthpiece and trach adaptor for a tracheostomy or endotracheal tube.

7 **What devices connect 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.

8 **Why is there a WI-FI connection option?**

BiWaze Cough can send data to an online portal, Arc Connect, for healthcare providers to review the therapy usage data. The data transmission functionality can be enabled or disabled through the administrative screen. The WI-FI also allows the device to synchronize the date and time with configured time servers. There is no other communication allowed through WI-FI connection.

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

Any 22mm ISO ID/OD breathing tube, filter and patient interface can be used. ABM Respiratory Care sells breathing circuit kits that come with various sizes of face masks, a mouthpiece or a flexible trach adaptor.

- 10 **Can the device be locked so patients are unable to edit the programmed therapy?**
The device has the ability to lock therapy settings so users in the home cannot edit them. The password to lock and unlock the device is 81021011.
- 11 **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.
- 12 **Can patients travel with this device?**
Yes, BiWaze Cough is portable. It comes with an internal battery and carrying case.
- 13 **What is the recommended cleaning protocol?**
After each therapy session, the patient circuit (except the filter) should be washed with warm, soapy water. Allow it to thoroughly dry before it is used in a therapy. See the User Manual for complete instructions.
- 14 **What are the dimensions for device?**
The dimensions are 10"5 L x 9.2" W x 3.5" H (27.5cm L x 23.5cm W x 9.0cm H).
- 15 **What is needed if traveling to a different country?**
When traveling to a country with a different line voltage, a country specific power cord or an international plug adaptor will be required. Always check with the airline to determine what regulations may apply.
- 16 **Does the device update automatically for Daylight savings time and Leap Year?**
The device will update automatically if connected to a WI-FI network.
- 17 **What is the password used to access the administrator screens?**
The password to access the administrator screens is 11012018.
- 18 **What to do if the device doesn't reach peak pressure?**
- Review the therapy settings:
 - If the Flow option is set to Low, then update the Flow option to High
 - If after updating the Flow, the peak pressure is reached but patient feels that the flow is too high to breathe, reduce the Flow option to Medium
 - If at Low or Medium flow, the patient feels comfortable but the pressure is not reached, try increasing the I-Time slightly to allow the slower flow to achieve desired pressure in the lung
 - Check the entire circuit for a leak (review from the patient to the device)
 - Check to make sure all parts of the circuit are assembled correctly and fit together tightly
 - Make sure there no cracks/holes in the circuit
 - If there is a leak at the mask:
 - Apply firm and steady pressure to hold the mask to the patient's face

- Make sure the mask is the correct size for the patient's face; there should be a tight seal around the patient's nose and mouth
- If there is a leak at the mouthpiece:
 - Instruct the patient to form a tight seal at the mouthpiece
 - If patient is unable to form a tight seal with the mouthpiece, switch to a mask
- If there is a leak around the track adapter:
 - Make sure it is the correct size and pieces are fit together tightly

19 **What languages are available in the BiWaze Cough System?**

Currently only English is available but support for additional languages will be added soon.

Therapy Questions

20 **What is the difference between Automatic and Manual therapy mode?**

The Manual mode requires the caregiver to manually deliver the therapy of inhale and exhale including the duration of each phase by press and hold buttons. The Auto mode delivers therapy based on the following pre-programmed prescription settings: Inhale Pressure, Inhale Time, Exhale Pressure, Exhale Time, Pause Pressure, Pause Time and Number of Cycles.

21 **What position should the patient be in to receive therapy?**

To receive therapy, it is recommended the patient's head be at 30 degree or higher angle, or as directed by a healthcare provider.

22 **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).

23 **What are the therapy parameters?**

Inspiratory Pressure = 0 to 70 cmH₂O

Pause Time = 0 to 5 seconds

Inspiratory Time = 0 to 5 seconds

Oscillation Frequency = 5 to 20 Hz

Expiratory Pressure = 0 to -70 cmH₂O

Oscillation Amplitude = 1 to 5 level

Expiratory Time = 0 to 5 seconds

Cycle count = 1 to 20

Pause Pressure = 0 to 15 cmH₂O

24 **How does BiWaze Cough apply oscillations?**

For Inhale Pressure < 50 cmH₂O, the amplitude setting 1 corresponds to about 20% of the set pressure, 2 corresponds to about 22% of set pressure and so on with an increment of 2% of set pressure for each amplitude with about 30% being the highest.

For Inhale Pressure > 50 cmH₂O, the amplitude setting 1 corresponds to about 30% of the set pressure, 2 corresponds to about 33% of set pressure and so on with an increment of 3% of set pressure for each amplitude with about 42% being the highest.

The amplitude and its tolerance depends on the set pressure, resistance and compliance of the lungs.



25 **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.

26 **What are the most common PAP on Pause settings?**

The typical pressure used during the pause phase is 5 to 10 cm H₂O. This is a comfort setting and should be adjusted per patient preference.

27 **Can the therapy be used on children?**

Yes, the BiWaze Cough System is indicated for pediatric and adult patients.

28 **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 |

Reimbursement

29 **What is the reimbursement code for BiWaze Cough?**

PDAC approved the BiWaze Cough System under HCPCS code E0482, cough stimulating device, and it is a 13-month capped rental. The monthly reimbursement varies from \$425 - \$600 per month, depending on the insurance company.

30 **What is the reimbursement for the BiWaze Cough breathing circuit?**

PDAC approved the BiWaze Cough breathing circuit under HCPCS A7020, interface for cough stimulating device, and it is a monthly rental. The monthly reimbursement varies from \$14.30 - \$20.00 per month, depending on the insurance company.

Maintenance

31 **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.

32 **How often should the device be serviced or have preventative maintenance?**

The BiWaze Cough System doesn't require any routine or preventative maintenance.

33 **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 when used in the home care environment.

34 **Does the device need to be calibrated?**

The device does not need to be calibrated as it performs a self-calibration each time the device is powered-on.

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