



BreatheSuite

User Manual



BreatheSuite Metered Dose Inhaler (MDI) Device

BreatheSuiteMDIV1

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How it Works

The BreatheSuite MDI Device collects information on how you use your inhaler:



It measures how long you shake your inhaler.



It senses if you hold your inhaler correctly.



It senses how long and forcefully you inhale.



It senses if you push down on your inhaler at the right time.



It records inhaler use.

This information is sent to the BreatheSuite app on your smartphone using a Bluetooth connection.

The BreatheSuite app displays information on inhaler usage and technique. It also provides tips on how to use your inhaler better.

Not feeling well?

Don't wait. Call your doctor right away.

The BreatheSuite MDI Device and app provide feedback on inhaler usage, but the communication of data can be delayed. You know your health best, never wait to call a doctor if you are not feeling well.

If you have any questions, please contact us!
1-855-667-8931; help@breathesuite.com

Getting Started

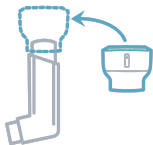
1. Take the BreatheSuite MDI Device out of the packaging.



2. Press down on the BreatheSuite MDI Device to begin setup, a blue light will appear on the Device.



3. Attach the BreatheSuite MDI Device to the top of the canister of your inhaler.



4. Download the BreatheSuite app from the Google Play Store or the Apple App Store.



5. Open the app and follow the on-screen instructions to set-up your BreatheSuite MDI Device.



If you need any help setting up your BreatheSuite MDI Device, send an email at help@breathesuite.com or call toll-free 1-855-667-8931

Product Description

The BreatheSuite MDI Device will automatically track your inhaler medication use and technique. When you take your medication, the BreatheSuite MDI Device monitors elements of inhaler technique such as:



It measures how long you shake your inhaler.



It senses if you hold your inhaler correctly.



It senses how long and forcefully you inhale.



It senses if you push down on your inhaler at the right time.



It records inhaler use.

This information is then stored on the BreatheSuite MDI Device and transferred to the BreatheSuite app.

The BreatheSuite MDI Device is an inhaler add-on compatible with certain types of metered dose inhalers. Check www.breathesuite.com/compatibility for details on which inhalers are compatible with the BreatheSuite MDI Device.

Bluetooth Pairing & Syncing

To pair your BreatheSuite MDI Device, follow the instructions in the BreatheSuite app.

After the initial pairing, the BreatheSuite MDI Device will automatically connect to the BreatheSuite app when the app is open.

To view your inhaler usage, you must sync your BreatheSuite MDI Device to the BreatheSuite app.

To keep your data up-to-date, sync your Device to the BreatheSuite app at least once a day.

To sync your BreatheSuite MDI Device:

1. Shake the BreatheSuite MDI Device and wait for the blinking blue light to appear.



2. Open the BreatheSuite app on your smartphone and ensure Bluetooth is enabled.



3. Wait for the app to retrieve the data from the BreatheSuite MDI Device.



Frequently Asked Questions

A comprehensive list of FAQ can be found through the BreatheSuite app by navigating to the Settings page, and clicking on Help Center.

What does my BreatheSuite MDI Device track?

The BreatheSuite MDI Device tracks the following aspects of your inhaler technique:

- It measures how long you shake your inhaler.
- It senses if you hold your inhaler correctly.
- It senses how long and forcefully you inhale.
- It senses if you push down on your inhaler at the right time.
- It records inhaler use.

Upon syncing your Device, all of this information is sent to your BreatheSuite app. You can use your smartphone to view technique feedback, get tips on how to improve your technique, and view trends about your inhaler use.

How do I sync my BreatheSuite MDI Device?

1. Shake the BreatheSuite MDI Device and wait for the blinking blue light.
2. Open the BreatheSuite app on your smartphone and ensure Bluetooth is enabled.
3. Wait for the app to retrieve the data from the BreatheSuite MDI Device.

Why is tracking inhaler technique important?

Inhaler technique is important to ensure the best therapeutic success. Studies show that correct inhaler usage results in less frequent rescue inhaler usage.

Will the BreatheSuite MDI Device work if I'm not in close proximity to my smartphone?

The BreatheSuite MDI Device will keep track of your inhaler use even if you're not in close proximity to your smartphone. The next time you sync your Device, it will send the stored information to the BreatheSuite app automatically.

If you want your BreatheSuite MDI Device to send the information automatically:

- Do not turn Bluetooth off in your smartphone settings.
- Do not “Swipe Close” the BreatheSuite app on your smartphone.

Will the BreatheSuite app work if I am offline?

No, the BreatheSuite app requires a stable internet connection to function as intended.

What do I do if I get a new inhaler?

When you get a new inhaler or refill a prescription, attach your BreatheSuite MDI Device to the new inhaler and continue using it as normal. If your

prescription changes and you're required to add a different inhaler, you can do so in the "Prescriptions" tab on the BreatheSuite app.

Can I clean my BreatheSuite MDI Device?

Do not put your Device under water or in a dishwasher or sterilizer. This could damage your Device. Remove the Device from your inhaler before cleaning. Clean the outside of the Device using a mild soap on a slightly damp cloth. Allow it to air dry.

Why is my BreatheSuite MDI Device not lighting up?

The Device battery may no longer have adequate charge. Please contact the BreatheSuite support team at help@breathesuite.com or call toll-free 1-855-667-8931 so we can resolve the issue. The

battery included with every BreatheSuite MDI Device has a lifespan of one year.

Why is my dose missing?

If you "Swipe Close" the app during dose sending, this could result in your dose not being recorded in the app. Ensure that while your dose is being sent to your smartphone (while you see the BreatheSuite wheel spinning), you do not close the app.

There are a number of reasons why your dose may not be recorded in the app, including:

- A poor Bluetooth connection.
- An interruption of internet connection.

- The battery in the BreatheSuite MDI Device does not have adequate charge.

To guarantee that your dose is recorded in the BreatheSuite app ensure that:

- The BreatheSuite MDI Device and your smartphone are in close proximity and Bluetooth is enabled when syncing.
- You have a stable internet connection.
- The blue light on the BreatheSuite MDI Device is blinking when taking a dose.

If a dose was not recorded you can manually track the dose and mark it as taken in the BreatheSuite app.

Instructions on how to manually mark a dose as taken can be found in the Help Center:

1. Open the BreatheSuite app
2. Click on the Settings page
3. Click on Help Center for a list of topics

If you have any questions, please contact us!
1-855-667-8931; help@breathesuite.com

Warnings and Precautions

The BreatheSuite MDI Device is not meant to communicate emergencies.

If you're having an asthma attack or a medical emergency, call your doctor right away.

Device information can be delayed, and your doctor/circle of care may not be aware of your condition.

The BreatheSuite MDI Device can help patients and their care teams understand patterns over time. If there is a medical emergency or emergency use, care teams will not be immediately informed.

If your BreatheSuite MDI Device interferes with use of your inhaler, remove your BreatheSuite MDI Device immediately.

Send an email at help@breathesuite.com or call 1-855-667-8931 to report your BreatheSuite MDI Device interfering with inhaler usage.

Never delay using your inhaler in order to attach your BreatheSuite MDI Device.

Rescue inhalers are meant to be used for shortness of breath. Do not delay using your inhaler to ensure your BreatheSuite MDI Device is attached.

The BreatheSuite MDI Device is not a dose counter.

Please use the dose counter on your inhaler (if it includes one).

The BreatheSuite MDI Device may not be immersed in liquid.

Do not place the Device under water or put it in a dishwasher or a sterilizer. It could damage the BreatheSuite MDI Device and cause it to not function properly.

Choking Hazard

Keep away from pets and small children.

Do not try to remove the battery from the BreatheSuite MDI Device or try to service the Device yourself.

This could damage the Device and cause it to malfunction. If you are having a problem with your Device or think your battery does not have an adequate charge, please email

help@breathesuite.com or call 1-855-667-8931.

Changes and/or modifications not expressly approved by BreatheSuite for compliance could void the user's authority to use the BreatheSuite MDI Device.

The BreatheSuite MDI Device is not intended to tell you how much medication reaches your lungs.

The BreatheSuite MDI Device is meant to track the way you use your inhaler. BreatheSuite provides tips for use and does not replace your inhaler's packaged guidelines. Always follow your doctor's advice and inhaler's packaged guidelines to learn how to use your inhaler.

WARNING: No modification of this equipment is allowed.

Indications for Use

The BreatheSuite MDI Device is an electronic device intended for single-patient use of patients 4 years of age and older. It assists asthma and COPD patients in recording and monitoring the actuations and technique of prescribed metered dose inhaler (MDI) usage. The BreatheSuite System is composed of the disposable, battery powered, portable BreatheSuite MDI Device and a mobile application.

The BreatheSuite MDI Device is an accessory designed to work with an MDI by attaching to the top of the canister of the inhaler. The BreatheSuite MDI Device does not interfere with regular MDI usage and can be removed and reattached with ease. The BreatheSuite MDI Device does not actuate the inhaler

but rather gathers information based on manual MDI usage.

The BreatheSuite MDI Device measures the parameters of MDI use and records them for review by the patient. The BreatheSuite application records, stores, and transmits usage events from the BreatheSuite MDI Device to a remote storage system. Furthermore, BreatheSuite MDI reminds the patient of important steps of MDI use through visual feedback in the BreatheSuite application.

The output of the BreatheSuite System is not intended to diagnose or replace a diagnosis provided by a licensed physician. The BreatheSuite system is not intended for use as a MDI medication dose counter, nor is it intended to indicate the quantity of

medication remaining in an MDI. The BreatheSuite MDI Device is not intended to replace a physician's advice or inhaler labels; patients are expected to always follow their doctor's advice and inhaler labels.

The BreatheSuite System may also be used in clinical trials where researchers need to know information about use of a MDI Medication(s) by a participant.

Contraindications

The output of the BreatheSuite System is not intended to diagnose or replace a diagnosis provided by a licensed physician.

The BreatheSuite system is not intended for use as an MDI medication dose counter, nor is it intended to indicate the quantity of medication remaining in an MDI.

The BreatheSuite MDI Device is not intended to be used as a tool to report how much medication reached the lungs, but rather the technique of the patient during use.

A patient should not change their prescribed medication plan based on feedback from the

BreatheSuite system, but rather attempt to practice proper inhaler technique based on the feedback.

Troubleshooting

A list of troubleshooting topics can be found through the BreatheSuite app by navigating to the Settings page, and clicking on the Help Center.

Turning on your BreatheSuite MDI Device

Turn on your BreatheSuite MDI Device by shaking it. Shake your inhaler with the BreatheSuite MDI Device attached to ensure all the data is captured.

Marking a dose as taken







Instructions on how to manually mark a dose as taken can be found in the Help Center:



1. Open the BreatheSuite app
2. Click on the Settings page

3. Click on Help Center for a list of topics

Appendix

Symbols

	Serial Number.
	Product should not be disposed of in a landfill.
	Date of manufacture (YYYY-MM-DD).
	Name of manufacturer.
IP22	Protected from safety risks due to dripping water when Device is tilted up to 15 degrees.
	Refer to the instruction manual.
	Federal Communications Commission.

	Device is an RF transmitter.
	TUV SUD Safety.

Operating and Storage Conditions

- Operating temperature: -20 to 40 C
- Storage temperature: -25 to 70 C
- Relative Humidity: 5% to 95% non condensing
- Altitude: 700 to 1060 hPa

Device Performance

If you notice one of the following things not working, your Device is likely not functioning as intended correctly as a result of electromagnetic interference:

- Blue light no longer lighting up after shaking
- Device unable to connect to BreatheSuite app via Bluetooth

If your BreatheSuite MDI Device stops working, Please contact the BreatheSuite support team at help@breathesuite.com or call toll-free 1-855-667-8931 so we can resolve the issue. The battery included with every BreatheSuite MDI Device has a lifespan of one year.

The main functionality of the BreatheSuite MDI Device is an inhaler add-on. If you think at any time that there is a possibility your Device is interfering with your inhaler usage, please remove it and use your inhaler as normal.

Electromagnetic Compatibility

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the information provided in this user manual.

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment. The following table provides

recommended separation distances between portable and mobile RF communications equipment and the BreatheSuite Bluetooth-enabled MDI Device.

Recommended Portable and Mobile RF Communications Equipment and BreatheSuite MDI Device

The BreatheSuite MDI Device is intended for use in an electromagnetic environment in which radiated radiofrequency (RF) disturbances are controlled. The user and/or installer of the unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communications equipment (emitters) and the BreatheSuite MDI Device, according to the maximum output power of the equipment, as recommended in the table below.

Rated maximum output power of transmitter	Separation distance according to the frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
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 in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to 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.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and antennas should be used no closer than 30 cm (12 inches) to any part of the BreatheSuite MDI Device. Otherwise, degradation of the performance of this equipment could result.

Declaration – electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group1 Class B	The BreatheSuite MDI 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.

Electromagnetic Immunity	Test Level
IEC 61000-4-2 - Electrostatic Discharge	+/- 2, 4, 6 and 8kV contact discharge +/- 2, 4, 6, 8 and 15kV air discharge
IEC 61000-4-3 - Radiated RF EM fields	10 V/m 80 MHz - 2.7 Ghz 80% AM at 1 kHz
IEC 61000-4-3 - Proximity fields from RF wireless communications equipment	2450 (Bluetooth), Pulse modulation: 217Hz, 2W, 0.3m, 28 V/m
IEC 61000-4-8 - Rated power frequency magnetic fields	30 A/m, 50 Hz or 60 Hz

RF Transmission

Technical Specification	Value
Radio Frequency	2.4 GHz
Modulation	GFSK
Channels	40 channels, 2MHz/channel, FHSS
Protocol	Bluetooth Low Energy
Power Source	One 3V CR2477 Lithium Battery

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories, transducers 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.

If you have any questions, please contact us!
1-855-667-8931; help@breathesuite.com

User Manual Information

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