



BreatheSuite

User Manual



BreatheSuite Metered Dose Inhaler (MDI) Device

BreatheSuiteMDIV1 (v1.1)

Table of Contents

Indications for Use	4
How it Works	7
Getting Started	10
Sign Up	10
Assigning a device to a prescription	13
Taking a puff and syncing a dose	15
Bluetooth Pairing & Syncing	19

Product Description	22
Frequently Asked Questions	24
Precautions	33
Warnings	38
Contraindications	40
Troubleshooting	41
Appendix	43

Indications for Use

The BreatheSuite MDI Device is an electronic device intended for single-patient use of patients 5 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 can be used both indoors and outdoors as well as in home and work settings.

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.

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 the inhaler mouthpiece is horizontal.



It measures how long you inhale.



It senses if you push down on your inhaler as you start to breathe in.



It records the date and time of each inhaler use.

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

The BreatheSuite app assists the user in recording and monitoring inhaler usage and technique.

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

For detailed instruction on how to use the BreatheSuite MDI Device and app, including how-to videos and in-app screenshots, visit www.breathesuite.com/help/gettingstarted.

Sign Up

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



2. Create an account in the BreatheSuite app by pressing the “Sign Up” button and then entering your email and creating a password.



3. Verify your account using the verification code sent to your

email.	
--------	--

4. You're done! You're now ready to assign your device to a prescription.

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

Assigning a device to a prescription

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



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



-
3. A “Prescription Setup” page will appear in the app. Select your:
- a. Medication Type (Controller or Rescue)
 - b. Medication Name
 - c. Medication Dosage
 - d. Number of AM puffs (Controller Only)
 - e. Number of PM puffs (Controller Only)
- and press “Save”. This will bring you to the homepage of the BreatheSuite app.

4. Attach the BreatheSuite MDI Device to the top of the canister of your inhaler by gently pressing it down until it stops. You're now ready to use BreatheSuite!



Taking a puff and syncing a dose

When it's time to take a dose from your inhaler, follow the instructions below.

1. Make sure your BreatheSuite MDI device is attached to the top of the canister of your inhaler.



2. Shake your inhaler and the BreatheSuite MDI Device to mix your medication and to wake up your device.




3. Take a puff from your inhaler as prescribed, pressing down on the top of the BreatheSuite MDI Device similar to how you'd press on the top of the inhaler canister.



4. Open the BreatheSuite app on your smartphone and ensure you are connected to the

internet and that Bluetooth is enabled.

5. The dose will be automatically synced in the app. If the dose does not appear, shake the device and press the  button in the app to sync the device manually.



Note: 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.

Bluetooth Pairing & Syncing

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

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. Ensure that Bluetooth is enabled on your smartphone and open the BreatheSuite app.



3. Wait for the app to retrieve the data from the BreatheSuite MDI Device. If the dose does not appear, shake the device and press the  button in the app to sync the device manually.



Product Description

The BreatheSuite MDI Device will help you record and monitor 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 the inhaler mouthpiece is horizontal.



It measures how long you inhale.



It senses if you push down on your inhaler as you start to breathe in.



It records the date and time of each 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/help/compatible-inhalers

for details on which inhalers are compatible with 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 records the following aspects of your inhaler technique for each dose:

- How long you shook the inhaler (seconds).
- The angle of the inhaler mouthpiece compared to the horizontal (degrees).
- How long you inhaled (seconds).
- The time between pushing down on your inhaler and when you start to inhale (seconds).
- The date and time of each inhaler use.

Upon syncing your Device, all of this information is sent to your BreatheSuite app. You can use your

smartphone to monitor technique feedback 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. If the dose does not appear, make sure the BreatheSuite MDI device is blinking and press the  button to sync the device manually.

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 1.5 years.

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

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

Do not try to remove the battery from the BreatheSuite MDI Device or try to service it 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 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 assists in recording and monitoring of inhaler usage 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.

Warnings

WARNING: No modification of this equipment is allowed.

WARNING: Choking hazard, keep away from pets and small children.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper functioning. 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 malfunctioning.

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.

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 replace a physician's advice or inhaler labels; patients are expected to always follow their doctor's advice and inhaler labels.

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

 SN	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 may not be functioning as intended 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 been selected to last for 1.5 years of service without maintenance.

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 Separation Distances for BreatheSuite MDI

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	Minimum separation distance according to the frequency of transmitter (m)	
	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	0.23
0.1	0.38	0.73
1	1.2	2.3

10	3.8	7.3
100	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.

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

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

User Manual Information:

Copyright BreatheSuite Inc.

Model: BreatheSuiteMDIV1

Date of Issue: 2021-05-14