Quick Start Guide | Propeller Sensor for BREEZHALER®

What's included

1 BREEZHALER® and inhalation capsules

- Your inhaler and medication. You'll find instructions on how to use them in the box they come in.

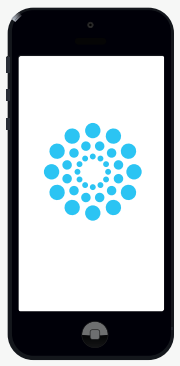
2 Propeller Sensor for BREEZHALER®

- Attaches to your BREEZHALER®
- Tracks when you use your BREEZHALER®
- Sends information to the Propeller mobile app

3 Access to the Propeller mobile app

You can use the Propeller mobile app to:

- Set up reminders so that your Propeller Sensor for BREEZHALER® chimes when it's time to take a dose
- Track your triggers and learn about factors that can cause your disease to flare up
- Print a report of your inhaler use to share with your doctor



Repeat prescriptions

- Your BREEZHALER® repeat prescription will not come with a new Propeller Sensor for BREEZHALER®.
- This Propeller Sensor will last for one year from the date of activation. The Propeller mobile app will remind you when it's time to get a new sensor.
- Check the Propeller mobile app for instructions on how to move your sensor from your old BREEZHALER® to your new one.

Please remember the Propeller Sensor and app are tools to help with the management of your asthma. Always make sure that you follow the manufacturer's guidelines when administering your BREEZHALER®.

Set-up instructions

⚠ The Propeller Sensor for BREEZHALER® will not work without the Propeller mobile app. To set up the sensor, you must first download the Propeller app onto your smartphone and follow the in-app instructions.

Step 1: Download the Propeller mobile app

Download on the App Store | GET IT ON Google Play

Here's how you do it:

- **Get out** your smartphone or tablet
- **Open** the 'App Store' app (on your iPhone) or the 'Google Play Store' app (on your Android phone)
- **Search** for 'Propeller'
- **Tap or click** to download and install the app

Step 2: Open the app and follow the in-app instructions to:

- **Create an account** that lets you use the sensor to better manage your symptoms
- **Activate your Propeller Sensor for BREEZHALER®** so that it can track how you use your inhaler
- **Attach your Propeller Sensor** to your BREEZHALER®

Need help getting set up?

- **You must still take your BREEZHALER® doses as prescribed**, even if the Propeller Sensor for BREEZHALER® is not attached.
- **Contact our Support Team** at help@propellerhealth.com or visit www.propellerhealth.com/call for our freephone number.

Warnings

The sensor is not meant to communicate emergencies
Call your doctor right away if you need care.

Sensor information can be delayed,
and your care team may not be aware of your condition
Propeller can help people to understand patterns over time, but it is not a real-time patient monitoring system; data can be delayed. If you are sharing your Propeller data with your healthcare provider, they may not be aware of your current condition.

If your sensor interferes in any way with use of your inhaler, remove your sensor
Send an email to help@propellerhealth.com.

Never delay using your inhaler in order to attach your sensor

The Propeller Sensor for BREEZHALER® should only be used with the BREEZHALER® inhaler provided with your prescribed medication

Do not put the sensor under water
Do not place the sensor under water or put it in a dishwasher or steriliser. It could damage the sensor and cause it to not function properly.

Do not try to remove the battery from the sensor or service the sensor
This could damage the sensor and cause it to not work properly. If you are having a problem with your sensor, please send an email to help@propellerhealth.com. Changes or modifications not expressly approved by Propeller for compliance could void the user's authority to operate the equipment.

Choking hazard
Keep away from small children.

Indications for use

Intended use for Sensor Model 2017-B

The Propeller System is intended to assist patients, carers and providers in monitoring a treatment regime to manage respiratory disease by automatically capturing, storing, calculating and displaying medication use information, reminders, trends and patterns in the day-to-day life of a patient with respiratory disease. The Propeller System includes inhaler sensors, mobile/web applications and the Propeller Web Platform.

The Propeller Sensor Model 2017-B (Propeller Sensor for BREEZHALER®):

- Is a device intended for single-patient use to assist patients and their doctors in confirming the inhalation and use of prescribed DPI by recording and monitoring the actuations of the BREEZHALER® device and the whirring noise of the spinning capsule during inhalation
- Provides on-sensor audio and/or visual reminders to aid the user in staying compliant with prescribed DPI medication schedules

The Propeller Sensor Model 2017-B connects via *Bluetooth*® technology (such as through the Propeller mobile application) to the Propeller Platform.

The Propeller mobile application is a mobile application intended to:

- Be used as a display to provide calculated outputs from the Propeller Platform
- Connect with the Propeller Sensors, including the Propeller Sensor Model 2017-B, and other Bluetooth devices
- Provide an interface for users to configure their accounts to add their doctor or carer as information recipients, as well as including information such as prescribed medications and associated dose schedules
- Capture user inputs such as surveys, symptoms, triggers and other information about a user's day-to-day disease monitoring

The Propeller web application is similar to the Propeller mobile application in functionality except that it does not provide a direct connection to the Propeller Sensors. The Propeller web application adds additional functionality for a doctor to log in to view patient accounts.

The Propeller Platform system is a cloud-based device which is intended to:

- Act as a remote storage system to store information captured from Propeller Sensors as well as user inputs
- Provide analysis capability to calculate trends and patterns associated with individual user behaviour such as adherence, control levels, trends, patterns, triggers and symptoms
- Provide summary reports and detailed information on patients that health care professionals can use for clinical decision support and professional diagnosis
- Allow for further connections to third-party systems such as Electronic Medical Records (EMR) integrations via an application programming interface (API)

The Sensor Model 2017-B is intended for adult use only.

The Propeller Sensor Model 2017-B and Propeller mobile application can be used both indoors and outdoors where it is safe to use portable wireless devices.

The output of the Propeller system is not intended to diagnose or replace a diagnosis provided by a medical doctor. The Propeller system is not intended for use as a DPI dose counter, nor is it intended to indicate the quantity of medication remaining in a DPI.

Appendix

Symbols used

ISO 7000 Sixth edition 2019-07: Graphical symbols for use on equipment

Serial number. Indicates the manufacturer's serial number so that a specific medical device can be identified. ISO 7000-2498.

Date of manufacture. Indicates the date when the medical device was manufactured (YYYY-MM-DD). ISO 7000-2497.

Manufacturer. Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. ISO 7000-3082.

Consult instructions for use. Indicates the need for the user to consult the instructions for use. ISO 7000-1641.

Caution. Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. ISO 7000-0434A.

Temperature limit. Indicates the temperature limits to which the medical device can safely be exposed. ISO 7000-0632.

Atmospheric pressure limitation. Indicates the range of atmospheric pressure to which the medical device can safely be exposed. ISO 7000-2621.

Humidity limitation. Indicates the range of atmospheric pressure to which the medical device can safely be exposed. ISO 7000-2620.

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IEC 60417:2002 DB: Graphical symbols for use on equipment

Type BF applied part. To identify a type BF applied part complying with IEC 60601-1. IEC 60417-5333.

Non-ionising electromagnetic radiation. To indicate equipment or systems e.g. in the medical electrical area that include RF transmitters. IEC 60417-5140.

Miscellaneous

Dispose of device in accordance with local regulations.

Federal Communications Commission.

Device meets requirements of European Medical Device Directive 93/42 /EEC.

EC REP **Indicates the authorised representative in the European Community.**

Single patient multiple use.

MD **Medical device.**

Quality of service

1. **Bluetooth**® wireless technology uses several low-level data handling techniques to ensure the integrity of data transmission to and from the sensor. Additionally, the sensor uses its own, higher-level data handling measures to ensure that events are received accurately. If the sensor is not able to establish a reliable wireless connection for any reason, the sensor has been designed to internally record data for automatic retransmission when a reliable connection can be established.
2. This is a wireless device. Wireless devices can cause interference with other medical electrical equipment.
3. This device uses Bluetooth Smart wireless technology to communicate securely and reliably in areas with high levels of radio interference. This technology uses advanced frequency-hopping techniques to maintain high levels of accuracy in the most saturated radio environments and was selected specifically for these features.

Electromagnetic compatibility

1. 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.
2. The sensor is designed to automatically resume normal operation in the unlikely event of interference from common electromagnetic systems (for example, anti-theft systems, metal detectors and radio-frequency identification readers). Move away from the system and the sensor will resume normal operation.
3. 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 Propeller sensor.

Recommended separation distances between portable and mobile RF communications equipment and the Propeller Sensor Model 2017-B

The Propeller Sensor Model 2017-B is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Propeller Sensor Model 2017-B can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Propeller Sensor Model 2017-B as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 0.35\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.70\sqrt{P}$
0.01	0.035	0.035	0.070
0.1	0.11	0.11	0.22
1	0.35	0.35	0.70
10	1.1	1.1	2.2
100	3.5	3.5	7.0

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in metres (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.

Guidance and manufacturer's declaration – Electromagnetic immunity

The Propeller Sensor Model 2017-B is intended for use in the electromagnetic environment specified below. The customer or the user of Propeller Sensor Model 2017-B should ensure 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%.
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 location in a typical commercial or hospital environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the Propeller Sensor Model 2017-B than the recommended separation distance calculated using the equation applicable to the frequency of the transmitter. For these equations and the resulting recommended separation distances, see the table, 'Recommended separation distances between portable and mobile RF communications equipment and the Propeller Sensor Model 2017-B'. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

[a] Field strengths from fixed transmitters, such as base stations for radio (mobile/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 caused by fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Propeller Sensor Model 2017-B is used exceeds the applicable RF compliance level above, the Propeller Sensor Model 2017-B should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Propeller Sensor Model 2017-B.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Guidance and manufacturer's declaration – Electromagnetic emissions

The Propeller Sensor Model 2017-B is intended for use in the electromagnetic environment specified below. The customer or the user of Propeller Sensor Model 2017-B should ensure it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – Guidance
RF emissions CISPR 11	Group 1	The Propeller Sensor Model 2017-B 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 Propeller Sensor Model 2017-B is suitable for use in all establishments, including domestic establishments.

ERP: Effective radiated power is the power required at the input of a lossless reference antenna to produce, in a given direction at any specified distance, the same power flux density as that radiated by a given device. The effective radiated power for the antenna is 0 dBm.

RF Transmission

FC Contains US Federal Communications Commission ID: QOQBGM12LMA (HVIN: BGM123A)
Contains Industry Canada: 5123A-BGM12LMA (HVIN: BGM123A)

This device complies with Industry Canada's licence-exempt RSSs. Operation is subject to the following two conditions:
1. This device may not cause interference; and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

This device complies with RoHS 2011/65/EU.

Technical specification	Value
Radio frequency	2.4GHz
Modulation	GFSK
Channels	40 channels, 2MHz/channel, FHSS
Transmit Power	0 dBm
Protocol	Bluetooth Smart
Power source	One non-replaceable lithium manganese CR2032 battery. Under normal use conditions, the sensor battery is expected to last for one year after first use. Battery life is based on the sensor being synchronised prior to the 'Sync by' date that appears on the packaging.

General

The Propeller Sensor for BREEZHALER® is for patients who have been prescribed BREEZHALER®.

The sensor is intended to be used as a single-patient device. Each sensor should only be used for one medication. You can re-attach the sensor to refills of the same prescription for the lifetime of the sensor's battery. The sensor will remain synced to your smartphone even when moved to a refill of the same medication. The sensor is not provided sterile, nor does it require sterilisation. Remove the sensor from your inhaler before cleaning. Clean the outside of the sensor with a clean, dry cloth. Do not put the sensor under water or in a dishwasher or steriliser – this could damage the sensor.

The sensor cannot be used without the Propeller Mobile App. See the Propeller Mobile App for all setup instructions, including sensor attachment. The sensor can be removed from BREEZHALER® by pressing inwards on the clear tab on the front of the sensor while pulling upwards on the BREEZHALER® inhaler. The sensor can be attached to BREEZHALER® by snapping the BREEZHALER® inhaler base into the top of the sensor with the front of the BREEZHALER® inhaler aligned with the clear portion of the sensor.

Operating and storage conditions

- Operating temperature: 0° to 40° C
- Storage temperature: -10° to 60° C
- Relative humidity: 5% to 95% non-condensing
- Altitude: 700 to 1060 hPa

Compliance information

This device conforms to:
- IEC 60601-1:2005/(R)2012
- IEC 60601-1-2:Edition 3:2007-03
- IEC 60601-1-6:Edition 3:2010-01
- IEC 60601-1-11:2011

Your sensor may contain >.1% of 1,2-Dimethoxyethane (EGDME). This chemical is used in the production of the lithium battery that provides power to your sensor. Under normal use conditions, you should not come into contact with the battery. You should not attempt to replace the battery.

MD Propeller Sensor for BREEZHALER® is a medical device intended for direct distribution to and use by the public. Report any serious incidents to the competent authority and to:

Reciprocal Labs Corporation
1 South Pinckney Street, Suite 610
Madison, WI 53703
USA
Assembled in the USA

CE ResMed SAS
EC REP Parc Technologique de Lyon
292 Allée Jacques Monod
69791 Saint-Priest Cedex FRA

Additional instructions for use are available in electronic format at support.propellerhealth.com. You may request these additional instructions in paper format by emailing help@propellerhealth.com.

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