Legal

Asthmapolis copyright language, patents other IP

"Made for iPod," "Made for iPhone," and "Made for iPad" mean that an electronic accessory has been designed to connect specifically to iPod, iPhone, or iPad, respectively, and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPod, iPhone, or iPad may affect wireless performance.

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What's Inside?

(1) Asthmapolis(TM) sensor

[picture here]

(1) Asthmapolis sensor MAC Address label

[picture]

(10) Adhesive Pads

[picture here]

(1) Small Adapter Cap (color for the small ones?)

[picture here]

(2) Large Adapter Caps (color for the large ones?)

[picture here]

(1) IEC 60950 Charging cable and adapter [needs a part number from LaBarge]*

[picture here]

(1) User's Guide (this document)

*Do not use a different charging cable and adapter other than the one that is provided with the sensor. Using a different charging cable and adapter may damage the sensor or cause the sensor to operate incorrectly.

Indications for Use

The Asthmapolis Sensor is a prescription only device, intended to assist physicians and patients in tracking a patient's use of their inhaled medications. The Asthmapolis Sensor is not intended for use as a dose counter.

Introduction

The Asthmapolis Sensor attaches to the top of your inhaler and monitors your inhaler usage. With a compatible mobile phone, the Sensor also records the location of each inhaler use. This information can provide insight into when and where you are using your rescue inhaler, and how well you're adhering to your controller medication.

The Sensor uses Bluetooth® wireless technology transmit inhaler use data and is compatible with:

Android devices

Apple devices

Qualcomm Life 2net™ Hub

Some Bluetooth-enabled feature phones

Please see the corresponding section of the User Guide for setup instructions for your device.

Note that the Sensor can only pair to one device at a time—pairing with a new device will associate the Sensor with the new device and remove the link to the previously paired device.

Sensor Features

The Sensor has two buttons, a primary button that detects when you use your inhaler, and a secondary button that is used for other functions like Pairing and placing the sensor in Airplane Mode.

The Sensor has two green and amber status lights that are used to indicate the success or failure of the operations described in the User Guide.

[image of sensor indicating button locations]

[image of sensor indicating light locations]

Attaching the Sensor

The Sensor uses a disposable adapter cap to attach to your inhaler. Inhaler canisters come in different sizes. Two sizes of adapter caps, blue and white, are available to fit the majority of medications. Select the adapter cap that fits your medicine canister.

Remove one of the adhesive foam disks from the paper strip.

Place the adhesive disk on top of your inhaler canister and remove the paper backing.

Firmly press on the appropriate adapter cap.

Next, align the notches in the sensor with the pins on the adapter cap. Press them together and gently twist the sensor clockwise until it snaps into place.

When your inhaler runs out, detach the sensor by gently twisting it counter clockwise.

The adapter cap on the used inhaler can be discarded.

If this is your first time using the Sensor, you will need to Pair the sensor according to the instructions that follow. If you are attaching the Sensor to a different medication, be sure to change the medication type affiliated with the Sensor in your account.

[image of canister, adhesive disk, adapter cap, and sensor going together]

Android Device

The Asthmapolis sensor has tested with a wide range of Android devices[?]

Initial setup:

Download and install the Asthmapolis App from the Android Marketplace.

Launch the app and create a new account.

Log in to the application and select the Add a New Sensor option. Follow the on screen instructions to select your medication.

Press and hold the secondary button on the sensor until the status lights begin flashing.

The sensor and the Android device will now pair automatically.

The status lights will flash green four times to indicate successful pairing, or amber if pairing fails.

Usage:

Use your inhaler as you normally would. The Sensor will automatically connect to your phone, even if you have it in your pocket. If you choose, the Asthmapolis App will also attempt to determine your location and then upload your usage data to your account.

Apple iOS Device

The Sensor is compatible with several Apple iOS devices.

Made for:

iPod touch® (3rd and 4th generation)

iPhone 4®

iPhone 3GS®

iPhone 3G®

iPad 2®

iPad®

The Asthmapolis App requires an Internet connection (via cellular network or WiFi) for full functionality.

Initial setup:

Download and install the Asthmapolis App from the App Store.

Launch the application and create a new account.

Close the app and navigate to Settings -> General -> Bluetooth and turn Bluetooth "On."

Press and hold the secondary button on the Sensor until the indicator lights begin flashing.

The sensor and the iOS device will now pair automatically.

The indicator lights will flash green four times to indicate successful pairing, or amber if pairing fails.

Launch the app and follow the on screen instructions to select your medication.

Usage:

Use your inhaler as normal. Periodically, you will need to sync your Sensor with the Asthmapolis App to view and analyze your inhaler usage data.

To sync the Sensor with your iOS device:

Launch the Asthmapolis App.

Press the secondary button.

The status light will glow green when the sync has completed.

See the Troubleshooting section if the status lights do not glow green.

Qualcomm Life 2net™ Hub

Initial setup:

Plug the 2net™ Hub into a standard power outlet and wait until the indicator light glows green.

Press and hold the secondary button on the Sensor until the status lights begin flashing.

The green indicator light on the 2net™ Hub will flash four times to indicate successful pairing, or amber if pairing fails.

Once paired, you will receive instructions on associating your medication via the Asthmapolis web application [how?].

Usage:

Use your inhaler as you normally would. Every few hours the Sensor will automatically attempt to sync with the 2net™ Hub. However, if you are out of range of the Hub when the Sensor attempts to sync, you may need to sync manually.

To manually sync the Sensor with the 2net™ Hub:

Be sure you are in the same room as the 2net™ Hub.

Press the secondary button.

The status lights on the sensor will glow green when the sync has completed.

See the Troubleshooting section if the status light does not glow green.

Feature Phone

The Sensor is compatible with several Bluetooth-enabled feature phones. The Sensor uses your phone to automatically send a text message containing information about your inhaler use back to your Asthmapolis account. Standard messaging rates apply, [messages sent per

day]. To view a list of phones known to be compatible with the Sensor visit: [feature phone list here]

Initial setup:

Access your phone's Bluetooth Settings.

Press and hold the secondary button on the sensor until the status lights begin flashing.

Select "Scan for Devices" or a comparable option and select the "Asthmapolis Sensor" when it appears.

You may be asked to enter a PIN code, if so type "1234".

If available, select the "Connect Automatically" option.

The status lights will flash green four times to indicate pairing success, or amber if pairing fails.

Additional configuration may be required, view [website] for additional information.

Usage:

Use your inhaler as you normally would. The Sensor will automatically connect to your phone, even if you have it in your pocket, and transmit data back to the Asthmapolis web site via text message.

Charging the Sensor

Under normal use, the sensor battery should last several weeks before it needs to be recharged. If the battery needs to be recharged, the status lights will glow amber after any button is pressed.

[image of USB charge port location]

To recharge the Sensor:

Plug the Sensor into the provided charger or the USB port of a computer using the included cable.

While charging, the status lights will glow amber.

When charging is complete, the status lights will glow green.

Disconnect the Sensor from the charger if you need to use the inhaler during charging.

Airplane Mode

Most airlines permit the use of Bluetooth devices, such as wireless headphones, during flight. However, some airlines require Bluetooth devices to be disabled. To comply with these regulations, the Sensor has an Airplane Mode that disables all wireless communication.

While in Airplane Mode the Sensor continues to record inhaler use data to be transmitted when the Sensor exits Airplane Mode.

To enable Airplane Mode:

Press and hold the secondary button for 5 seconds until the amber status lights flash.

Release the button and immediately press it again while the amber status lights are still flashing.

The green status lights flash three times to indicate that the sensor is in Airplane Mode.

To exit Airplane Mode:

Press the secondary button.

The Sensor will automatically transmit any saved usage data.

Caring for the Sensor

When necessary, the Asthmapolis Sensor may be cleaned using mild soap on a damp, clean cloth, followed with a rinse using a damp, clean cloth. Allow the sensor to air dry.

Warning:

Do not immerse the Asthmapolis Sensor or place it in a dishwasher, or sterilizer. Doing this may damage the sensor and cause it to not function properly.

Troubleshooting

During data transmission, the status lights flash green when the sensor has successfully transmitted data.   If the sensor cannot transmit data, it will indicate the reason using different status light patterns described below.

Alternating green and amber flashes: the Sensor is not paired to a device. Follow the instructions in the Initial Setup section of the appropriate device.

Amber glow: the battery is low. The inhaler use has been tracked but will not be transmitted until the battery is charged following the instructions in the Charging the Sensor section.

Green flashes: the sensor is in airplane mode. The inhaler use has been recorded but will not be transmitted. Press the secondary button to exit Airplane Mode and transmit all pending data.

No status light activity: the sensor battery may be fully discharged. Charge the sensor following instructions in the Charging the Sensor section. In most cases the inhalation event was not tracked if the status lights do not glow—you can use the web dashboard or mobile app to manually enter inhaler use details.

Contraindications

Detach the sensor from the medication canister when charging.

When charging, the Asthmapolis sensor is not functional.

The Asthmapolis Sensor may not be immersed in liquid.

The Asthmapolis Sensor is not intended to communicate an emergency.

The Asthmapolis Sensor is not a dose counter. Please make sure that you use the dose counter provided with your inhaler medication if it has one.

Never delay use of your inhaled medications if you are experiencing symptoms because the Asthmapolis Sensor is not attached.

In areas where wireless devices should not be used, put the Sensor in Airplane Mode to avoid interference. If you are experiencing symptoms in an area where wireless devices should not be used, use the inhaler first and then put the Sensor in Airplane Mode when possible.

Compliance Information

This device conforms to:

IEC 60601,

IEC 60601-1,

IEC 60601-1-2

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and

2. This device must accept any interference received, including interference that may cause undesired operation.

This portable transmitter with its antenna complies with FCC RF exposure limits for general population / uncontrolled exposure.

Warning: Changes or modifications not expressly approved by Asthmapolis for compliance could void the user's authority to operate the equipment.

- Do not attempt to remove the battery from the device or perform servicing activities on the device. This may cause damage to the device or cause it to work incorrectly. If you are having a problem with your sensor, please dial: (XXX) XXX-XXXX.

- Do not use a different charger than the one that is provided with the sensor, a failure to do so may damage, or cause the device to operate incorrectly.

- This is a wireless device. Wireless devices can cause interference with other medical electrical equipment. If you intend to use your medication around other medical electrical equipment, step through the sequence of events above for synching the sensor and placing it in airplane mode and verify that it is operating according to the instructions. Even if the sensor does not transmit an event due to interference, the event will be stored on the sensor and will be sent at a later time.