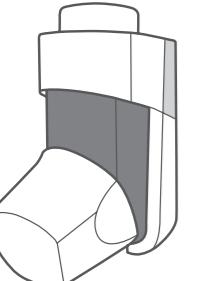




USA Medications: For use only with
Teva ProAir™ HFA or
Teva Albuterol Sulfate HFA

EN Product Manual



This Product Manual will help you to get the most out of your Hailie® sensor. Please read the manual before using the sensor.

Hailie® Sensor Intended Use

The Hailie® sensor is intended for single-patient use in the home environment as an electronic data capture accessory for monitoring and recording actuations, inspiratory flow, and inhaler shake, for prescribed inhaler usage.

The Hailie® sensor may be used in the following applications: in clinical practice or clinical trials, where specialists, general practitioners,

nurses, and educators need to know if a patient has used their prescribed medication, or assess inspiratory flow and inhaler technique; and in patient self-management.

The Hailie sensor is compatible only with the **Teva ProAir™ HFA** or **Teva Albuterol Sulfate HFA** inhalers.

The Hailie® sensor is not intended to indicate remaining quantity of medication in an Inhaler and does not include a dose counting function. The Hailie sensor is not intended to provide spirometry measurements.

Important User Information

Warnings identify actions or situations that could lead to personal injury. Take note of all warnings before using the Hailie® sensor.

Precautions identify actions or situations that could damage the Hailie® sensor or other equipment, or affect the accuracy or availability of recorded usage data.

Notes contain advisory information about some aspect of the Hailie® sensor or its use.

Warnings and Precautions

⚠ To ensure your Inhaler functions correctly, do not use the Hailie® sensor with any other Inhaler or medication than that indicated on the Hailie® sensor label.

⚠ Refer to the labelling provided with the Inhaler for instructions on use. Carry out all steps required to use your Inhaler according to the instructions.



⚠ The Hailie® sensor is intended to track medication usage. It is not intended to diagnose your condition or to replace the diagnosis of a licensed physician.

⚠ This manual does not provide information on how to use prescription medication, and is not intended to replace the advice provided by a health professional. Directions for using prescription medication should be obtained from a health professional and followed accordingly. Any questions related to prescription medication should be referred to a health professional.

⚠ Remove the Hailie® sensor from the Inhaler before cleaning the Inhaler.

⚠ User to store the device when not in use and avoid unnecessary shaking or motion to maintain battery service life.

⚠ Do not expose the Hailie® sensor to excessive perspiration during exercise.

⚠ For hygiene and data integrity reasons, do not use the Hailie® sensor with more than one patient.

⚠ The Hailie® sensor must be paired with a compatible Bluetooth® mobile device in order to sync stored usage data.

⚠ Download a compatible mobile app to communicate with your sensor. For more information go to support.hailie.com.

What is the Hailie® Sensor?

The Hailie® sensor is a companion tool that tracks your prescribed medication use and reminds you when to take your prescribed medication.

The Hailie® sensor is a small battery-powered electronic data logger that attaches to an Inhaler. The Hailie® sensor contains an electronic clock and calendar that is used to log the date and time of Inhaler usage. Usage data can be uploaded via a wireless Bluetooth® connection.

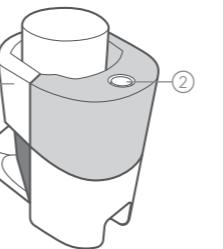
⚠ If your prescribed Inhaler changes, do not use it with this Hailie® sensor. Only use a Hailie® sensor that is labelled as compatible with your prescribed Inhaler.

⚠ The Hailie® sensor records parameters of inhaler use, including inspiratory flow and shaking the inhaler before use, which may be used by your doctor to help assess your inhaler usage.

⚠ Since the time of printing certain information might have changed. For an up to date list of compatible inhalers please refer to www.adherium.com/compatibility.

⚠ The Hailie® sensor intended population is identical to the intended population of the compatible Inhaler.

Hailie® Sensor Components



Key

1. Door Slide
2. Status Button/Light Emitting Diode (LED)

Compatible Inhalers

The Hailie® sensor is designed to work only with the Inhaler and medication indicated on the Hailie® sensor label.

Country	Medication	Strength
US	Teva ProAir™ HFA	90 mcg
	Teva Albuterol Sulfate HFA	90 mcg

⚠ Since the time of printing certain information might have changed. For an up to date list of compatible inhalers please refer to www.adherium.com/compatibility.

⚠ If pairing is not successful within 60 seconds the LED will flash red. The pairing process can be repeated if necessary by pressing the Status Button 3 times quickly to initiate pairing.

Preparation for First Use

⚠ Setup and use of the Hailie® sensor for patients under 12 years of age requires assistance from a parent or caregiver.

Following manufacture, the Hailie® sensor is placed in Deep-Sleep mode to conserve battery life.

⚠ The Hailie® sensor will re-enter Deep-Sleep mode within 24 hours if no activity occurs.

Installing and Removing an Inhaler

Installation



Ensure Bluetooth® is enabled on your mobile device.

1. Open the compatible mobile app and follow the prompts to complete the pairing process.
2. Wake up the Hailie® sensor by pressing the Status Button.
3. The Hailie® sensor will wake up and the LED will flash green.
4. After 5 seconds the Hailie® sensor will automatically enter Bluetooth® pairing mode and the LED will flash blue for 60 seconds.
5. Follow the prompts to complete the pairing process.
6. The LED will flash green to indicate successful pairing.

⚠ If pairing is not successful within 60 seconds the LED will flash red. The pairing process can be repeated if necessary by pressing the Status Button 3 times quickly to initiate pairing.



The Hailie® sensor intended population is identical to the intended population of the compatible Inhaler.



<p>Keep the Hailie® sensor clean and free of chemicals, steam, water and dust. Clean the outside plastic enclosure with a lightly dampened cloth. Check the Hailie® sensor is clean and repeat if necessary. Leave it to dry in a warm place that is less than 30°C (86°F).</p> <p>Such as contactless payment or anti-theft systems, can affect the Hailie® sensor, and should be kept at least 30cm (12in) away.</p> <p>Increase the separation distance between the Hailie® sensor and any such devices if this could be causing problems.</p> <p>Warranty The Hailie® sensor includes a 12 month warranty against manufacturing defects from date of first use. This warranty may be voided under the following circumstances: damage to the Hailie® sensor including dropping, water damage resulting from condensation or immersion, tampering, attempts to service, or other forms of abuse.</p> <p>If this does not help, contact the supplier or manufacturer for further assistance.</p> <p>Customer Support For support on this product, go to support.hailie.com.</p> <p><input checked="" type="checkbox"/> For information about your medical condition or your medication, contact your healthcare provider.</p> <p>The Hailie® sensor warranty expires 4 years from date of manufacture.</p> <p>Storage To help maintain battery capacity, store your Hailie® sensor below 30°C (86°F). Keep out of direct sunlight and avoid extreme temperatures.</p> <p>The inhaler medication has its own storage recommendations. Refer to the labelling provided with the inhaler medication.</p> <p>Troubleshooting If the Hailie® sensor is not responding to Bluetooth® communications, check the Hailie® sensor battery level as per <i>Reviewing the Battery Level</i> in this manual. Ensure Bluetooth® is enabled in your mobile device.</p> <p>Other wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, and equipment</p> <p>EU only: Do not dispose of the Hailie® sensor as unsorted municipal waste. The Hailie® sensor must be recycled in accordance with Directives 2012/19/EU and 2006/66/EC. To arrange for return or disposal of the Hailie® sensor contact the supplier.</p> <p>Wireless Technology Bluetooth® 4.0: 2.40 - 2.48 GHz, 1.0 mW Low Energy</p> <p>Battery Type Lithium Coin Cells, Non-rechargeable</p> <p>Shelf Life 3 years</p> <p>Service Life 1 year</p> <p>Operating Temperature 0 to 40°C (32 to 104°F)</p> <p>Storage Temperature -20 to 60°C (-4 to 140°F)</p> <p>Operating / Storage Humidity 15 to 90% RH (non-condensing) at water vapour pressure ≤ 50 hPa</p> <p>Regulatory Compliance</p> <table border="1"> <tr> <td></td> <td>AU only: Regulatory compliance mark</td> </tr> <tr> <td></td> <td>EU only: European conformity mark</td> </tr> <tr> <td></td> <td>EU only: Medical Device</td> </tr> <tr> <td></td> <td>EU only: Do not dispose Hailie® sensor as unsorted municipal waste</td> </tr> <tr> <td></td> <td>NZ only: Regulatory compliance mark</td> </tr> <tr> <td></td> <td>UK only: UK conformity mark</td> </tr> </table> <p>FCC Statement (US) This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:</p> <ol style="list-style-type: none"> 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including interference that may cause undesired operation. <p>Electromagnetic Compatibility The Hailie® sensor does not perform any clinical function where loss or degradation would result in unacceptable risk.</p> <table border="1"> <thead> <tr> <th>Emissions / Immunity Test and Standard</th> <th>Compliance Level</th> </tr> </thead> <tbody> <tr> <td>Radiated EMI CISPR11</td> <td>Group 1 Class B</td> </tr> <tr> <td>Electrostatic Discharge IEC 61000-4-2</td> <td>± 8 kV contact, ± 2/4/8/15 kV air</td> </tr> </tbody> </table>		AU only: Regulatory compliance mark		EU only: European conformity mark		EU only: Medical Device		EU only: Do not dispose Hailie® sensor as unsorted municipal waste		NZ only: Regulatory compliance mark		UK only: UK conformity mark	Emissions / Immunity Test and Standard	Compliance Level	Radiated EMI CISPR11	Group 1 Class B	Electrostatic Discharge IEC 61000-4-2	± 8 kV contact, ± 2/4/8/15 kV air
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Adherium (NZ) Ltd declares that the radio equipment type Hailie® sensor is in compliance with Directive 2014/53/EU.

Product specifications may change without notice.

For patent and trade mark information, including third-party trademarks, refer to www.adherium.com/ip.

ProAir is a trademark of Teva Respiratory, LLC.

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