hailie

For use only with
Advair™ Diskus™ and **Flovent™ Diskus™**

Product Manual

For customer support, go to **support.hailie.com**

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

Table of Contents

❶ Safety Statement

1.1. Hailie™ Sensor Intended Use

The Hailie™ sensor is intended for single patient use in the home environment as a medication reminder and electronic data capture accessory for recording usage of prescribed Inhaler medication. This may be used in the following applications:

• In clinical trials, where researchers need to know when a patient has used their trial Inhaler medication.

• In clinical practice, where specialists, general practitioners, nurses, and educators need to know if a patient has used their prescribed Inhaler medication.

• In self-management, where patients need to track their medication use as part of their management plan.

The Hailie™ sensor is compatible only with the **Advair™ Diskus™** and **Flovent™ Diskus™** Inhalers.

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

1.2 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.

1.3 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.

⚠ **US only:** Important instructions for use of the Inhaler are printed on each side of the Inhaler. The labels are covered when the Hailie™ sensor is installed. The labels can be checked at any time by removing the Hailie™ sensor from the Inhaler, and replacing it after the labels are checked. Follow the steps in *Installing and Removing an Inhaler*.

⚠ **US only:** Read the labels on both sides of the Inhaler before installing into the Hailie™ sensor.

⚠️ 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.

⚠️ The Hailie™ sensor does not contain a dose counter. Do not use data collected by the Hailie™ sensor to determine the number of doses remaining in an Inhaler.

⚠️ 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.

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

❗ To ensure accuracy of Inhaler usage records, only open the Inhaler when you take your medication, and always close it again afterwards.

❗ The Hailie™ sensor is a battery-powered electronic device. Do not immerse the Hailie™ sensor in water. Do not use the Hailie™ sensor if it is not in good condition.

❗ Take care to not spill liquids on the Hailie™ sensor or immerse it in water. 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.

❗ Remove the Hailie™ sensor from the Inhaler before cleaning the Inhaler.

❷ Hailie™ Sensor Overview

2.1 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.

The Hailie™ sensor has a built-in audio-visual alert to remind you when to take your prescribed medication — and tracks when you did — so you can have confidence you're following your prescription.

2.2 Hailie™ Sensor Components

Front View
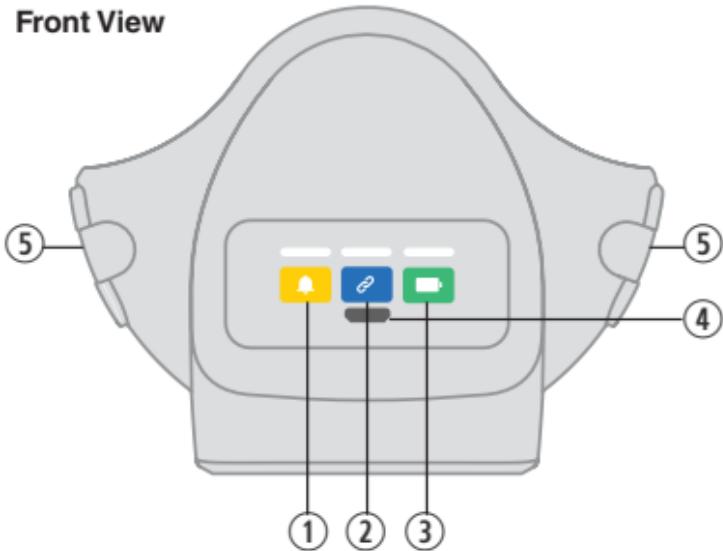
Back View
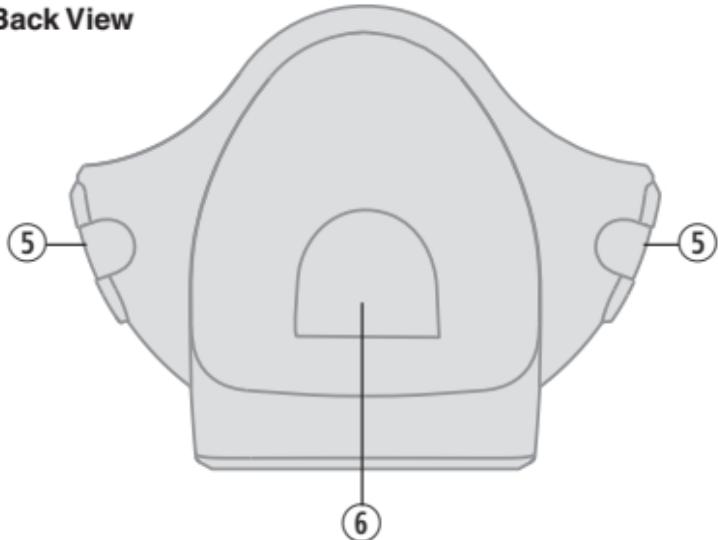
Key

1. Reminder Button and Reminder LED
2. Pair Button and Pair LED
3. Battery Button and Battery LED
4. USB Port
5. Clips
6. Serial Number Label

2.3 Compatible Inhalers

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

The compatible Inhalers are:
• **GSK Advair™ Diskus™** (100/50, 250/50, 500/50 mcg)
• **GSK Flovent™ Diskus™** (50, 100, 250 mcg)

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

❸ Setting up the Hailie™ Sensor

3.1 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. To check if the Hailie™ sensor is still in Deep-Sleep mode, press the Pair Button once. The Pair LED will flash white if it is still in Deep-Sleep.

Before first use, place the Hailie™ sensor on charge for up to 8 hours or until the Battery LED stops flashing green. This will wake the Hailie™ sensor from Deep-Sleep mode.

When recharging is completed, disconnect the Hailie™ sensor from the power supply. Press the Battery Button once to check the battery level. The Battery LED should flash green prior to first use.

3.2 Installing and Removing an Inhaler

Installation
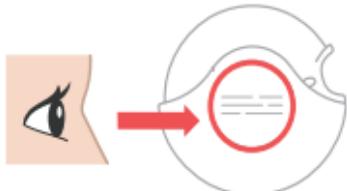
⚠️ **US Only** - Read the labels on both sides of the Inhaler before installing into the Hailie™ sensor.

①
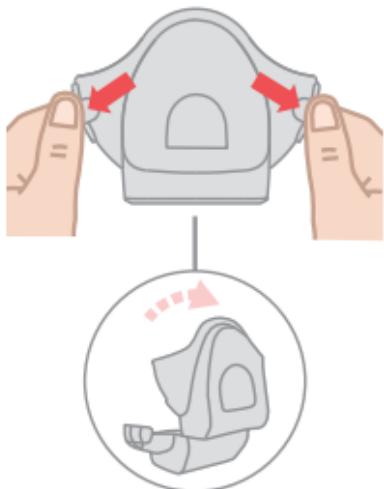
To install the Inhaler hold the Hailie™ sensor in an upright position.

Open the Hailie™ sensor by pushing the clips and opening the side latches.

②
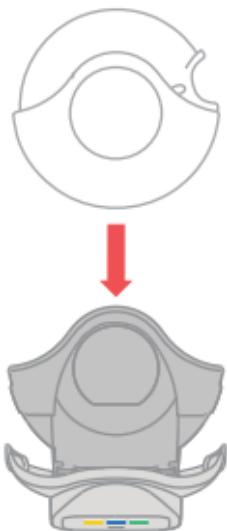
Place the Inhaler into the Hailie™ sensor with the Inhaler dose counter facing upwards.

③
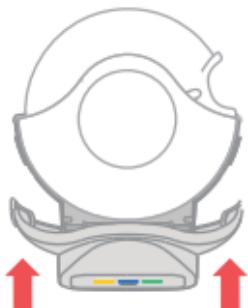
Close the Hailie™ sensor, ensuring the clips snap shut on both sides.

④

The Hailie™ sensor is ready to pair with a compatible mobile app. Follow the instructions below in *Setting Up Bluetooth® Communications*.

Removal
1. To remove the Inhaler hold the Hailie™ sensor in an upright position.
2. Open the Hailie™ sensor by pushing the clips and opening the side latches.
3. Pull the Inhaler to remove it from the Hailie™ sensor.
4. Close the door so it clicks into place.

3.3 Setting Up *Bluetooth®* Communications

The Hailie™ sensor must be paired with a compatible *Bluetooth®* phone or tablet computer 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**.

1. Ensure *Bluetooth*® is enabled on your phone or tablet computer.
2. Open the compatible mobile app and follow the prompts to complete the pairing process.
3. On the Hailie™ sensor, hold down the Pair Button for 1 second to enter pairing mode. The Pair LED will flash blue when the Hailie™ sensor is in pairing mode.
4. The Pair LED will flash green to indicate successful pairing.

☑ If pairing is not successful within 60 seconds the Pair LED will flash red. The pairing process can be repeated if necessary.

☑ The Hailie™ sensor can only be paired with a single phone or tablet computer at one time. Successful pairing with a new phone or tablet computer will remove the current pairing. If pairing on the new phone or tablet computer fails, the existing pairing will be retained.

❹ Using the Hailie™ Sensor

4.1 Delivering a Dose of Medication

⚠ 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 logs Inhaler usage by monitoring when the Inhaler is opened and closed.

❗ To ensure accuracy of Inhaler usage records, only open the Inhaler when you take your medication, and always close it again afterwards.

13

The Hailie™ sensor Battery LED flashes green, orange, or red (to indicate battery level) 3 seconds after detecting medication usage and the Inhaler is closed.

If the Battery LED flashes red or if there is no flash, the Hailie™ sensor is not monitoring usage. Check the battery level according to *Reviewing the Battery Level*.

⚠ 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.

☑ The Hailie™ sensor does not detect or record the quantity of medication delivered by the Inhaler.

4.2 Medication Reminders

Audio-visual reminders may be available to set up from a compatible mobile app. If enabled, the medication reminders are generated on the Hailie™ sensor with increasing frequency for up to 24 minutes, until either the prescribed medication dose is taken or the reminder is cancelled. The Reminder LED flashes green and the Hailie™ sensor emits a beeping sound when the reminder alert is triggered.

To cancel the reminder, hold down the Reminder Button until you hear a beeping sound and the Reminder LED flashes red.

4.3 Reviewing Inhaler Usage Data

The Inhaler usage history can be automatically uploaded via a compatible paired phone or tablet computer.

The upload of new information will occur automatically as long as the Hailie™ sensor is within range (10 meters or 32 feet) of the phone or tablet computer with *Bluetooth*® enabled.

> When travelling ensure your phone or tablet computer is set to the local time zone for accuracy of Inhaler usage data.

4.4 Manually Uploading Stored Information

The Hailie™ sensor can manually upload data to a paired *Bluetooth*® phone or tablet computer.

1. Hold down the Pair Button for 3 seconds until the Pair LED shows white, then release.
2. The Pair LED will flash white while the Hailie™ sensor attempts to upload, then flash green if the upload is successful.

> The Hailie™ sensor Pair LED will flash red if the upload is not successful. Check the Hailie™ sensor is within range of the paired phone or tablet computer, and ensure *Bluetooth*® communications are enabled.

4.5 Reviewing the Battery Level

The Battery LED on the Hailie™ sensor indicates the battery level after detecting medication usage, or when the Battery Button is pressed once.

LED Colour	Battery Status
Green	The battery level is good. The Hailie™ sensor is monitoring Inhaler usage.
Orange	The battery level is getting low. The Hailie™ sensor is still monitoring Inhaler usage.
Red	The battery is depleted. The Hailie™ sensor has stopped monitoring Inhaler usage.
No Flash	The battery is depleted, or the Hailie™ sensor has failed, e.g. due to liquid immersion or mechanical stress.

4.6 Recharging the Hailie™ Sensor

The Hailie™ sensor contains a rechargeable battery that is recharged via the USB Port. To recharge the Hailie™ sensor, connect it to a computer USB port or USB wall plug adaptor, using the supplied USB cable or a micro-USB cable less than 3 metres (9ft 10in) in length.

When connected to a charging source, the Battery LED will flash slowly in a colour according to the battery level. When charging is complete, the Battery LED will turn off. The Hailie™ sensor should not be used while charging.

Allow up to 8 hours to fully recharge a Hailie™ sensor that is displaying a red flashing Battery LED. Charging times will significantly increase in temperatures below 10°C (50°F).

The Hailie™ sensor should be recharged every 4 months as a minimum to ensure continued battery function.

❺ Maintenance

5.1 Cleaning the Hailie™ Sensor and Inhaler
Check the instructions from the Inhaler manufacturer for keeping the Inhaler and mouthpiece clean.

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

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).

⚠️ The Hailie™ sensor is a battery-powered electronic device. Do not immerse the Hailie™ sensor in water. Do not use the Hailie™ sensor if it is not in good condition.

The cleaning method is intended to support single patient use. If the sensor is contaminated by another individual, it is recommended that the Hailie™ sensor be discarded and replaced with a new sensor.

5.2 Storage
To help maintain battery capacity, store your Hailie™ sensor below 30°C (86°F). Keep out of direct sunlight and avoid extreme temperatures.

The Inhaler medication has its own storage recommendations. Refer to the labelling provided with the Inhaler medication.

❻ Troubleshooting

If the Hailie™ sensor is not responding to *Bluetooth®* communications, check the Hailie™ sensor battery level as per *Reviewing the Battery Level* in this manual. Ensure *Bluetooth®* is enabled in your phone or tablet computer.

Other wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, and equipment such as contactless payment or anti-theft systems, can affect the Hailie™ sensor, and should be kept at least 30cm (12in) away.

Increase the separation distance between the Hailie™ sensor and any such devices if this could be causing problems.

If this does not help, contact Customer Support for further assistance.

❼ Customer Support and Servicing

7.1 Customer Support
For support on this product, go to **support.hailie.com**.

📝 For information about your medical condition or your medication, contact your healthcare provider.

7.2 Servicing

Contact Customer Support for Hailie™ sensor servicing.
Do not attempt to open or service the Hailie™ sensor.
Tampering with the Hailie™ sensor voids the warranty.

❽ Disposal

Dispose of or recycle the Hailie™ sensor in accordance
with regulations for your country, as applicable for
electronic devices containing a lithium polymer battery.
Ensure that the Inhaler is removed from the Hailie™
sensor prior to disposal.

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 Customer Support.

❾ Warranty

The Hailie™ sensor includes a 24 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.

The Hailie™ sensor warranty expires 4 years from date
of manufacture.

❿ Technical Information and Symbols

10.1 Specifications

Model Number	NF0100
Usage Log Precision	1 second
Usage Log Capacity	5120 usage logs and sensor status records
Internal Clock Accuracy	± 1 hour after 12 months ***Note:** the Hailie™ sensor clock is updated every time data is uploaded to a compatible mobile app.*
Compatible with	iOS or Android phones and tablet computers. Go to **support.hailie.com** for more information.
Wireless Communication	*Bluetooth*® 4.0: 2.40 - 2.48 GHz, 2.5 mW Low Energy
Battery Type	Lithium Polymer 400mAh, Rechargeable
Shelf Life	2 years
Service Life	2 years
Operating Temperature	0 to 40°C (32 to 104°F)

Storage Temperature	-20 to 60ºC (-4 to 140ºF)
Operating / Storage Humidity	15 to 90% RH (non-condensing) at water vapour pressure ≤ 50 hPa

10.2 Symbols

▲	Manufacturer: Adherium (NZ) Ltd
SN	Serial Number
REF	Part Number
�	Year of Manufacture
☂	Keep dry
⊕	Rechargeable Sensor
☒	EU only: Do not dispose Hailie™ sensor as unsorted municipal waste
CE	EU only: European conformity mark
⊘	AU only: Regulatory compliance mark
R-NZ	NZ only: Regulatory compliance mark
✦	Temperature limit
⊘%	Humidity limitation

⑪ Regulatory Statements

11.1 Electromagnetic Compatibility
The Hailie™ sensor does not perform any clinical function where loss or degradation would result in unacceptable risk.

Emissions / Immunity Test and Standard	Compliance Level
Conducted and Radiated EMICISPR 11	Group 1 Class B
Electrostatic Discharge IEC 61000-4-2	± 8 kV contact, ± 2/4/8/15 kV air
Radiated RF EM Fields IEC 61000-4-3	10 V/m: 80 - 2700 MHz
Proximity fields from RF wireless communications equipment IEC 61000-4-3	9 V/m: 710, 745, 780, 5240, 5500, 5785 MHz 27 V/m: 385 MHz 28 V/m: 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz
Power frequency magnetic fields IEC 61000-4-8	30 A/m
Voltage dips and Interruptions IEC 61000-4-11	0 % U_T: 0.5 cycle 0 % U_T: 1 cycle 70 % U_T: 25/30 cycles 0 % U_T: 250/300 cycles

11.2 FCC Statement

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.

"Harmful interference" is defined by FCC as any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radiocommunications service operating in accordance with FCC rules.

The Grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.

11.3 Declaration of Conformity

Adherium (NZ) Ltd declares that this Hailie™ sensor is in compliance with the essential requirements and other relevant provisions of Directive 93/42/EEC. Email contact@hailie.com for a copy of the declaration of conformity.

Hereby, Adherium (NZ) Ltd declares that the radio equipment type Hailie™ sensor is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at: **www.hailie.com/RDC**

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Product specifications may change without notice.

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Customer Support

For support on this product, go to **support.hailie.com**. For information about your medical condition or your medication, contact your healthcare provider.