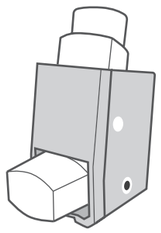
hailie

For use only with **Ventolin, Advair™/Seretide™, Flovent™/Flixotide™,** or **ProAir™**, as indicated on the Hailie® sensor label and in this manual. For more information see the "Compatible Inhalers" section.

EN Product Manual



adherium

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 and other parameters, including inspiratory flow, of 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 including medication reminders.

The Hailie® sensor is compatible only with the **Ventolin, Advair™/Seretide™, Flovent™/Flixotide™,** or **ProAir™** inhalers.

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

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.

US only: Read the label on the front panel of the Inhaler before installing into the Hailie® sensor.

US only: Important instructions for use of the Inhaler are printed on the front panel of the inhaler. The label is covered when the Hailie® sensor is installed. The label can be checked at any time by removing the Hailie® sensor from the Inhaler, and replacing it after the label is checked. Follow the steps in *Installing or Removing an Inhaler*.

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.

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.

Keep the Hailie® sensor outside MRI scanner rooms.

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

The Hailie® sensor is a battery-powered electronic device. Take care to not spill liquids on the Hailie® sensor or immerse it in water. Do not use the Hailie® sensor if it is not in good condition.

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.

NF0090 only: Do not use the Hailie® sensor while charging to avoid risk of electric shock.

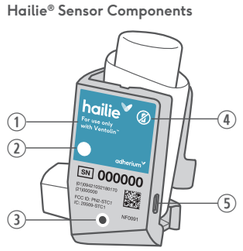
What is the Hailie® Sensor?

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 audiovisual 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.

Hailie® Sensor Components



Key
1. Use only with this medication
2. Light Emitting Diode (LED)
3. Status Button
4. Battery type – see Symbols section for more information
5. USB Port

Compatible Inhalers

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

Country	Medication	Strength
AUS	Ventolin™ MDI	100 mcg
	Seretide™ MDI	50/25, 125/25, 250/25 mcg
	Flixotide™ MDI	50, 125, 250 mcg
CAN	Ventolin™ HFA	100 mcg
	Advair™ HFA	125/25, 250/25 mcg
	Flovent™ HFA	50, 125, 250 mcg
EU	Ventolin™ MDI	100 mcg
	Seretide™ MDI	50/50, 50/125, 50/250 mcg
	Flixotide™ MDI	50, 125, 250 mcg
NZL	Ventolin™ MDI	100 mcg
	Seretide™ MDI	50/25, 125/25, 250/25 mcg
	Flixotide™ MDI	50, 125, 250 mcg
UK	Ventolin™ Evohaler™	100 mcg
	Seretide™ Evohaler™	50/25, 125/25, 250/25 mcg
	Flixotide™ Evohaler™	50, 125, 250 mcg
USA	Ventolin™ HFA	90 mcg
	Advair™ HFA	45/21, 115/21, 230/21 mcg
	Flovent™ HFA	44, 110, 220 mcg
	ProAir™ 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.**

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

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 Status Button once. The LED will flash white if it is still in Deep-Sleep.

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**.

Ensure *Bluetooth*® is enabled on your mobile device.

Non-Rechargeable Sensor - NF0091

1. Open the compatible mobile app and follow the prompts to complete the pairing process.
2. Wake up the Hailie® sensor by holding down the Status Button for 3 seconds.
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. The LED will flash green to indicate successful pairing.

Rechargeable Sensor - NF0090

1. Before first use, place the Hailie® sensor on charge for a minimum of 3 hours or until the LED stops flashing green.
2. When charging is completed, open the compatible mobile app and follow the prompts to complete the pairing process.
3. Disconnect the Hailie® sensor from the power supply. This will wake the Hailie® sensor from Deep-Sleep mode.
4. The Hailie® sensor will automatically enter *Bluetooth*® pairing mode and the LED will flash blue for 60 seconds.
5. The LED will flash green to indicate successful pairing.

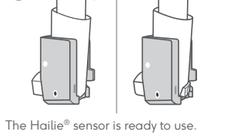
If pairing is not successful within 60 seconds the LED will flash red. The pairing process can be repeated if necessary by pressing the Status Button 3 times quickly to initiate pairing.

The Hailie® sensor can only be paired with a single mobile device at one time. Successful pairing with a new mobile device will remove the current pairing. If pairing on the new mobile device fails, the existing pairing will be retained.

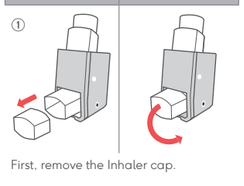
Installing and Removing an Inhaler

Installation

for Inhaler with non-tethered cap	for Inhaler with tethered cap



US only: Read the label on the front panel of the Inhaler before installing into the Hailie® sensor.



To install the Inhaler, remove the Inhaler cap and align the Inhaler with the back of the Hailie® sensor.

Push the Inhaler firmly into the Hailie® sensor, ensuring the mouthpiece of the Inhaler goes through the front window on the Hailie® sensor.

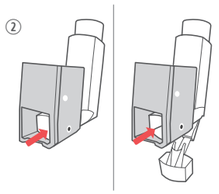
Replace the Inhaler cap.

The Hailie® sensor is ready to use.

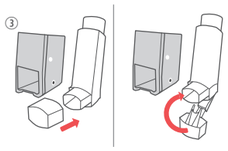
Removal

for Inhaler with non-tethered cap	for Inhaler with tethered cap

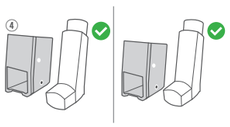
First, remove the Inhaler cap.



While holding each side of the Hailie® sensor, push the mouthpiece of the Inhaler to remove the Inhaler from the Hailie® sensor.



Replace the Inhaler cap.



The Hailie® sensor has been successfully removed.

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.

To use the Hailie® sensor, hold the Hailie® sensor in one hand with the thumb under the base of the Hailie® sensor and the index finger and second finger on top of the medication canister.

The Hailie® sensor LED flashes green, orange or red (to indicate battery level) 3 seconds after detecting the medication usage.

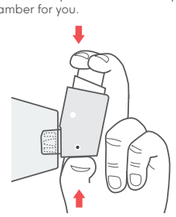
If the LED flashes red or if there is no flash, the Hailie® sensor is not monitoring usage. Check the battery level according to *Reviewing the Battery Level*.

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

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

To use the Hailie® sensor with a spacer, hold the Hailie® sensor in one hand with the thumb at the base of the Hailie® sensor and the index finger and second finger on top of the medication canister. Use the other hand to support the spacer chamber.

If necessary, you may require assistance from another person to hold the spacer chamber for you.



Medication Reminders

Audiovisual reminders may be 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 LED flashes green and the Hailie® sensor emits a beeping sound when the reminder alert is triggered.

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

Reviewing Inhaler Usage Data

The Inhaler usage history can be automatically uploaded via a compatible paired mobile device.

The upload of new information will occur automatically as long as the Hailie® sensor is within range (5 meters or 16 feet) of the mobile device with *Bluetooth*® enabled.

When travelling ensure your mobile device is set to the local time zone for accuracy of Inhaler usage logs.

Manually Uploading Stored Information

The Hailie® sensor can manually upload data to a paired *Bluetooth*® mobile device.

1. Hold down the Status Button until the LED shows white, then release.
2. The LED will flash white while the Hailie® sensor attempts to upload, then flash green if the upload is successful.

The Hailie® sensor LED will flash red if the upload is not successful. Check the Hailie® sensor is within range of the paired mobile device and ensure that *Bluetooth*® communications are enabled.

Reviewing the Battery Level

The LED on the Hailie® sensor indicates the battery level after detecting medication usage, or when the Status 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 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.

Recharging the Hailie® Sensor - NF0090 only

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 LED will flash slowly in a colour according to the battery level. When charging is complete, the LED will turn off.

Do not use the Hailie® sensor while charging to avoid risk of electric shock.

Allow up to 3 hours to fully recharge a Hailie® sensor that is displaying a red flashing 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.

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.

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.

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 mobile device.

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 the supplier or manufacturer for further assistance.

Any serious incident that has occurred in relation to the Hailie®sensor should be reported to Adherium and the health authority of the Member State where it occurred.

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.

EU only: Any serious incident that has occurred in relation to the Hailie® Sensor should be reported to Adherium and the health authority of the EU Member State where it occurred.

Servicing

Contact the supplier or manufacturer for Hailie® sensor servicing. Do not attempt to open or service the Hailie® sensor. Tampering with the Hailie® sensor voids the warranty.

Disposal

Dispose of or recycle the Hailie® sensor in accordance with regulations for your country, as applicable for electronic devices containing a lithium polymer or lithium coin cell 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 the supplier.

Warranty

The Hailie® non-rechargeable sensor (NF0091) includes a 12 month warranty against manufacturing defects from date of first use.

The Hailie® rechargeable sensor (NF0090) includes a 24 month warranty against manufacturing defects from date of first use.

This warranty maybe 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.

Specifications

Model numbers	NF0090, NF0091
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 mobile devices. Go to **support.hailie.com** for more information.
Wireless Technology	*Bluetooth*® 4.0: 2.40 - 2.48 GHz, 1.0 mW Low Energy
Operating Temperature	0 to 40°C (32 to 104°F)
Storage Temperature	-20 to 60°C (-4 to 140°F)
Operating / Storage Humidity	15 to 90% RH (non-condensing) at water vapour pressure ≤ 50 hPa

Non-Rechargeable Sensor

Model number	NF0091
Battery Type	Lithium Coin Cell
Shelf Life	3 years
Service Life	1 year

Rechargeable Sensor

Model number	NF0090
Battery Type	Lithium Polymer
Shelf Life	2 years
Service Life	2 years

Symbols

Product Use	
	Read manual before use
	Keep dry
	Non-rechargeable Sensor
	Rechargeable Sensor
	Temperature limit
	Humidity limitation

Product Details	
	Manufacturer: Adherium (NZ) Limited
SN	Serial Number
REF	Part Number
#	Model Number
	Date of Manufacture
TH	Country of Manufacture

Regulatory Compliance	
	AU only: Regulatory compliance mark
CE	EU only: European conformity mark
MD	EU only: Medical Device
	EU only: Do not dispose Hailie® sensor as unsorted municipal waste
R-NZ	NZ only: Regulatory compliance mark
UK CA	UK only: UK conformity mark

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
Radiated EMI CISPR 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

FCC Statement (US)

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.

ISED Statement (Canada)

This device contains a licence-exempt transmitter/receiver that complies with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

This equipment complies with the RSS-102 radiation exposure limits set forth for an uncontrolled environment.

Déclaration de l'ISED (Canada)

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1. L'appareil ne doit pas produire de brouillage;
2. L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Cet appareil est conforme avec les limites d'exposition de rayonnement RSS-102 établies pour un environnement non contrôlé.

Declaration of Conformity (EU)

Adherium (NZ) Ltd declares that this Hailie® sensor is in compliance with the General Safety & Performance Requirements and other relevant provisions of Regulation EU 2017/745.

Adherium (NZ) Ltd declares that the radio equipment type Hailie® sensor is in compliance with Directive 2014/53/EU.

EU Declarations of Conformity are available at:
www.adherium.com/EUDoC

CE EU 2017/745, 2014/53/EU, 2011/65/EU

Contact Information

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

UK Responsible Person
Emergo Consulting (UK) Limited
c/o Cr360 – UL International
Compass House, Vision Park Histon
Cambridge CB24 9BZ
United Kingdom

Australian Sponsor
Adherium Ltd
Collins Square | Tower Four
Level 18, 727 Collins Street
Melbourne VIC 3008
Australia

Hailie® sensor is manufactured by:
Adherium (NZ) Ltd
16 Kingston Street
Auckland 1010
New Zealand
support@hailie.com
www.hailie.com

Hailie® Sensor Product Manual
Part Number: ND0400
Version: 5
Issue Date: 14 July 2021

Product specifications may change without notice.