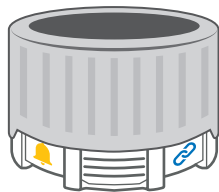




For use only with **medication**
indicated on the Hailie® sensor label

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
Bricanyl™ and **Symbicort™ Turbuhaler™** 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.

⚠ 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.

⚠ Ensure the grip around the base of the
installed inhaler is twisted anticlockwise and
then back within a minute so that Inhaler
usage is recorded.

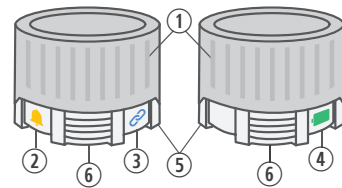
What is the Hailie® Sensor?

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. Cover
2. Reminder Button/LED
3. Pair Button/LED
4. Battery Button/LED
5. Base
6. Release Buttons
7. USB Port

Compatible Inhalers

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

Medication	Strength	Compatible Sensor
Bricanyl™ Turbuhaler™	250 mcg 500 mcg	Hailie® for use only with Bricanyl™ Turbuhaler™
Symbicort™ Turbuhaler™	100/6, 200/6, 400/12 mcg	Hailie® for use only with Symbicort™ Turbuhaler™

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.

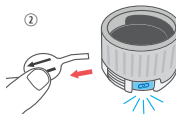
The Hailie® sensor must be paired with a
compatible *Bluetooth®* mobile device in order to
sync stored usage data.

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.



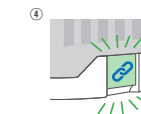
Open the compatible
mobile app



Remove the Battery
Saver Pull Tab from
the Hailie sensor. The
Pair LED will flash
blue when the Hailie®
sensor is in pairing
mode.



Follow the prompts in
the app to complete
the pairing process.



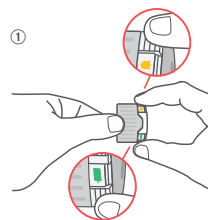
The Pair LED will flash
green to indicate
successful pairing.

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

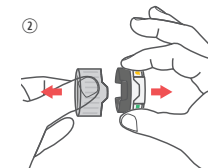
📋 The Hailie® sensor can only be paired with a
single mobile device at one time. Successful
pairing with a new mobile device will
remove the current pairing. If pairing on the
new mobile device fails, the existing pairing
will be retained.

Installing and Removing an Inhaler

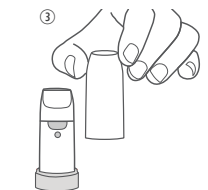
Installation



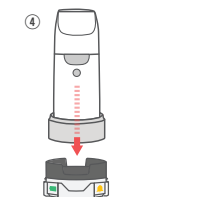
Remove the Cover of
the Hailie® sensor by
squeezing the
Release Buttons
on the base
simultaneously.



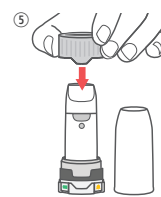
Pull the Cover and
the Base apart.



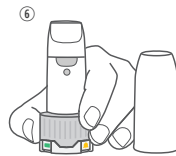
Remove the Inhaler
cap.



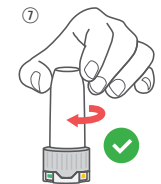
Position the Inhaler
in the Hailie® sensor
Base.



Place the Cover back
over the Inhaler and
align the Cover and
the Base.



Push down the Cover
until it clicks.



Once the Hailie®
sensor is installed,
put the Inhaler cap
back on firmly. The
Hailie® sensor is
ready to be used.

⚠ The Hailie® sensor will not monitor inhaler
use for 5 seconds after the inhaler is installed
into the sensor.

📋 Attaching a Hailie® sensor to the Inhaler will
cover the identifying Braille inscriptions on
the base of the Inhaler, potentially rendering
the Inhaler incompatible with visually
impaired/blind patients.

Removal

⚠ To ensure medication usage is detected, wait
for 3 seconds after medication usage before
removing the inhaler from the Hailie® sensor.

1. Remove the Inhaler cap.
2. Remove the Cover of the Hailie® sensor by
squeezing the Release Buttons on the base
simultaneously.
3. Remove the Inhaler and put the Inhaler cap
back on.
4. Put the Hailie® sensor Cover back on to the Base
and click into place.

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

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 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.

📋 With the Hailie® sensor installed, the Hailie®
sensor becomes what the prescribed Inhaler
medication leaflet refers to as “the grip”.

⚠ Ensure the grip around the base of the
installed inhaler is twisted anticlockwise
and then back within a minute so that
Inhaler usage is recorded.

Medication Reminders

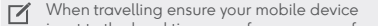
Audiovisual reminders may be set up from a
compatible mobile app. If enabled, the medication
reminders are generated on the Hailie® sensor
with increasing frequency for up to 24 minutes,
until either the prescribed medication dose is
taken or the reminder is cancelled. The Reminder
LED flashes green 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.

Reviewing Inhaler Usage Data

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

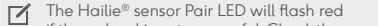
The upload of new information will occur automatically as long as the Hailie® sensor is within range (10 meters or 32 feet) of the mobile device with *Bluetooth®* enabled.

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

Manually Uploading Stored Information

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

- Hold down the Pair Button for 3 seconds until the Pair LED shows white, then release.
- 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 mobile device and ensure that *Bluetooth®* communications are enabled.

Reviewing the Battery Level

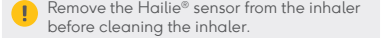
The Battery LED on the Hailie® sensor indicates the battery level after detecting medication usage, or when the Battery Button is pressed once.

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.

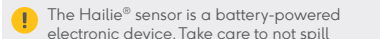
-  The battery is not rechargeable. Once depleted, a new Hailie® sensor will be required.

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. 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.

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.

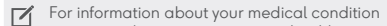
Other wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, and equipment such as contactless payment or anti-theft systems, can affect the Hailie® sensor, and should be kept at least 30cm (12in) away.

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.

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.

A copy of this product manual is available on www.hailie.com/collections/hailie-sensors

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 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® 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.






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







Specifications






Model number	NF0097
Usage Log Precision	1 second
Usage Log Capacity	5120 usage logs and sensor status records
Internal Clock Accuracy	±1 hour after 12 months <i>Note: the Hailie® sensor clock is updated every time data is uploaded to a compatible mobile app.</i>

Compatible with	iOS or Android mobile devices. Go to support.hailie.com for more information.
Wireless Technology	<i>Bluetooth®</i> 4.0: 2.40 - 2.48 GHz, 1.0 mW Low Energy
Battery Type	Lithium Coin Cell, Non-rechargeable
Shelf Life	3 years
Service Life	1 year
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

Symbols

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

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

Regulatory Compliance	
	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

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 CISPR11	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
Power frequency magnetic fields IEC 61000-4-8	28 V/m: 450, 610, 870, 930, 1720, 1845, 1970, 2450 MHz
	30 A/m

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:

- This device may not cause interference.
- 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:

- L'appareil ne doit pas produire de brouillage;
- 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

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

Contact Information

EC	REP
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Emergo Europe
Westervoortedijk 60
6827 AT, Arnhem
The Netherlands

UK RP

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
63 Albert Street
Auckland 1010
New Zealand
support@hailie.com
www.hailie.com

Hailie® Sensor Product Manual
Part Number: ND0503
Version: 4
Issue Date: 5 April 2023

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

Symbicort (budesonide/fomoterol fumerate dihydrate), Bricanyl (terbutaline sulphate) and Turbuhaler, are trademarks of the AstraZeneca group of companies.

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