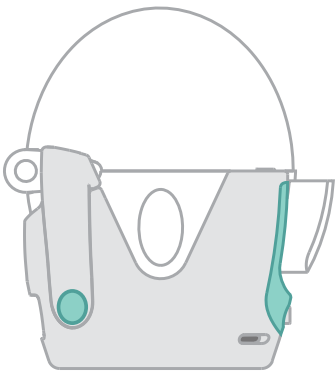


hailie

For use only with **HandiHaler™**



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

1	Safety Statement	5
	1.1 Hailie™ Sensor Intended Use	5
	1.2 Important User Information	5
	1.3 Warnings and Precautions	6
2	Hailie™ Sensor Overview	7
	2.1 What is the Hailie™ Sensor?	7
	2.2 Hailie™ Sensor Components	8
	2.3 Compatible Inhalers	10
3	Setting up the Hailie™ Sensor	10
	3.1 Preparation for First Use	10
	3.2 Installing and Removing an Inhaler	11
	3.3 Setting up <i>Bluetooth</i> ® Communications	13
4	Using the Hailie™ Sensor	14
	4.1 Delivering a Dose of Medication	14
	4.2 Medication Reminders	15
	4.3 Reviewing Inhaler Usage Data	16
	4.4 Manually Uploading Stored Information	16
	4.5 Reviewing the Battery Level	17
	4.6 Recharging the Hailie™ Sensor	17

5	Maintenance	18
	5.1 Cleaning the Hailie™ Sensor and Inhaler	18
	5.2 Storage	19
6	Troubleshooting	19
7	Customer Support and Servicing	20
	7.1 Customer Support	20
	7.2 Servicing	20
8	Disposal	20
9	Warranty	21
10	Technical Information and Symbols	21
	10.1 Specifications	21
	10.2 Symbols	23
11	Regulatory Statements	24
	11.1 Electromagnetic Compatibility	24
	11.2 FCC Statement	25
	11.3 Declaration of Conformity	25

① 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 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 **HandiHaler™** Inhaler.


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 HandiHaler™ are printed on the front 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 HandiHaler™, and replacing it after the label is checked. Follow the steps in *Installing and Removing an Inhaler*.

 **US only:** Read the label on the front of the HandiHaler™ 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.

 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.

! To ensure accuracy of Inhaler usage records, use the Inhaler within 5 minutes of opening the cap, and always close it again afterwards.

! Take note of the following to prevent triggering a false usage record. Avoid using the sensor in excessively noisy environments. Do not handle the sensor excessively or slide it across a table, while the cap is open.

! 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.

2 Hailie™ Sensor Overview

2.1 What is the Hailie™ Sensor?

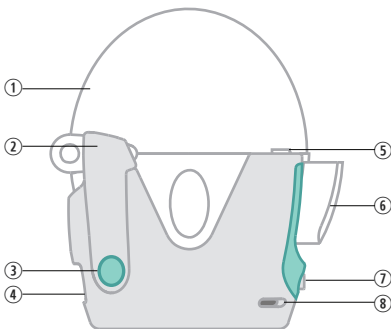
The Hailie™ sensor is a companion tool that tracks your prescribed medication use and reminds you when to take your prescribed medication.

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.

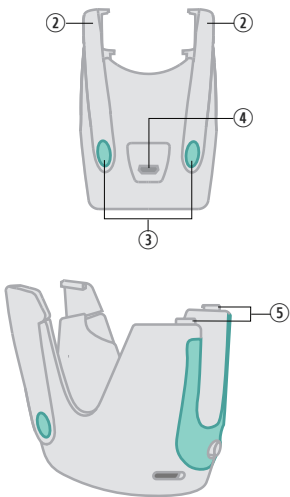
The Hailie™ sensor has a built-in audio-visual alert to remind you when to take your prescribed medication — and tracks when you did — so you can have confidence you're following your prescription.

2.2 Hailie™ Sensor Components

With the HandiHaler™ installed



Without the HandiHaler™



Key

- | | |
|-------------------------|--------------------------------|
| 1. HandiHaler™ Dust Cap | 6. HandiHaler™ Piercing Button |
| 2. Clips | 7. Status Button |
| 3. Release Buttons | 8. LED |
| 4. USB Port | |
| 5. Retaining Fingers | |

2.3 Compatible Inhalers

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

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

③ Setting up the Hailie™ Sensor

3.1 Preparation for First Use

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 LEDs will flash white if it is still in Deep-Sleep.

Before first use, place the Hailie™ sensor on charge for up to 4 hours or until the LEDs stop flashing green. This will wake the Hailie™ sensor from Deep-Sleep mode.

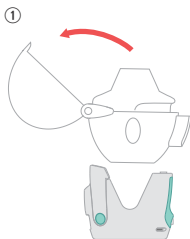
When recharging is completed, disconnect the Hailie™ sensor from the power supply. Press the Status Button once more to check the battery level. The LEDs should flash green prior to first use.

3.2 Installing and Removing an Inhaler

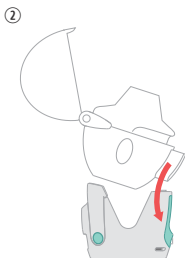
Installation



⚠ US Only - Read the label on the side of the HandiHaler™ before installing into the Hailie™ sensor.

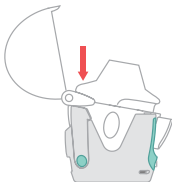


To install the HandiHaler™, open the HandiHaler™ Dust Cap.



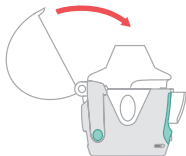
Rest the HandiHaler™ on top of the Hailie™ sensor so that the Piercing Button rests underneath the Retaining Fingers.

③



Gently push the HandiHaler™ down towards a horizontal position until both Clips click into position on the HandiHaler™ hinge.

④



Replace the HandiHaler™ Dust Cap.

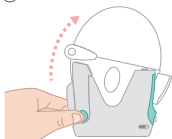
⑤



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

Removal

①



Press the Release Buttons on each side simultaneously to release the HandiHaler™.

②



Gently lift the HandiHaler™ out of the Hailie™ sensor.


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 press the Status Button 3


- times quickly to enter pairing mode. The LEDs will flash blue when the Hailie™ sensor is in pairing mode.
4. The LEDs will flash green to indicate successful pairing.

 If pairing is not successful within 60 seconds the LEDs 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 a 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.

4 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 the sound made by inhaling the medication, when the Inhaler Dust Cap is opened and closed.

 To ensure accuracy of Inhaler usage records, use the Inhaler within 5 minutes of opening the cap, and always close again afterwards.

- ! Take note of the following to prevent triggering a false usage record. Avoid using the sensor in excessively noisy environments. Do not handle the sensor excessively or slide it across a table, while the cap is open.

The Hailie™ sensor LEDs flash green, orange or red (to indicate battery level) 3 seconds after detecting medication usage and the Dust Cap is closed.

If the LEDs flash 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 LEDs flash 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 LEDs flash 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 Status Button for 3 seconds until the LEDs show white, then release.
2. The LEDs will flash white while the Hailie™ sensor attempts to upload, then flash green if the upload is successful.

 The Hailie™ sensor LEDs 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 LEDs on the Hailie™ sensor indicate 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.

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

Allow up to 4 hours to fully recharge a Hailie™ sensor that is displaying red flashing LEDs. 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.

5 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.

6 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.

7 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.

8 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.

9 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.












10 Technical Information and Symbols

10.1 Specifications

Model Number	NF0101
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	<i>Bluetooth</i> ® 4.0: 2.40 - 2.48 GHz, 2.5 mW Low Energy
Battery Type	Lithium Polymer 85mAh, Rechargeable
Shelf Life	2 years
Service Life/ Battery Life	2 years
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

10.2 Symbols

	Manufacturer: Adherium (NZ) Ltd
	Serial Number
	Part Number
	Year of Manufacture
	Keep dry
	Rechargeable Sensor
	EU only: Do not dispose Hailie™ sensor as unsorted municipal waste
	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 % UT : 0.5 cycle 0 % UT : 1 cycle 70 % UT : 25/30 cycles 0 % UT : 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

No part of this document may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of Adherium (NZ) Ltd.

Product specifications may change without notice.

EC REP

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands

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
Level 2, 204 Quay Street
Auckland 1010
New Zealand
contact@hailie.com

Hailie™ Sensor Product Manual
Part Number: ND0271
Version: 4
Issue Date: 04 Sep 2018

© 2018 Adherium (NZ) Ltd. All rights reserved.



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

HandiHaler is a trademark of Boehringer Ingelheim Pharma GmbH & Co. KG.

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.