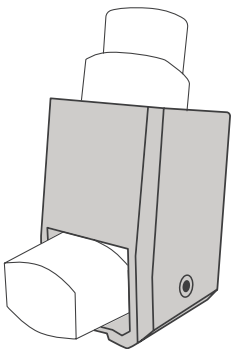


# smartinhaler™

PRODUCT MANUAL **en**



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## Preparation for First Use

### Rechargeable Sensor - NF0090

Following manufacture the Smartinhaler™ sensor is placed in Deep-Sleep mode to conserve battery life.


Before first use, place the Smartinhaler™ sensor on charge for a minimum of 3 hours or until the LED stops flashing green. This will wake the Smartinhaler™ sensor from Deep-Sleep mode and the Smartinhaler™ sensor is ready to use.


### Non-Rechargeable Sensor - NF0091

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

To wake up the Smartinhaler™ sensor, hold down the Status Button for 3 seconds and then release. Press the Status Button once more to check the battery level. The Smartinhaler™ sensor LED should flash green prior to first use.

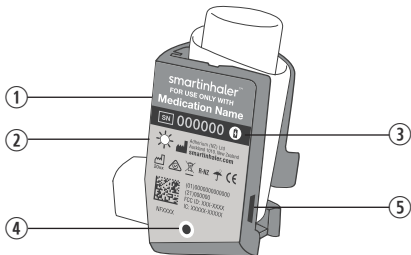
## Warnings, Cautions, and Notes

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

 **Cautions** identify actions or situations that could damage the Smartinhaler™ sensor or other equipment, or affect the accuracy or availability of recorded actuation data.

 **Notes** contain advisory information about some aspect of the Smartinhaler™ sensor or its use.

# Smartinhaler™ Sensor Components



## Key:

1. Use only with this medication
2. Light Emitting Diode (LED)
3. Battery type – see *Symbols* section for more information
4. Status Button (reminder button/battery check button)
5. USB port (only used for NF0090 to recharge battery)

## Terms and Abbreviations

**MDI** Metered Dose Inhaler.

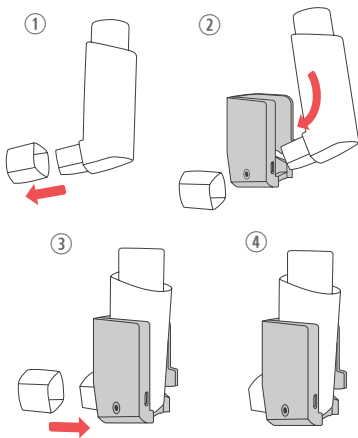
## Compatible MDI Devices

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

## Installing or Removing an MDI

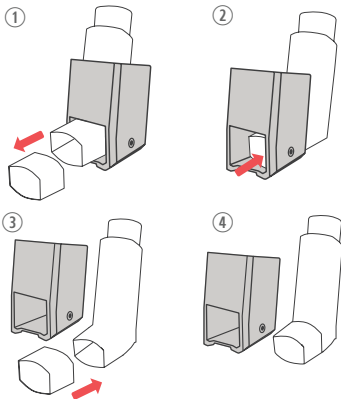
### Installation (for non-tethered MDI)

To install the Smartinhaler™ sensor, align the MDI with the back of the Smartinhaler™ sensor. Push the MDI firmly into the Smartinhaler™ sensor, ensuring the mouth piece of the MDI goes through the front window on the Smartinhaler™ sensor.



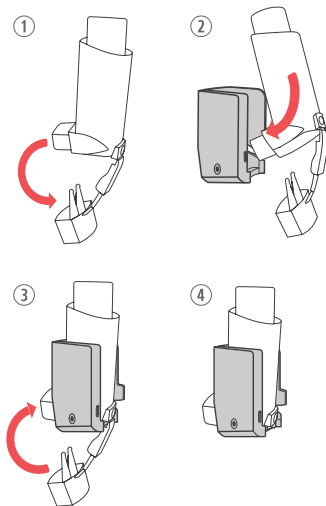
## Removal (for non-tethered MDI)

While holding each side of the Smartinhaler™ sensor, gently push the mouthpiece of the MDI to remove the MDI from the Smartinhaler™ sensor.



### Installation (for tethered MDI)

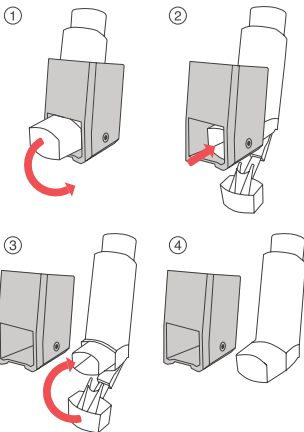
To install the Smartinhaler™ sensor, open the MDI cap, and align the MDI with the back of the Smartinhaler™ sensor. Push the MDI firmly into the Smartinhaler™ sensor, ensuring the mouth piece of the MDI goes through the front window on the Smartinhaler™ sensor. Close the MDI cap.





### Removal (for tethered MDI)


Open the MDI cap. While holding each side of the Smartinhaler™ sensor, gently push the mouthpiece of the MDI to remove the MDI from the Smartinhaler™ sensor. Close the MDI cap.




## Setting Up *Bluetooth*<sup>®</sup> Communications

The Smartinhaler™ sensor must be paired with a compatible *Bluetooth*<sup>®</sup> smartphone or tablet computer in order to upload stored usage data. Refer to **Smartinhaler™ App** on App store or on Google Play for more information. To pair the Smartinhaler™ sensor with a smartphone or tablet computer:

1. Follow the instructions on your smartphone or tablet computer to put it in pairing mode.
2. On the Smartinhaler™ sensor press the Status Button 3 times quickly to enter pairing mode. The LED will flash blue when the Smartinhaler™ sensor is in pairing mode.
3. Follow any prompts on your smartphone or tablet computer to select and accept pairing with the Smartinhaler™ sensor. The LED will flash green to indicate pairing is successful.

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

 The Smartinhaler™ sensor can only be paired with a single smartphone or tablet computer at a time. Starting the pairing process removes the current paired Smartinhaler™ sensor.

## Delivering a Dose of Medication

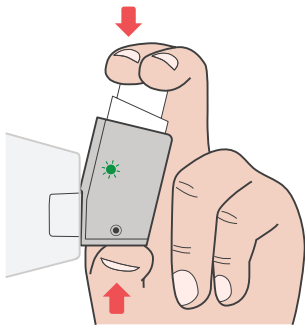
Refer to the labelling provided with the inhaler for instructions on use. Carry out all steps required to use your inhaler according to the instructions.

The Smartinhaler™ sensor LED flashes after detecting a medication dose has been actuated.



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

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



The Smartinhaler™ sensor LED flashes after detecting a medication dose has been actuated.

## Reminders

Audio-visual reminders can be set up from a Smartinhaler™ app.

If enabled, the medication reminders are generated with increasing frequency for up to 24 minutes until either the prescribed medication dose is taken or the reminder is cancelled. The LED always flashes green when the reminder activates.

To cancel the reminder, hold down the status button until the LED flashes red. There will be a beep sound along with the red flash to notify that the reminder is now cancelled.

## Reviewing Smartinhaler™ Sensor Usage Data

The MDI usage history can be automatically uploaded via a compatible paired smartphone or tablet computer. The upload of new information will occur automatically as long as the Smartinhaler™ sensor is within range (5 meters or 16 feet) of the smartphone or tablet computer.



When travelling ensure your communications device is set to the local time zone for accuracy of MDI actuation logs.

## Manually Uploading Stored Information

To ensure all current data has been transferred, the Smartinhaler™ sensor can manually upload information to a paired *Bluetooth*® smartphone or tablet computer.

## To manually upload stored usage data from the Smartinhaler™ sensor

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



The Smartinhaler™ sensor LED will flash red if the upload is not successful. Check the Smartinhaler™ sensor is within range of the paired smartphone or tablet computer, and ensure that *Bluetooth*® communications enabled.

## Reviewing the Battery Level

The LED on the main face indicates the battery level of the Smartinhaler™ sensor after medication is actuated, or when the Status Button is pressed:

Colour	Meaning
Green	The battery level is good, and the Smartinhaler™ sensor is monitoring actuations.
Orange	The battery level is getting low. The Smartinhaler™ sensor is still monitoring actuations.
Red	The battery is dead. The Smartinhaler™ sensor has stopped monitoring actuations.
No Flash	The battery is dead, or the Smartinhaler™ sensor has failed, e.g. due to liquid immersion or mechanical stress.

## Recharging the Smartinhaler™ Sensor - NF0090 only

The Smartinhaler™ sensor contains an internal rechargeable battery and is recharged via the USB port. To recharge the Smartinhaler™ sensor, connect it to a computer USB port or USB wall plug adaptor, using the supplied connector.

When connected to a charging source, the LED will flash slowly according to the battery level. When charging is complete, the LED will stop flashing. The Smartinhaler™ sensor should not be used while charging.

Allow up to 3 hours to fully recharge a Smartinhaler™ sensor that is displaying a red flashing LED.

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

## Cleaning the Smartinhaler™ Sensor and MDI

Check the instructions from the MDI manufacturer for keeping the mouthpiece clean. Keep the Smartinhaler™ sensor clean and free of chemicals, steam, water and dust. Clean the outside plastic enclosure with a lightly dampened cloth. Check the Smartinhaler™ sensor is clean and repeat if necessary. Leave it to dry in a warm place that is less than 30°C (86°F).



The Smartinhaler™ sensor is battery-powered and electronic. Do not immerse the Smartinhaler™ sensor in water. Do not use the Smartinhaler™ sensor if it is not in good condition.

## Storage

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

## Troubleshooting

If the Smartinhaler™ sensor is not responding to *Bluetooth*® communications, check the Smartinhaler™ sensor battery level as per *Reviewing the Battery Level* in this manual.

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

Increase the separation distance between the Smartinhaler™ 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, email us at [support@smartinhaler.com](mailto:support@smartinhaler.com) or call us on +64 9 307 2771. For information about your medical condition, please speak to your healthcare provider directly.

## Servicing

Please contact the supplier or manufacturer for Smartinhaler™ sensor servicing. Do not attempt to open or service the Smartinhaler™ sensor. Tampering with the Smartinhaler™ sensor voids the warranty.

## Disposal

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

**EU only:** Do not dispose of the Smartinhaler™ sensor as unsorted municipal waste. The Smartinhaler™ sensor must be recycled in accordance with Directives 2012/19/EU and 2006/66/EC. To arrange for return or disposal of the Smartinhaler™ sensor contact your local supplier.

## Smartinhaler™ Sensor Intended Use

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

- In clinical trials, where researchers need to know when a patient has actuated their trial MDI medication.
- In clinical practice, where specialists, general practitioners, nurses, and educators need to know if a patient has actuated their prescribed MDI medication.
- In self-management, where patients need to track their medication use as part of their management plan



The intended MDI is specified on the product label.

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

## How the Smartinhaler™ Sensor Works

The Smartinhaler™ sensor is a small battery-powered electronic data logger that attaches to an MDI. The Smartinhaler™ sensor contains an electronic clock and calendar that is used to log the date and time of MDI actuation. The Smartinhaler™ sensor registers MDI actuations. Usage data can be uploaded via a wireless *Bluetooth*® connection.

## Safety and Usage Information



To ensure your inhaler functions correctly, do not use the Smartinhaler™ sensor with any other MDI or medication than that indicated on the Smartinhaler™ sensor label.




The Smartinhaler™ sensor does not contain a dose counter. Do not use data collected by the Smartinhaler™ sensor to determine the number of doses remaining in a medication canister.




Smartinhaler™ sensor is not intended to diagnose your condition or to replace the diagnosis of a licensed physician.



For hygiene and data integrity reasons, do not use the Smartinhaler™ sensor with more than one patient.

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

 The Smartinhaler™ sensor does not record the quantity of medication delivered by the MDI.

## Symbols

	Manufacturer: Adherium (NZ) Ltd
	Serial Number
	Year of Manufacture
	Keep dry
	Rechargeable Sensor
	Non-rechargeable Sensor
	EU only: Do not dispose Smartinhaler™ sensor as unsorted municipal waste

## Warranty

The Smartinhaler™ 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 Smartinhaler™ sensor including dropping, water damage resulting from condensation or immersion, tampering, attempts to service, or other forms of abuse.

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

## Specifications

<b>Model numbers</b>	NF0090, NF0091
<b>Actuation Log Precision</b>	1 second
<b>Actuation Log Capacity</b>	5120 actuations and sensor status records
<b>Internal Clock Accuracy</b>	± 1 hour after 12 months. <b>Note:</b> <i>the Smartinhaler™ sensor clock is updated every time data is uploaded.</i>
<b>Compatible with</b>	iOS or Android smartphone and tablet devices. Refer to Apple App store or Google Play store for more information.
<b>Wireless Technology</b>	<i>Bluetooth®</i> 4.0: 2.40 - 2.48 GHz, 2.5 mW Low Energy
<b>Operating Temperature</b>	0 to 40°C (32 to 104°F)
<b>Storage Temperature</b>	-20 to 60°C (-4 to 140°F)
<b>Operating / Storage Humidity</b>	15 to 90% RH (non-condensing) at water vapour pressure ≤ 50 hPa

## Smartinhaler™ Sensor Specifications

### Rechargeable Sensor

<b>Model Number</b>	NF0090
<b>Battery Type</b>	Lithium Polymer
<b>Shelf Life</b>	2 years
<b>Service Life</b>	2 years

### Non-rechargeable Sensor

<b>Model Number</b>	NF0091
<b>Battery Type</b>	Lithium Primary
<b>Shelf Life</b>	3 years
<b>Service Life</b>	1 year

## FCC Statement

The Smartinhaler™ sensor complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. The Smartinhaler™ sensor may not cause harmful interference, and
2. The Smartinhaler™ sensor must accept any interference received, including interference that may cause undesired operation.



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.

## **IC Statement**

### **(Non-Rechargeable Sensor Only - NF0091)**

The Smartinhaler™ sensor complies with Industry Canada's license-exempt RSSs. Operation is subject to the following two conditions:

1. The Smartinhaler™ sensor may not cause interference; and
2. This Smartinhaler™ sensor must accept any interference, including interference that may cause undesired operation of the sensor.

*Le présent appareil est conforme aux CNR d'Industrie 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, et*
2. *l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.*

## **RF Exposure Statement**

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

## **Declaration of Conformity**

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

Hereby, Adherium (NZ) Ltd declares that the radio equipment type Smartinhaler™ sensor is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:  
[www.smartinhaler.com/RDC](http://www.smartinhaler.com/RDC)

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Product specifications may change without notice.

Patent/Design Notice -TBC



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Part Number: ND0400

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## Customer Support

For support on this product, email us at [support@smartinhaler.com](mailto:support@smartinhaler.com) or call us on +64 9 307 2771. For information about your medical condition, please speak to your healthcare provider directly.