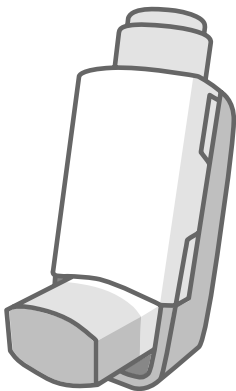


# SmartTouch™

For use only with Bevespi Aerosphere™



## Product Manual

For customer support,  
email [support@smartinhaler.com](mailto:support@smartinhaler.com)  
or call 1 833 3886 9688.

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## Compatible MDI Devices

The SmartTouch™ sensor is designed to work only with the MDI and medication indicated on the device label:

- For use with Bevespi Aerosphere™ MDI.


The SmartTouch™ sensor intended population is identical to the intended population of the Bevespi Aerosphere™ MDI.


## Preparation for First Use

Before first use remove the Battery Saver Pull Tab.

Download a compatible mobile application to communicate with your sensor. For more information see [www.smartinhaler.com](http://www.smartinhaler.com).

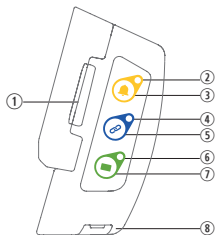
## Warnings, Cautions, and Notes

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

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

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

## SmartTouch™ Sensor Components



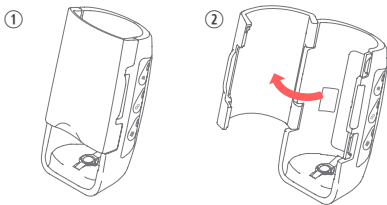
### Key:

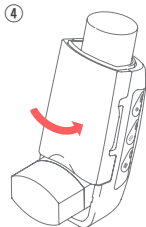
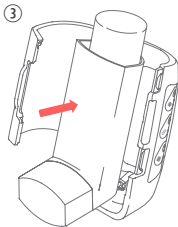
1. Door latch
2. Reminder LED
3. Reminder button
4. Pair LED
5. Pair button
6. Battery LED
7. Battery button
8. USB port (*not used*)

## Terms and Abbreviations

**MDI** Metered Dose Inhaler.

## Installing or Removing an MDI





### **Installation**

To install the inhaler, open the door of the SmartTouch™ sensor by pulling the Door Latch. Push the MDI into the SmartTouch™ sensor. Close the door so it clicks into place.

### **Removal**

To remove the inhaler, pull the Door Latch to open the door of the SmartTouch™ sensor. Pull the MDI to remove it from the SmartTouch™ sensor. Close the door so it clicks into place.


## **Setting Up *Bluetooth*® Communications**


The SmartTouch™ sensor must be paired with a compatible *Bluetooth*® smartphone or tablet computer in order to upload stored usage data.

To pair the SmartTouch™ 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 SmartTouch™ sensor hold down the Pair Button for 1 second to enter pairing mode. The Pair LED will flash blue when the SmartTouch™ sensor is in pairing mode.

3. Follow any prompts on your smartphone or tablet computer to select and accept pairing with the SmartTouch™ sensor. The Pair 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 SmartTouch™ sensor can only be paired with a single smartphone or tablet computer at one time. Successful pairing with a new smartphone or tablet computer will remove the current pairing. If pairing on the new smartphone or tablet computer fails, the existing pairing will be retained.

## **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 SmartTouch™ sensor battery status LED will flash green, orange, or red depending on battery status. The flash will occur 3 seconds after the medication actuation is detected.

 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.

## Reminders

Audio-visual reminders can be set up from the SmartTouch™ 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.

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

## Reviewing SmartTouch™ 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 if the SmartTouch™ sensor is within range (5 meters or 16 feet) of the smartphone or tablet computer.



When travelling ensure your smartphone or tablet computer is set to the local time zone for accuracy of MDI actuation logs.

## Manually Uploading Stored Information

The SmartTouch™ sensor can manually upload information to a paired *Bluetooth*® smartphone or tablet computer.

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

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





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

## Reviewing the Battery Level

The Battery LED indicates the battery level of the SmartTouch™ sensor after medication is actuated, or when the Battery Check Button is pressed.

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



The battery is not rechargeable. Once depleted, a new SmartTouch™ sensor will be required. Contact Customer Support for more information.

## Cleaning the SmartTouch™ Sensor and MDI

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



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

## Storage

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

## Troubleshooting

If the SmartTouch™ sensor is not responding to *Bluetooth*® communications, check the SmartTouch™ 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 SmartTouch™ sensor, and should be kept at least 30cm (12in) away.

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

If this does not help, contact Customer Support 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 or your medication, contact your healthcare provider.

## Servicing

Please contact the Customer Support for SmartTouch™ sensor servicing. Do not attempt to open or service the SmartTouch™ sensor. Tampering with the SmartTouch™ sensor voids the warranty.

## Disposal

Dispose or recycle the SmartTouch™ 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 SmartTouch™ sensor prior to disposal.

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

## SmartTouch™ Sensor Intended Use

The SmartTouch™ 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 SmartTouch™ sensor is compatible only with **Bevespi Aerosphere™ MDI**.

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


## How the SmartTouch™ Sensor Works


The SmartTouch™ sensor is a small battery-powered electronic data logger that attaches to an MDI. The SmartTouch™ sensor contains an electronic clock and calendar that is used to log the date and time of MDI actuation. The SmartTouch™ 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 SmartTouch™ sensor with any other MDI or medication than that indicated on the SmartTouch™ sensor label.

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







 SmartTouch™ 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 SmartTouch™ sensor with more than one patient.

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

 The SmartTouch™ sensor does not detect or record the quantity of medication delivered by the MDI.

## Symbols

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

## Warranty

The SmartTouch™ sensor includes a 12 month warranty against manufacturing defects from date of first use.

This warranty maybe voided under the following circumstances: damage to the SmartTouch™ sensor including dropping, water damage resulting from condensation or immersion, tampering, attempts to service, or other forms of abuse.

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

## Specifications

|                                   |   |
|-----------------------------------|---|
| <b>Model number</b>               | NF0096  |
| <b>Weight</b>                     | 24 grams, excluding MDI   |
| <b>Size</b>                       | 41 x 36 x 66mm (L x W x H) excluding MDI  |
| <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<br><b>Note:</b> <i>the SmartTouch™ sensor clock is updated every time data is uploaded.</i>                |
| <b>Compatible with</b>            | iOS or Android smartphone and tablet devices. Refer to <a href="http://smartinhaler.com">smartinhaler.com</a> for more information. |
| <b>Wireless Communication</b>     | <i>Bluetooth®</i> Low Energy 4.0: 2.40 - 2.48 GHz, 2.5 mW Low Energy  |
| <b>Battery Type</b>               | Lithium coin cell, non-rechargeable   |
| <b>Shelf Life</b>                 | 3 years   |
| <b>Battery Life/ Service Life</b> | 1 year  |

|                                     |   |
|-------------------------------------|---|
| <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)<br>at water vapour pressure $\leq$ 50 hPa |

## 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.

Note: 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

## Declaration of Conformity

Adherium (NZ) Ltd declares that this SmartTouch™ 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 SmartTouch™ sensor is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at:

**[www.smartinhaler.com/RDC](http://www.smartinhaler.com/RDC)**

Product specifications may change without notice.

**EC****REP**

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Made in Thailand

SmartTouch™ Sensor Product Manual

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