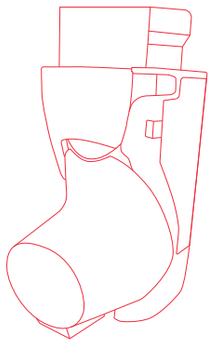
SmartTouch™
Symbicort®
Product Manual



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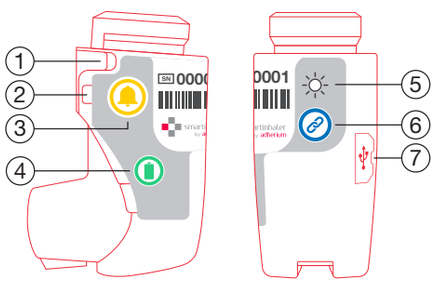
Preparation for First Use
Before first use remove the Battery Saver Pull Tab.

If you plan to use Smartinhaler Connection Center™ to review usage data, please refer to instructions on SmartinhalerLive.com before first use.

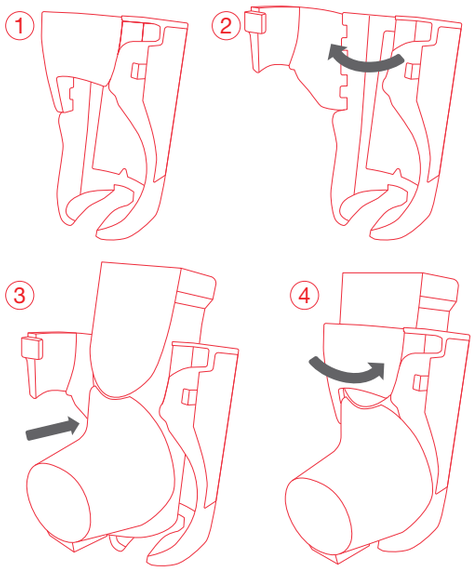
SmartTouch Components



Key
1. Door Latch
2. Light Emitting Diode (LED)
3. Reminder Button
4. Battery Check Button
5. Pair LED
6. Pair Button
7. USB Port

Compatible MDI Devices
The SmartTouch is designed to work only with the MDI and medication indicated on the device label:
- For use with Symbicort® MDIs.

Installing or Removing an MDI



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

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

Setting Up Bluetooth Communications
The SmartTouch must be paired with a compatible Bluetooth communications device in order to upload stored usage data. To pair the SmartTouch with a communications device:
1) Follow the communications device instructions to put it in pairing mode.
2) On the SmartTouch press the Pair Button 3 times to enter pairing mode.
   The Pair LED will flash blue when the SmartTouch is in pairing mode.
3) Follow any communications device prompts to select and accept pairing with the SmartTouch. The Pair LED will flash green to indicate pairing is successful.

Note: If pairing is not successful within 60 seconds the Pair LED will flash red. The pairing process can be repeated if necessary.
Note: The SmartTouch can only be paired with a single communications device at a time. Starting the pairing process removes the current paired device.

Delivering a Dose of Medication
Caution: This manual does not provide information on how to use prescription MDI 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. Please refer to the labeling provided with the inhaler for instructions on use.

The SmartTouch LED flashes after detecting a medication dose has been actuated.

Dose Check
You can check if the prescribed dose has been taken within the last 6 hours by pressing the Reminder Button once. If the LED flashes green the prescribed dosage has not been taken, if the LED flashes red no doses are overdue.

Reminders
Audio-visual reminders can be set up from a Smartinhaler app or via Smartinhaler Connection Center.
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 by holding down the Reminder Button.

Reviewing SmartTouch Usage Data
The MDI usage history can be automatically uploaded via a compatible paired communications device such as a smartphone.

The upload of new information will occur automatically as long as the SmartTouch is within range (5 meters or 16 feet) of the communication device.

Note: Refer to the instruction manual for your specific communication device for more information on this process.

Manually Uploading Stored Information
If required to ensure all current data has been transferred, the SmartTouch can manually upload information to a paired Bluetooth communications device. To manually upload stored information from the SmartTouch:
1) Hold down the Pair Button for 3 seconds until the Pair LED shows white, then release.
2) The Pair LED will flash white while the SmartTouch attempts to upload, then flash green if the upload is successful.

Note: The SmartTouch Pair LED will flash red if the upload is not successful. Check the SmartTouch is within range of the paired communications device, and the communications device has Bluetooth® communications enabled.

Reviewing the Battery Level
The LED on the main face indicates the battery level of the SmartTouch after medication is actuated, or when the Battery Check Button is pressed:
- **Green** – the battery level is good, and the SmartTouch is monitoring actuations.
- **Orange** – the battery level is getting low. The SmartTouch is still monitoring actuations.
- **Red** – the battery is flat. The SmartTouch has stopped monitoring actuations.
- **No flash** – the battery is flat, or the SmartTouch device has failed, e.g. due to liquid immersion or mechanical stress.

Cleaning the SmartTouch and MDI
Check the instructions from the MDI manufacturer for keeping the mouthpiece clean. Keep the SmartTouch clean and free of chemicals, steam, water and dust. Clean the outside plastic enclosure with a lightly dampened cloth. Leave it to dry in a warm place that is less than 30°C.
Warning: The SmartTouch is a battery powered electronic device. Do not immerse the SmartTouch in water.
Do not use the SmartTouch if it is not in good condition.

Storing the SmartTouch
To help maintain battery capacity, store your SmartTouch below 30°C. Keep out of direct sunlight and avoid extreme temperatures.

Troubleshooting
If the SmartTouch is not responding to Bluetooth communications, check the SmartTouch 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. Increase the separation distance between the SmartTouch and any such devices if this could be causing problems.

If this does not help, contact the supplier or manufacturer for further assistance.

Servicing
Please contact the supplier or manufacturer for device servicing. Do not attempt to open or service the SmartTouch. Tampering with the device voids the warranty.

Disposal
Dispose or recycle the SmartTouch in accordance with regulations for your country, as applicable for electronic devices containing a lithium polymer battery.

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

Warnings, Cautions, and Notes

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

Cautions identify actions or situations that could damage the SmartTouch, or other equipment, or affect the accuracy or availability of compliance data.

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

Terms and Abbreviations

MDI Metered Dose Inhaler

SmartTouch Intended Use

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

How the SmartTouch Works

The SmartTouch is a small battery- powered electronic data logger that attaches to an MDI. The SmartTouch contains an electronic clock and calendar that is used to log the date and time of MDI actuation.

The SmartTouch registers MDI actuations. Usage data can be uploaded via a wireless Bluetooth connection.

Safety and Usage Information

Warning: To ensure your inhaler functions correctly, do not use the SmartTouch with any other MDI or medication than that indicated on the device label.
Warning: The SmartTouch does not contain a dose counter. Do not use data collected by the SmartTouch to determine the number of doses remaining in a medication canister.
Caution: For hygiene and data integrity reasons, do not use the SmartTouch with more than one patient.
Caution: Take care to not spill liquids on the SmartTouch or immerse it in water.
Note: The SmartTouch does not detect or record inhalation by the user. The SmartTouch does not record the quantity of medication delivered by the MDI.

Symbols

	Manufacturer: Adherium (NZ) Ltd.
SN	Serial Number
	Year of Manufacture
	Keep Dry
	Non-Rechargeable Device
	EU only: Do not dispose of the SmartTouch as unsorted municipal waste
Rx ONLY	US only: Caution - Federal law restricts this device to sale by or on the order of a physician

Warranty

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

The SmartTouch warranty expires 5 years from date of manufacture.

Specifications

Weight	24 grams, excluding MDI
Size	41 x 36 x 66mm (L x W x H) excluding MDI
Actuation Log Precision	1 second
Actuation Log Capacity	6144 actuations and device status records
Internal Clock Accuracy	± 1 hour after 12 months *Note: the SmartTouch clock is updated every time data is uploaded*
Compatible With	iOS 7.1 and above, running on: • iPhone 4 and later • iPad 3 and later • iPad mini 1st Gen and later • iPod touch 5th Gen and later Android v4.4 and above
Wireless Technology	Bluetooth 4.0: 2.40-2.48 GHz, 2.5 mW Low Energy
Battery Type	Lithium Coin Cell, Non-rechargeable
Shelf Life	3 years
Service Life	1 year
Battery Life	12 months, depending on usage
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 95% RH (non-condensing)

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.

IC Statement

This device complies with Industry Canada's licence-exempt RSSs.
Operation is subject to the following two conditions:
1) This device may not cause interference; and
2) This device must accept any interference, including interference that may cause undesired operation of the device.

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 SmartTouch is in compliance with the essential requirements and other relevant provisions of Directives 1999/5/EC and 93/42/EEC.
Email contact@smartinhaler.com for a copy of the declaration of conformity.

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.

Product covered by a NZ Design Application No. 421072.
Patent pending.

EC REP

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