

SmartTouch™ AV

Product Manual

Preparation for First Use

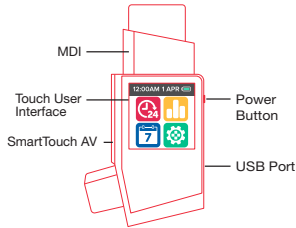
Following manufacture the SmartTouch AV is placed in Deep-Sleep mode to conserve battery life.

Before first use place the SmartTouch AV on charge for 1.5 hours or until the battery indicator is showing a full charge. This will wake the device from Deep-Sleep mode.

When SmartTouch AV is fully recharged, disconnect from the power supply.

If you plan to use SmartInhaler Connection Centre™ to review usage data, please refer to instructions on SmartInhalerLive.com before first use.

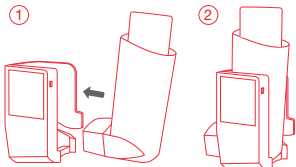
SmartTouch AV Components



Compatible MDI Devices

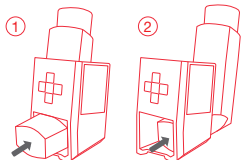
The SmartTouch AV is designed to work only with the MDI and medication indicated on the device label.

Installing or Removing an MDI



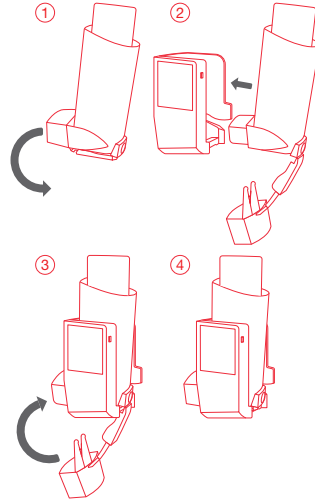
Installation (for non-tethered MDI)

To install the SmartTouch AV, align the MDI with the back of the SmartTouch AV, and push the MDI firmly into the SmartTouch AV, ensuring the mouth piece of the MDI goes through the front window on the SmartTouch AV.



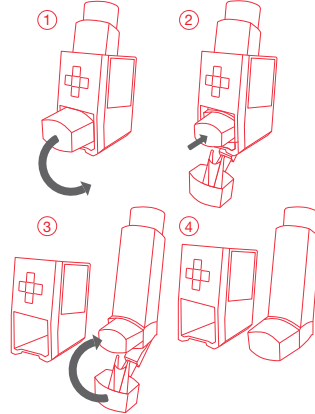
Removal (for non-tethered MDI)

While holding each side of the SmartTouch AV, gently push the mouthpiece of the MDI to remove the MDI from the SmartTouch AV.



Installation (for tethered MDI)

To install the SmartTouch AV, open the MDI cap, align the MDI with the back of the SmartTouch AV, and push the MDI firmly into the SmartTouch AV, ensuring the mouth piece of the MDI goes through the front window on the SmartTouch AV, close the MDI cap.



Removal (for tethered MDI)

Open the MDI cap, while holding each side of the SmartTouch AV, gently push the mouthpiece of the MDI to remove the MDI from the SmartTouch AV, close the MDI cap.

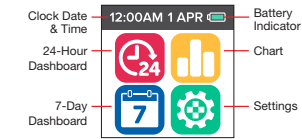
Delivering a Dose of Medication

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 AV will show a dose taken image on its screen after detecting a medication dose has been actuated. This is followed by **Dose Taken** question, which the user can answer Yes (✓) or No (✗). If no response is registered the SmartTouch AV will record as a medication dose.

Navigating the SmartTouch AV Menu

The SmartTouch AV main menu can be accessed after the SmartTouch AV is switched on by pressing the power button. You can navigate to the sub menus of each of the four icons on the main menu. The date and time of the internal clock, and the battery indicator are shown on the top of the main menu.



Once a menu has been entered, the following icons can be used to navigate around each individual page:

- ▲ Scroll Up ✓ Select
- ▼ Scroll Down ✗ Cancel
- ↶ Return

24-Hour Dashboard

The **24-Hour Dashboard** menu indicates when the medication was last used and how much was used in last 24 hours. Tap the screen to show this information.

Taken last 24 hours indicates the number of doses taken in the previous 24 hours.

Preventer Only Adherence today indicates the percentage

adherence with the prescribed dose during the current day.

Reliever Only

Including Night uses indicates the total number of doses taken between midnight and 6 am.

7-Day Dashboard

The **7-Day Dashboard** menu indicates how many doses were taken in the last 7 days, the percentage adherence and when last taken.

Taken last 7 days indicates the number of doses taken during the last 7 days, including the current day.

Preventer Only

Adherence last 7 days indicates the percentage adherence with the prescribed dose during the last 7 days.

Reliever Only

Including Night uses indicates the total number of doses taken between midnight and 6 am during the last 7 days.

Chart

The **Chart** menu displays the total number of doses actuated by day over the last 7 days, including the current day. Use the **Scroll Down** arrow to view medication usage for previous weeks.

Settings

The **Settings** menu allows you to change the internal clock settings, set reminders, upload data and pair SmartTouch AV with a Smartphone.

Set Clock

The **Set Clock** allows the SmartTouch AV internal clock to be changed.

To change the internal clock, navigate to the **Set Clock** menu. Use the **Scroll Up** or **Scroll Down** buttons to change the time zone, press **Select** to confirm. Use the **Scroll Up** or **Scroll Down** buttons to change the date and time value (selection to change flashing). Holding down the **Scroll Up** or **Scroll Down** buttons will change the value quickly. Press **Select** to confirm and move to the next time unit in the order of day, month, year, hour and minute.

Reminders

Note: The reminder functionality is only available on monitors which are designed for preventer medications.

Reminders Sub Menu - On/Off

The **Reminder On/Off** Menu enables or disables the reminder. Press **Select** to enter the **Reminder On/Off** screen. Change the **Reminder On/Off** setting using the **Scroll Up** or **Scroll Down** buttons to set it to Play All, Play Selected or Off. Press **Select** to confirm or **Cancel** to exit.

If enabled, the medication reminder tunes play at the times configured in the **Reminder Times** screen for up to 25 minutes, or until the installed pMDI is actuated the number of times set in the "Doses" menu.

Reminders Sub Menu - Ringtones

The **Ringtones** screen allows an audio reminder tune to be listened to. Press **Select** to enter the **Ringtones** screen.

Use the **Scroll Up** or **Scroll Down** buttons to change the selection. Press **Select** to preview and select the displayed tune or press **Return** to exit. Note when **Select** is pressed for a tone selection, that tune will play at the next reminder time. If **Select** is not pressed the selection will remain unchanged.

Note: When a tune is playing press **Select** or **Return** to stop the playback.

Reminders Sub Menu - Volume

The **Volume** Menu sets the reminder volume to Normal or Loud. Press **Select** to enter the **Volume** screen. Change the **Volume** setting using the **Scroll Up** or **Scroll Down** buttons. Press **Select** to confirm or **Return** to exit.

Reminders Sub Menu - Times

Press **Select** to configure the Weekday AM/PM and Weekend AM/PM medication reminder times.

Use the **Scroll Up** or **Scroll Down** buttons to change the time value (selection to change flashing). Holding down the **Scroll Up** or **Scroll Down** buttons will change the value quickly. Press **Select** to move from the hour value to the minute value and to cycle through the Weekday AM, Weekday PM, Weekend AM, Weekend PM Reminder times. Press **Return** to exit.

Reminders Sub Menu - Doses

The **Doses** screen sets the number of doses that will stop the audio reminder while the reminder is playing. Note that if the number of doses indicated is actuated any time in the previous 6 hours before the reminder is scheduled, then the reminder will not play until the next scheduled time is reached.

Upload

The **Upload** Menu is used to set up Bluetooth communications with other devices, such as Smartphones.

Upload Sub Menu - Upload Now

The **Upload Now** Menu allows the SmartTouch AV to upload the data manually to SmartInhalerLive mobile app. Press **Select** to enter the **Upload Now** screen. The data will start to upload and will give a confirmation of Upload Success or Failure.

Upload Sub Menu - Pair

The **Pair** Menu allows the SmartTouch AV to Pair with other devices, such as Smartphones. Press **Select** to enter the **Pair** screen. The SmartTouch AV will start pairing and will give a confirmation of Pairing Success or Failure.

Starting the pairing process removes the current paired device.

Locks

The **Locks** Menu enables selected screens to be locked to the user. The default setting is no locked screens.

The default lock code is **00000**

The master unlock code is **13201**

The code must be entered to access the lock menu.

Locks Sub Menu - Set Locks

Set Lock is used for changing the lock code. A new 5-digit code must be entered twice to complete the set lock process.

Locks Sub Menu - Options

The **Options** menu allows the SmartTouch AV reminder and device pairing menus to be lock to the user.

Options are:

- **Reminder Menu** (the entire reminder menu)
- **Reminder Doses** (the menu where the number of doses is set)
- **Reminder Mode** (the menu where the reminder on/off is set)
- **Reminder Times** (the menu where the reminder times are set)
- **Device Pairing** (pairing of a new device)

Reviewing SmartTouch AV Usage Data

At a convenient time, the pMDI usage history can be uploaded to www.smartinhalerlive.com for review. This can be done as often as required. However, it is recommended that uploads are performed at least once every month. The SmartTouch AV can store at least one year of medication usage data under normal usage.

Note: Refer to the online training at SmartInhalerLive.com for more information on reviewing medication usage.

Upload via USB

To upload data to SmartInhalerLive.com for review, log in to www.smartinhalerlive.com and download and install the **SmartInhaler Connection Center** software. Connect the SmartTouch AV to the computer via the USB connection. Follow the instructions on the Connection Center to

preview and upload the usage data to www.smartinhalerlive.com.

Note: Refer to the instruction manual for SmartinhalerLive.com for more information on downloading and installing the Smartinhaler Connection Center software.

Recharging the SmartTouch AV

The SmartTouch AV contains an internal rechargeable battery and is recharged via the USB connection. The Battery Indicator is shown on the screen when medication is taken or if the Power Button is pressed. When the Battery Indicator is red, the SmartTouch AV should be recharged. A battery low warning message will be displayed in conjunction with a red battery indicator.

To charge the internal battery, connect the SmartTouch AV to a computer USB port or USB wall plug adaptor.

When connected to a charging source, the Charging display is shown briefly, and a power connection symbol appears on the Battery Indicator with increasing charge level. Charge completion is indicated by a steady Battery Indicator showing full charge.

If the battery was flat before charging, the SmartTouch AV may have lost its internal date and time settings. After charging, enter the Settings menu to set the SmartTouch AV internal calendar and clock to the local date and time. Refer to *Set Clock* in this manual for more information.

Cleaning the SmartTouch AV and MDI

Check the instructions from the MDI manufacturer for keeping the mouthpiece clean. Keep the SmartTouch AV clean and free of chemicals, steam, water and dust.

Clean the SmartTouch AV by wiping 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 AV is a battery powered electronic device. Do not immerse the SmartTouch AV in water. Do not use the SmartTouch AV if it is not in good condition.

Storing the SmartTouch AV

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

Troubleshooting

If the SmartTouch AV is not responding to communications, check that the USB cable is plugged in correctly. If this does not help, please 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 AV. Tampering with the device voids the warranty.

Disposal

Dispose or recycle the SmartTouch AV 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 AV as unsorted municipal waste. The SmartTouch AV must be recycled in accordance with Directives 2012/19/EU and 2006/66/EC. To arrange for return or disposal of the SmartTouch AV 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 AV.

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

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

Terms and Abbreviations

MDI Metered Dose Inhaler

SmartTouch AV Intended Use

The SmartTouch AV is intended for single-patient use as an 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 AV is not intended to indicate remaining quantity of medication in an MDI and does not include a dose counting function.

How the SmartTouch AV Works

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

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

Caution: For hygiene and data integrity reasons, do not use the SmartTouch AV with more than one patient.

Caution: Take care to not spill liquids on the SmartTouch AV or immerse it in water.

Note: The SmartTouch AV does not detect or record inhalation by the user. The SmartTouch AV does not record the quantity of medication delivered by the MDI.

Symbols

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

Warranty

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

The SmartTouch warranty expires 4 years from date of manufacture.

Specifications

Weight	31 grams, excluding MDI
Size	36 x 41 x 59mm (L x W x H) excluding MDI
Actuation Log Resolution	1 second
Actuation Log Capacity	3712 actuations and device status records

Internal Clock Accuracy	± 1 hour after 12 months. <i>Note: the SmartTouch AV clock is updated every time data is uploaded</i>
Wireless Technology	Bluetooth 4.0: 2.40 - 2.48 GHz, 2.5 mW Low Energy
Battery Type	Lithium Polymer 80 mAh rechargeable
Service Life	2 years
Battery Life	6 weeks on full charge 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:

- This device may not cause harmful interference, and
- 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:

- This device may not cause interference; and
- 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 :

- l'appareil ne doit pas produire de brouillage, et*
- 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.

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Product specifications may change without notice.

New Zealand Patent No. 614928
Patents Pending: PCT/NZ2014/000184 and NZ Pat. Appl. No. 703739
New Zealand Design Appl. No. 419719

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Product specifications may change without notice.

New Zealand Patent No. 595367
New Zealand Design appl. No. 420386
Patents Pending: EP2758111 and US 2014-0182584



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