# SmartTouch ProAir Product Manual




Product specifications may change without notice.

SmartTouch ProAir is manufactured by:
Nexus6 Ltd
8 Commerce Street, Suite 205
Auckland 1010
New Zealand
Phone +64 9 307 2771
Fax +64 9 307 2773
Email contact@smartinhaler.com
Web www.smartinhaler.com

SmartTouch ProAir Product Manual

| | |
|---|---|
| Part Number | NL0034 |
| Revision | 5.1 |
| Issue Date | 23 October 2012 |
| Product Version | STOUCHPROAIR |

## 1 Who this Product Manual is intended for

This Product Manual is intended for users of the SmartTouch ProAir device, namely clinical trials investigators, healthcare professionals, patients with respiratory conditions, and patient caregivers.

## 2 Warnings, Cautions, and Notes

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

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

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

## 3 Terms and Abbreviations

| | |
|---|---|
| pMDI | Pressurized Metered Dose Inhaler |

## 4 Symbols

| | |
|---|---|
|  | Consult instructions for use |
|  | Manufacturer |
|  | Serial number |
|  | EU only: Do not dispose of the SmartTouch ProAir or used batteries as unsorted municipal waste. |
|  | US only: Caution - Federal law restricts this device to sale by or on the order of a physician. |

## 5 SmartTouch ProAir Intended Use

The SmartTouch ProAir device is intended for single-patient use as an electronic data capture accessory for recording actuations of prescribed pMDI usage. This may be used in the following applications:

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

## 6 How the SmartTouch ProAir Works

The SmartTouch ProAir is a small battery powered electronic data logger. The SmartTouch ProAir is powered by an internal non-rechargeable battery, and contains an internal electronic clock and calendar that is used to log the date and time of pMDI actuation. The SmartTouch ProAir registers pMDI actuations. Usage data can be uploaded via a wireless Bluetooth connection.

## 7 SmartTouch ProAir Components


ʒ Diode (LED)

n

## 8 Compatible pMDI Devices

The SmartTouch ProAir is designed to work with ProAir pMDI.

## 9 Safety and Usage Information

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

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

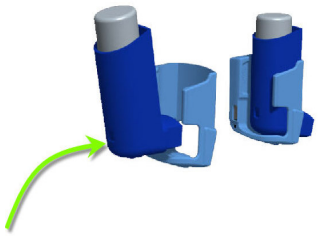
***Caution:*** *Take care to not spill liquids on the SmartTouch ProAir or immerse it in water.*

***Note:*** *The SmartTouch ProAir does not detect or record patient inhalation within the pMDI it is attached to. The SmartTouch ProAir does not record the quantity of medication delivered by the pMDI.*

## 10 Installing or Removing a pMDI

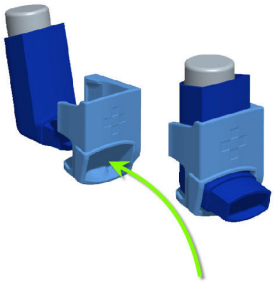
### Installation

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



### Removal

While holding each side of the SmartTouch ProAir, gently push the mouthpiece of the pMDI to remove the pMDI from the SmartTouch ProAir.



## 11 Delivering a Dose of Medication

***Caution:*** *This manual does not provide information on how to use prescription pMDI medication. This manual 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 ProAir inhaler for instructions.*

## 12 Uploading SmartTouch ProAir data

Data logged in the SmartTouch ProAir can be uploaded to the Smartinhaler Connection Center Desktop software for review. Data is transferred to the Connection Center Desktop software via Bluetooth wireless communication.

The Smartinhaler Connection Center Desktop software will need to be already installed onto the computer before data can be reviewed. The software can be downloaded from the SmartinhalerLive website (www.smartinhalerlive.com). Please follow the instructions on the SmartinhalerLive website to download and install the Smartinhaler Connection Center Desktop software.

### 12.1 Upload via Bluetooth

To upload data stored on the SmartTouch ProAir using Bluetooth communications, firstly click the Upload button on the Connection Center software. Press the Upload button located on the center of the SmartTouch ProAir main face (refer to image in Section 7). The button needs to be held down for 2 seconds before data communications commences. The SmartTouch ProAir searches for a Bluetooth device that it can communicate with, for example, Nexus6's SmartKey.

While communicating, the LED on the top right corner of the main flashes **blue**. If the LED does not flash after pressing the Upload button, either:

- the battery is flat, or
- the SmartTouch ProAir device has failed, e.g. due to liquid immersion or mechanical stress.

*Caution: Do not initiate wireless Bluetooth communications when travelling on an aircraft.*

## 13 Reviewing SmartTouch ProAir Usage Data on Smartinhaler Connection Center Desktop

At a convenient time, the pMDI usage history can be uploaded to the Smartinhaler Connection Center Desktop software for review. This can be done as often as required. However, it is recommended that uploads are performed at least every 6 weeks. The SmartTouch ProAir can store up to one year of medication usage data in its memory.

## 14 Reviewing the battery level of your SmartTouch ProAir

The SmartTouch ProAir contains an internal non-rechargeable battery. The LED on the top right corner of the main face of the device allows you to review the battery level of the SmartTouch ProAir. The LED on the SmartTouch ProAir flashes one of the following three colours when you actuate the SmartTouch:

- **Green** – Indicates that the battery level is good, and that the monitoring of actuations is being performed by the SmartTouch ProAir.

- **Orange** – Indicates that the battery level is getting low. The SmartTouch ProAir is still monitoring actuations.
  *Note: Do not deploy the SmartTouch ProAir to a new patient if the LED has switched to orange.*

- **Red** – Indicates that the battery is flat. The SmartTouch ProAir has stopped monitoring actuations.
  *Note: Do not deploy the SmartTouch ProAir to a new patient.*
- **No flash** – the battery is flat, or, the SmartTouch ProAir device has failed, e.g. due to liquid immersion or mechanical stress.

The SmartTouch ProAir has a shelf life of 3 years from its Use By date and an active service life of 1 year (at an average daily use of two puffs twice daily).

## 15 Cleaning the SmartTouch ProAir and pMDI

Keep the SmartTouch ProAir clean and free of chemicals, steam, water and dust. Clean the SmartTouch ProAir 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 ProAir is a battery powered electronic device. Do not submerge the SmartTouch ProAir in water. Do not use the SmartTouch ProAir if it is not in good condition.

## 16 Storing the SmartTouch ProAir

Store your SmartTouch ProAir below 30°C. Keep out of direct sunlight and avoid extreme temperatures. Keep the SmartTouch ProAir out of reach of children.

## 17 Trouble Shooting

If the SmartTouch ProAir is not responding to communications via Bluetooth, check the SmartTouch ProAir battery level as per section 14 of this manual. If this does not help, contact the supplier or manufacturer for further assistance.

## 18 Servicing

Please do not attempt to open or service the SmartTouch ProAir. Tampering with the device voids the warranty.

## 19 Disposal

Dispose or recycle the SmartTouch ProAir in accordance with regulations for your country.
EU only: Do not dispose of the SmartTouch ProAir as unsorted municipal waste at the end of the product's lifetime. The SmartTouch ProAir must be recycled in accordance with the WEEE Directive 2002/96/EC. To arrange for return or disposal of the SmartTouch ProAir contact your local supplier.
EU only: Do not dispose of waste batteries as unsorted municipal waste. Device batteries must be recycled in accordance with the Battery Directive 2006/66/EC. Return waste batteries to an appropriate local collection point or contact your local supplier for disposal information.

## 20 Warranty

The SmartTouch ProAir includes a 24 month warranty against manufacturing defects. 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.

## 21 Specifications

| | |
|---|---|
| Weight | 20 grams including battery, excluding pMDI |
| Size | 50mm High × 38mm Wide x 35mm Long excluding the pMDI |
| Actuation Log resolution | 1 second |
| Actuation Log Capacity | 4096 actuations and device status records |
| Internal Clock Accuracy | ± 20 minutes after 12 months<br>Note: the SmartTouch ProAir clock is updated every time data is uploaded to Nexus6 software. |
| Bluetooth | Bluetooth Low Energy (BLE) v4.0 |
| Battery Type | Lithium |
| Battery Life | 3 year shelf life and 1 year service life |
| Operating Temperature | 0 to 40 °C (32 to 104 °F) |
| Operating Humidity | 25 to 90% at 40 °C (non-condensing) |
| Storage Temperature | -20 to 60 °C (-4 to 140 °F) |
| Storage Humidity | 25 to 95% at 40 °C (non-condensing) |

## 22 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.