

SmartKey Product Manual



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SmartKey Product Manual

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Product Version SKEY

1 Who this Product Manual is intended for

This Product Manual is intended for users of the SmartKey, 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 SmartKey.

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

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

3 Terms and Abbreviations

BLE	Bluetooth Low Energy
pMDI	Pressurized Metered Dose Inhaler

4 Symbols



Consult instructions for use



Manufacturer



Serial number



EU only: Do not dispose of the SmartKey as unsorted municipal waste.



US only: Caution - Federal law restricts this device to sale by or on the order of a physician.

5 SmartKey Intended Use

The SmartKey is intended for patient use as an electronic data communications accessory for transferring information recorded by the SmartTouch ProAir monitoring device to the Nexus6 SmartInhaler Connection Center Desktop software. This data may be required in the following applications:

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

6 How the SmartKey Works

The SmartKey is a USB device that acts as a small, wireless communicator that plugs into a Personal Computer (PC). When the SmartKey is connected to a monitoring device such as the Nexus6 SmartTouch ProAir, it wirelessly receives information from the SmartTouch ProAir, and forwards the information to the Nexus6 SmartInhaler Connection Center software. The SmartKey transfers information that includes date and time of logs, as well as other properties of the communication process recorded by the SmartTouch ProAir device.

7 Compatible Devices

The SmartKey is designed to work with the Nexus6 SmartTouch ProAir monitoring device.

Warning: Do not use the SmartKey with any devices other than those listed above.

8 Safety and Usage Information

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

Note: The SmartKey does not detect or monitor patient use of the SmartTouch ProAir device. This information is recorded and transferred to the SmartKey from the SmartTouch ProAir device.

9 Using the SmartKey

The SmartKey is powered by the PC to which it is connected to. There is no on/off button for the SmartKey. The SmartKey is only able to transfer data from a SmartTouch ProAir device when the SmartKey is connected to a PC.

9.1 Connecting the SmartKey to a PC

To connect the SmartKey to a PC, firstly remove the cap from the SmartKey and insert the SmartKey into a USB port on the PC.

9.2 Using a Monitoring Device

Caution: This manual does not provide information on how to use a monitoring device such as the SmartTouch ProAir device. This manual is not intended to replace the advice provided by a healthcare professional. Directions for using a monitoring device should be obtained from a healthcare professional and the monitoring device Product Manual, and followed accordingly. Any questions related to use of a monitoring device should be referred to a healthcare professional.

9.3 Connecting the SmartKey to a Monitoring Device via Bluetooth

The SmartKey can only communicate wirelessly to a monitoring device when it is connected to a PC. Information is received by the SmartKey from a monitoring device via Bluetooth Low Energy (BLE) wireless communications.

9.4 Using the SmartKey to upload information stored in a monitoring device

The Smartinhaler Connection Center Desktop software is required to be installed on a PC before information from a monitoring device can be uploaded by the SmartKey. Please follow the instructions on the SmartinhalerLive website at www.smartinhalerlive.com to download and install the software.

When the SmartKey is connected to a PC, it receives new information from a monitoring device via Bluetooth and will automatically pass the received information to the Nexus6 Smartinhaler Connection Center Desktop software.

10 Caring for the SmartKey

10.1 Cleaning the SmartKey

Keep the SmartKey clean and free of chemicals, steam, water and dust. Clean the SmartKey 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 SmartKey is an electronic device. Do not submerge the SmartKey in water. Do not use the SmartKey if it is not in good condition.

11 Storing the SmartKey

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

12 Trouble Shooting

If the SmartKey is not responding to the monitoring device or the Connection Center Desktop software, make sure it is connected properly to the PC. If this does not help, contact the supplier or manufacturer for further assistance.

12.1 Servicing

Do not attempt to open or service the SmartKey. Tampering with the device voids the warranty.

12.2 Disposal

Dispose or recycle the SmartKey in accordance with regulations for your country.

EU only: Do not dispose of the SmartKey as unsorted municipal waste at the end of the product's lifetime. The SmartKey must be recycled in accordance with the WEEE Directive 2002/96/EC. To arrange for return or disposal of the SmartKey, contact your local supplier.

13 Specifications

Weight	10 grams
Size	8mm high × 22mm wide × 70mm long
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)

14 Warranty

The SmartKey includes a 24 month warranty against manufacturing defects. This warranty may be voided under the following circumstances: damage to the SmartKey including dropping, water damage resulting from condensation and immersion, tampering, attempts to service, or other forms of abuse.

15 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 UNDESIREED 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.