



SoloSmart

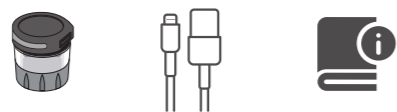
for SoloStar

USER MANUAL

Helping you keep track of your insulin injections

3 Package contents

- SoloSmart x1
PN : 0273971
- USB cable x1
PN : 0373707
- User manual x1 & Technical note x1

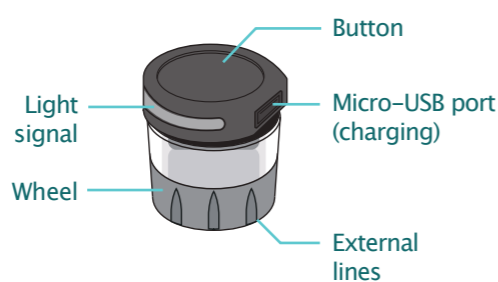


NOTE: the USB charger is not included. Use a Class II USB wall charger, with output 5V and at least 500mA.

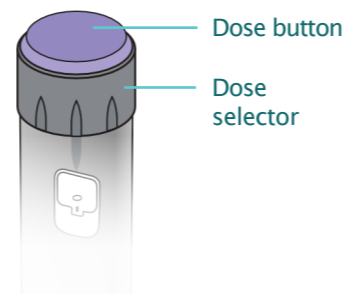


5V
≥500mA

4 Getting to know SoloSmart and the pen



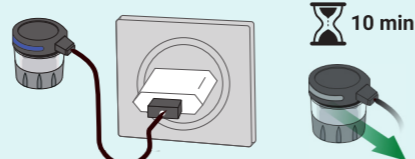
SoloSmart



Sanofi SoloStar® insulin pen

5

Charge and activate SoloSmart



10 min

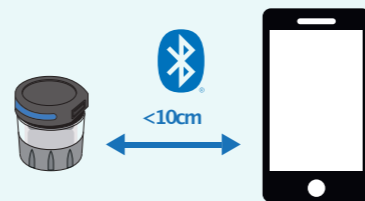
1. Connect SoloSmart to the supplied USB cable.
2. Connect the cable to a powered USB wall charger.
3. Let the device charge for at least 10 minutes before its first use.
4. Unplug the cable and SoloSmart, then unplug the charger.

The **blue** light signal indicates that the device is not paired.

Getting started

Download the App and pair SoloSmart

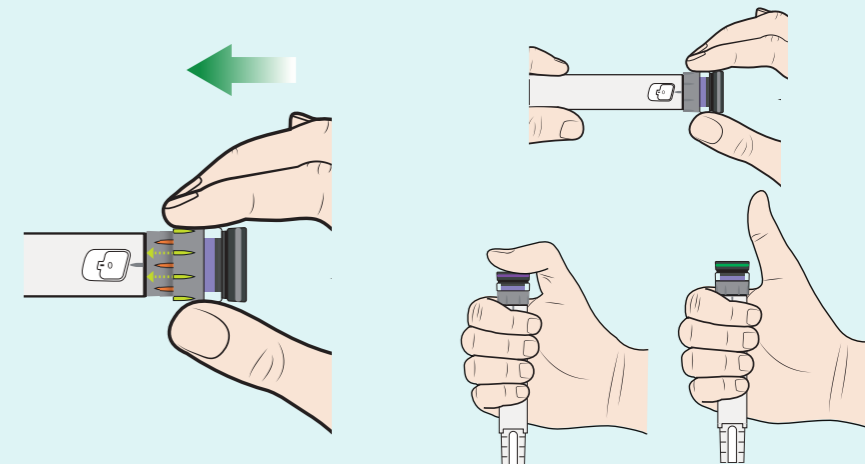
Before you can use your SoloSmart, you will need to pair it with a mobile application. Check the SoloSmart™ website for a list of free applications compatible with your SoloSmart: www.solosmart.sanofi.com



1. Download a compatible application to your smartphone on Google Play™ (Android) or the App Store® (Apple) and follow the on-screen instructions to create an account and pair your SoloSmart.
2. Activate the Bluetooth on your smartphone, if not already activated.
3. Keep SoloSmart less than 10 cm away from your smartphone.
4. Open the app and follow the on-screen instructions to pair SoloSmart, and **select the type of pen the device will be mounted on.**

At the end of the pairing step, the light signal turns **green**, then off.

Assemble SoloSmart on the pen



1. Hold the pen with one hand, keeping the dose button accessible, and protect the needle (if already mounted) with the pen cap.
2. With your other hand, hold SoloSmart by the wheel, without pressing on its button.
3. Insert SoloSmart on the pen dose button, placing the **external lines** of SoloSmart between the pen dose selector **ridges** (in orange and black), and push it all the way on the button, still holding SoloSmart by the wheel and without pressing on the button.
4. Make sure that SoloSmart is fully inserted on the pen dose button: the pen dose selector is completely covered.
5. Activate the « mounted » mode by pressing firmly on the SoloSmart button for at least 5 seconds, until you see the **purple** light. Lift your finger, the light turns **green**, indicating that SoloSmart mini is ready to be used.

NOTE: Do not forget to deactivate SoloSmart **BEFORE** transferring it on a new pen. Please refer to Section 9 for details.

1 Main features

SoloSmart is a smart sensor which can be mounted on a Sanofi SoloStar® disposable insulin pen.

SoloSmart allows you to:

- record the injected pen increment (insulin dose),
- record the date and time of each insulin injection,
- transmit the dose, date and time of each injection to a compatible mobile application on a smartphone, when the device is paired to it, thanks to Bluetooth technology.

2 Indications for use and intended use

The SoloSmart injection pen adapter is indicated for the capture and wireless transmission of dosing information from compatible disposable pen injectors.

SoloSmart is intended to be used by all users of the Sanofi SoloStar® insulin pens. SoloSmart can be used with a compatible mobile App (autonomous software installed on your smartphone) to visualize the log of your injected doses. The SoloSmart injection pen adapter is intended to be used by patients in the same use environment as their compatible injection pen. There are no known contraindications to the use of SoloSmart for these patients.

6 Using SoloStar

Refer to the Instructions for Use of your pen for the priming and injection instructions.

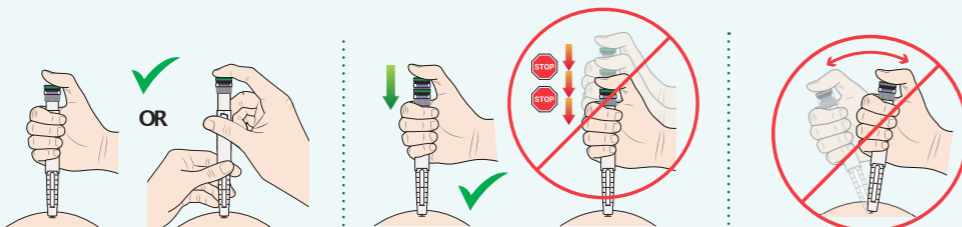


If you are not certain that you injected your insulin, do not start, or repeat your injection. Monitor your treatment and glycaemia as instructed by your healthcare provider. If you have any doubts about your treatment, please consult your healthcare provider.

TIPS FOR USE

Adapt your position in order to feel comfortable and be able to inject your dose in one single thrust, without changing position or finger during the injection. Use your thumb or index finger.

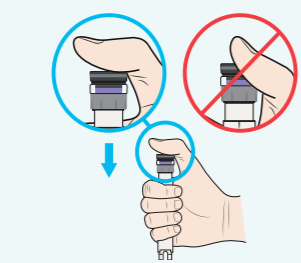
Press continuously at the center of the button.



Keep the same position and finger during injection

Inject in one single and continuous thrust.

Stay still.



Press at the center of the button, using your index finger if it is uncomfortable or not precise enough with your thumb.

NOTE: Safety tests performed to check the insulin flow (priming), will also be automatically detected and recorded by SoloSmart. Perform the safety test to check the insulin flow as described in the Instructions for Use of your pen. Please check your mobile application for correct identification of the safety tests performed.

7 Charging SoloSmart

The SoloSmart battery has a 1-week minimum autonomy in normal use conditions. When the battery is low, the light is **orange**.



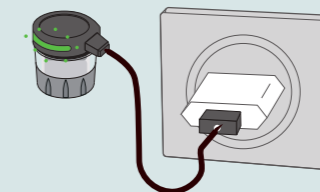
Connect SoloSmart to the supplied USB cable, then connect the cable to a powered USB wall charger, in order to charge SoloSmart.



Do not use any other cable.

Please connect the supplied USB cable to the USB port of a power adapter (IEC / UL 60950-1 or IEC / UL 62368-1 certified with CE or UL marking) suitable for your region.

While charging, the light signal is slowly flashing **green** and dose recording and detection is inactivated.



Never use SoloSmart while it is charging.



NOTE: Once the battery is fully charged, the light turns off (a full charge should not take more than 2 hours).

8 Reset and activation

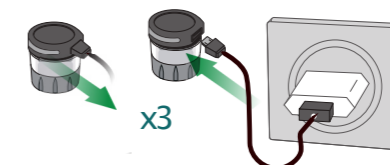
The reset procedure of SoloSmart may be necessary:

- if SoloSmart is not working properly (no response, etc...),
- if you need to pair SoloSmart with another mobile phone (smartphone),
- if you want to delete your personal health data from the device

Resetting SoloSmart deletes all the data stored on the device and its pairing parameters.

To reset SoloSmart:

- Connect the supplied USB cable to SoloSmart.
- Plug a USB wall charger to a power outlet
- Take the USB side of the cable and plug and unplug it in the USB wall charger at least 3 times, until SoloSmart flashes **red** and turns off.
- Wait for 30 seconds after the flashing light turns off: SoloSmart has been reset.



To restart SoloSmart:

- Connect the supplied USB cable to a USB wall charger, and then to SoloSmart.
- Unplug SoloSmart: the light turns **blue**, indicating that it is ready to be paired.

