sanofi

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0574317-2

SoloSmart
for SoloStar & DoubleStar

USER MANUAL

Helping you keep track of your insulin injections

Intended use

SoloSmart is intended to:

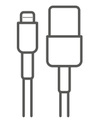
- record the increment injected by Sanofi SoloStar or Sanofi DoubleStar pen (insulin dose),
- record the date and time of each insulin injection,
- transmit information relating to the dose, time, and date of each injection to a compatible mobile application on a smartphone, when the device is connected to it, using Bluetooth technology.

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.

In the box

SoloSmart x1
PN : 0273971

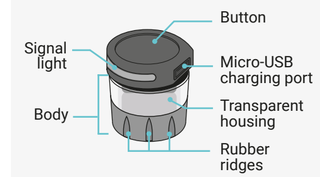
USB cable x1
PN : 0373707



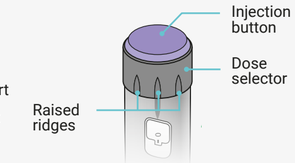
User manual x1

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

Getting to know SoloSmart



SoloSmart



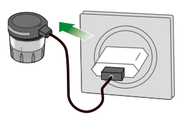
Your SoloStar® / DoubleStar® Pen

How to Setup Your SoloSmart

1 Wake Up and Charge the Device

The device is turned off when it is shipped. You will need to wake up the device and make sure it is charged enough before use.

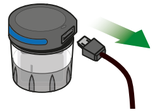
1.1 Connect SoloSmart to the supplied USB cable and connect the cable to a powered USB wall charger. This will wake up the device.



1.2 Let the device charge for at least 10 minutes before use.

Charge at Least 10 Minutes

1.3 Unplug SoloSmart from the USB cable and then unplug the wall charger.
When you are done, the SoloSmart signal light will turn blue indicating that the device is in pairing mode but not yet paired.



2 Download a Compatible App and Pair with SoloSmart

Before you can use your SoloSmart, you will need to pair it with a mobile application on your smartphone.

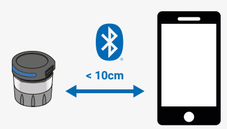
2.1 Download the application from Google Play™ (Android) or the App Store® (Apple).

Download on the App Store
GET IT ON Google Play

2.2 Pair SoloSmart by following the guidance in the App to:

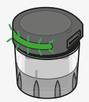
- Turn on your smartphone's Bluetooth (if not already on).
- Pair the SoloSmart with the App.

Note: you must keep SoloSmart within 10 centimeters of the smartphone during pairing.



At the end of the pairing step, you may notice the signal light turn green and then turn off.
Once paired your SoloSmart will enter **standby mode** and the light will turn off.

When paired light will flash green then turn off

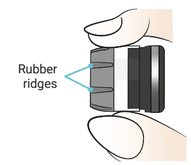


2.3 After pairing, follow the guidance in the app to select the insulin type.

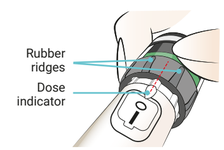
3 Attach SoloSmart to your Pen

SoloSmart attaches to the injection button of your pen. Carefully follow the steps below to attach it.

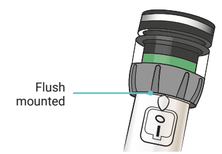
3.1 **Hold SoloSmart by the transparent housing**. Rubber ridges can be seen on the outside of SoloSmart.



3.2 Place SoloSmart on the pen so that the dose indicator of the pen is between the rubber ridges of SoloSmart.



3.3 Push SoloSmart on the transparent housing until the injection button is completely covered.

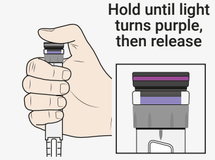


4 Put SoloSmart into Active Mode

To activate SoloSmart on the pen:

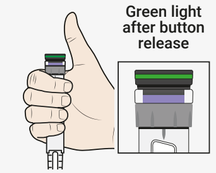
4.1 Firmly press and hold the SoloSmart button down for at least 5 seconds until the light turns purple.

Hold until light turns purple, then release



4.2 Then, lift your finger from the button. The light will then turn green showing the device is now in active mode.

Green light after button release



Note: If the light does not turn purple make sure SoloSmart is pushed all the way down.

Your SoloSmart is now ready to use.

Important: Follow the **"Injecting a Dose with SoloSmart Attached to Your Pen"** section below when you give an injection.

Injecting a Dose with SoloSmart Attached to Your Pen

Overview

SoloSmart allows you to inject with your pen as you normally would. Refer to the Instructions for Use of your pen for the safety test (priming) and injection instructions.

Note: Safety tests performed to check the insulin flow (priming) will also be automatically detected and recorded by SoloSmart. Check your mobile application for correct identification of the safety tests performed.

Before Injecting with SoloSmart

Before you inject, always check that SoloSmart is in active mode by quickly pressing and releasing the SoloSmart button.

- **If the light turns green** and then turns off, SoloSmart is in active mode and ready to be used for injection.
- **If the light does not turn on** after pressing and releasing the SoloSmart button, SoloSmart is in standby mode and needs to be put into active mode before performing an injection. **Follow Step 4 in the "How to Setup Your SoloSmart"** section above to put the device into active mode. Once SoloSmart is in active mode it is ready to be used for injection.

When Injecting With SoloSmart You Must Do the Following

Inject your dose in one single thrust, without changing finger or hand position during the injection.

Press firmly and continuously on the center of the button, and not at an angle.

Keep pen stable and straight while injecting.

After injecting, keep your thumb held down on the injection button until the rapidly flashing green light turns off.

Hold down until rapidly flashing green light turns off

Troubleshooting

Unsure If Dose is Delivered

If you are not certain that you injected your insulin, **do not** repeat your injection. Monitor your treatment and blood sugar as instructed by your healthcare provider.

Orange light

The battery is low. Charge SoloSmart following the instructions in the **"Charging SoloSmart"** section.

Charge the battery for at least 2 hours for a full charge.
Do not give an injection with SoloSmart while it is charging.

Solid red light

Error: the solid red light will come on when SoloSmart is in an error state and needs to be reset.

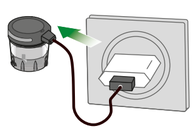
Follow the instructions in the **"Resetting SoloSmart"** section on the back side of these instructions to reset SoloSmart.

Charging SoloSmart

SoloSmart's battery will last at least 1-week on a full charge under normal conditions. When the battery is low, the orange light will show.

Orange = low battery

Charge the SoloSmart by connecting it to a powered USB wall charger (not supplied) using the supplied USB cable.



The signal light will slowly flash green when SoloSmart is charging.

Do not give an injection with SoloSmart when it is charging.

Let the device charge until the green flashing light turns off. (2 hours for a full charge). The light will turn off when fully charged.

Charge at Least 2 Hours for a Full Charge

Turn Over:
- Transfer
- Reset
- Indicator Lights
- Cleaning

Transferring SoloSmart to Another Pen

1 Put SoloSmart into standby mode

Before transferring SoloSmart to another pen, you must first put it into standby mode so that transferring the device won't cause false doses to be logged in the application.

1.1 Firmly press and hold the SoloSmart button down for at least 5 seconds until the green light turns purple and then turns off.

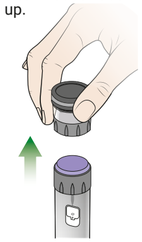
Hold until light turns off

2 Remove SoloSmart from the pen

2.1 **Hold** the SoloSmart by the body so your fingers only touch the sides of the device, being careful to not depress the button.

2.2 **Pull** SoloSmart straight off the pen.

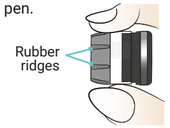
2.3 **Set** SoloSmart down upright onto a clean flat surface with the button up.



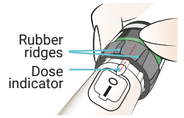
3 Attach SoloSmart to a new pen

Please proceed as described in **section 3** – Attach SoloSmart on your pen.

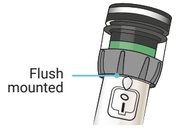
3.1 **Hold SoloSmart by the transparent housing.**



3.2 Place SoloSmart on the pen so that the dose indicator of the pen is between the rubber ridges of SoloSmart.



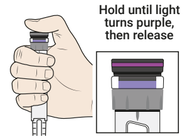
3.3 Push SoloSmart on the transparent housing until the injection button is completely covered.



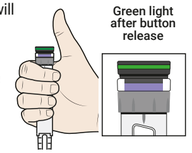
4 Activate SoloSmart on the new pen

To activate SoloSmart on the pen:

4.1 Firmly press and hold the SoloSmart button down for at least 5 seconds until the light turns purple.



4.2 Then, lift your finger from the button. The light will then turn green showing the device is now in active mode.



Resetting SoloSmart

If the following has occurred, SoloSmart may need to be reset:

- The SoloSmart signal light is solid red.
- You need to unpair your SoloSmart from your phone and pair with a new phone.
- You want to delete your personal health data from the device.

1 Remove SoloSmart from the Pen

1.1 **Hold** the SoloSmart by the body so your fingers only touch the sides of the device, being careful to not depress the button.

1.2 **Pull** SoloSmart straight off the pen.

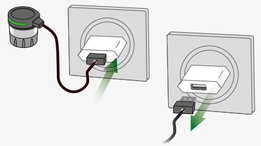
1.3 **Set** SoloSmart down upright onto a clean flat surface with the button up.

2 Reset SoloSmart

2.1 Connect SoloSmart to the supplied USB cable

2.2 **Plug-in** the USB cable into a powered USB wall charger, then quickly **unplug** it from the charger.

2.3 **Repeat** the plug in/unplug process at least 3 times **until the SoloSmart flashes red** and turns off.



Plug in and unplug at least 3 times.

2.4 Disconnect SoloSmart from the USB cable.

3 Let Sit for 30 seconds

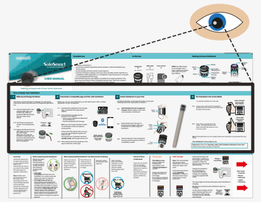
3.1 Allow SoloSmart to sit on a flat surface with the button up for 30 seconds.

Let sit for 30 seconds

SoloSmart is now reset.

4 What is Next

After reset, SoloSmart is powered off and must be setup again following the **"How to Setup Your SoloSmart"** section on the front page of these instructions, **starting with step 1.**



Important: You must complete all steps in the "How to Setup Your SoloSmart" section.

Signal Lights and Meanings

Solid Green

- **During setup**, a green solid light means that the SoloSmart is properly installed and paired.
- **During an injection**, a green solid light will turn on as you inject the medicine.

Rapid Flashing Green

- **During an injection,** a rapidly flashing green light will turn on when SoloSmart is sensing the end of an injection. Keep your finger on the button until the light is done flashing to ensure the full dose is delivered.

Slowly Flashing Green

- **SoloSmart is charging.** The green slow flashing light will turn off when the battery is fully charged.
- Charge the battery for at least 2 hours for a full charge.
- **Do not** give an injection with SoloSmart when it is charging.

Blue

- **During setup and when charging,** a blue light will turn on when SoloSmart is ready to be paired or is not paired.
- **During an injection,** if a blue light turns on, SoloSmart is not paired with your phone and is not recording injection information.

Purple

- **When transferring SoloSmart from one pen to another,** a purple light will turn on and then off after removing the SoloSmart from the pen and setting it on a flat surface.
- After mounting SoloSmart to another pen, a purple light will turn on before turning green to show that transfer mode is turned off and that SoloSmart is in active mode.

Orange

- **The battery is low.** The orange light will come on if the battery is low. Charge SoloSmart following the instructions in the **"Charging SoloSmart"** section.
- Charge the battery for at least 2 hours for a full charge.
- **Do not** give an injection with SoloSmart when it is charging.

Solid Red

- **Error:** the solid red light will come on when SoloSmart is in an error state and needs to be reset.
- Follow the instructions in the **"Resetting SoloSmart"** section to reset SoloSmart.

Flashing Red

- **During reset,** the light will flash red and then turn off when SoloSmart has been successfully reset/deactivated (see the "Resetting SoloSmart" section).

No Light

- The light automatically turns off after 30 seconds of inactivity.
- To check the status of SoloSmart, press lightly on the button to wake it up.
- If the light does not turn on, press firmly on the button for several seconds to remove it from standby mode and put it into active mode (see Step 4 of the "How to Setup Your SoloSmart" section).
- If the light still does not turn on despite a long and firm press, the battery may be empty. Charge SoloSmart following the instructions in the "Charging SoloSmart" section. Charge the battery for 2 hours for a full charge. The green slowly flashing light will turn off when charged.

Cleaning

SoloSmart is not sterile and can be reused. SoloSmart can be cleaned if necessary.

To clean SoloSmart:

- Make sure SoloSmart is unplugged and not connected to the USB charging cable.
- Wipe the external surfaces with a slightly damp lint-free cloth, being careful not to get the micro-USB port wet. If needed, a small amount of neutral detergent may be used.
- Dry surfaces with a soft cloth.

Important: SoloSmart is not waterproof, never wet the micro-USB port.

Technical safety information

In case of side effects or incident, please contact the manufacturer and the competent Health authority.

- *Improper operation may result in serious injury or death*
- If you are not certain that you injected your medication, do not start or repeat your injection. Monitor your treatment as instructed by your healthcare provider.
- Keep the device & USB cable away from lay users or patient when not used.
- Do not leave SoloSmart or its accessories within the reach of children (injury, choking and strangulation hazard). Do not attach or tighten cable to or around the head or neck.
- Do not expose the device to a temperature above 40°C (104°F) or flames. If SoloSmart is used at high temperatures exceeding our recommendations, the surface of the device may reach a maximum temperature of 43°C. In this case, the duration of use should be limited to 10 minutes to avoid any risk of burning
- SoloSmart contains a magnet. To guarantee optimal results, avoid contact with metallic parts during use, and avoid using SoloSmart near PACEMAKERS, DEFIBRILLATORS and BODY WORN INFUSION PUMPS or MRI ENVIRONMENT (Magnetic Resonance Imaging).
- Do not operate the device in a hazardous environment: presenting a risk of explosion, or containing volatile solvents (alcohol, etc.) or flammable substances (anesthetics, oxygen-rich environment, etc.).
- SoloSmart can only be used by patients already familiar with the pen injectors. Contact your healthcare provider, or a BIOCORP PRODUCTION authorized dealer to check your usual pen compatibility.

Improper use may result in bodily injury or property damage

- Do not expose the device to moisture. Do not immerse the device in liquids.
- Leave the device in a room at room temperature for 30 minutes before unpacking it to avoid possible malfunctions due to condensation
- Do not disassemble, modify, or repair the device by yourself: it may cause fire, electrical shock, bodily injury, or device malfunction. Your device's warranty will be void. Periodic maintenance of SoloSmart is not required.
- If there is any abnormal smell, sound, heat, or smoke when using the device, stop using SoloSmart.
- If the device experiences an external mechanical impact (knocking, bumping, dropping, etc.) or excessive stress, this may cause malfunctioning of the device. In case of malfunctioning, do not use the device and continue your injection pen treatment. Please contact the BIOCORP PRODUCTION authorized dealer as identified on the outside of the packaging for technical support.
- In case of visible damage, do not use SoloSmart and contact BIOCORP PRODUCTION or its authorized dealer for technical support.
- Do not leave your SoloSmart and its accessories next to animals/insects or dust/plush. After use, your device must be put away in its packaging.
- Only use your SoloSmart with Sanofi Solostar® and DoubleStar® disposable insulin pens, never use SoloSmart with any other pen.
- This device is not recommended for use by the blind or visually impaired without the help of someone trained to use the device.
- During handling operations, protect the needle with the pen cap, if it is assembled on the pen
- Separate collection for waste from electrical and electronic equipment (WEEE) is required

Wireless communication safety issues

- Protect your personal healthcare data with a password on your smartphone
- Contact Biocorp Production for list of approved compatible apps to be used with SoloSmart
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 inches (30 cm) to any part of the SoloSmart device, including cables specified by the manufacturer. This could result in degradation of the performance of this equipment.
- In case of Bluetooth transmission disturbance or loss, the SoloSmart device will continue to track and record the history of all your injections. More information is available on the technical note available online at http://www.solosmart.com.
- Never install a mobile application from unofficial stores on your phone.
- Protect your smartphone by installing antivirus software.
- The Cybersecurity nomenclature corresponding to the embedded software version is available on request. Please contact a BIOCORP PRODUCTION authorized dealer if you wish to consult it.
- You are responsible for properly securing and managing your phone. If you suspect an adverse cybersecurity event related to the SoloSmart device or related App, contact Customer Service.
- Make sure that your phone and the SoloSmart device are kept in a safe place, under your control. This is important to help prevent anyone from accessing or tampering with the System.
- The App used with the SoloSmart device is not intended for use on a phone that has been altered or customised to remove, replace or circumvent the manufacturer's approved configuration or use restriction, or that otherwise violates the manufacturer's warranty.
- On rare occasions, you may get inaccurate insulin dose readings. If you believe your readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose. If the problem continues, contact Customer Service.
- The App used with the SoloSmart device requires that your phone has the correct date and time for recording your health information. Your phone's date and time should be set to update automatically. You can check this in your phone settings.
- When using the App used with the SoloSmart device, you should keep your phone well charged and be sure you have access to a blood glucose monitoring system.
- Keep your phone well charged and turned on.
- Disable your phone's automatic operating system updates. After an operating system update, open your App and check your device settings to make sure it's working properly
- Before disposing of SoloSmart: reset the device to delete all your personal health data.
- Electrical medical devices and systems are subject to special measures concerning electromagnetic compatibility (EMC) and must be installed in accordance with the EMC instructions contained in the technical note available online at http://www.solosmart.com.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- In case of the parent application and the device are used in a noisy environment (in terms of electromagnetic signal near 2.4Ghz), the BLE communication is no more possible and the connection between then is closed. However, the device continues to track injection. Where perturbing electromagnetic signals disappear, the parent application and the device can communicate again.

Technical specifications

Intended Patients	Insulin-dependent patients, using an injector pen for insulin treatment
Intended Users	Users aged from 14 to 80 years old
Use environment	Home use or medical facility (indoors only)
Accuracy of recorded doses	99% ±1IU on test bench
Charge and autonomy	Charge by USB connection. Full charge in 2h, 1-week autonomy. USB AC adaptor (not provided): IEC/UL 60950-1 or IEC/UL 62368-1 certified with CE or UL marking, external module with automatic adaptation of the voltage, 90-264V input voltage range.
Electrical consumption	5V DC, 500mA minimum
Battery	Li-ion 3.6V 25mAh
Communication	Bluetooth Low Energy v4.2 operating in the frequency band of 2400 MHz to 2483.5 MHz. 40 channels, 2MHz spacing channel, 1 MHz channel bandwidth, 4dBm (2.5119 mW) max transmission power, -6,18dBm max EIRP (Equivalent Isotropic Radiated Power).
Software version	Firmware 5.3.x
Dimensions	23,3mm (h) x Ø 21,4mm
Weight	20g
Storage and transport conditions	-10°C / 40°C; 10% / 90%; 500hPa / 1060hPa The device must always be transported and stored in its original packaging designed to protect it from damage. Keep all original packaging for future use (in case of return / transport of the device).
Operating conditions	8°C / 35°C; 30% / 70%; 700hPa / 1060hPa
Overall expected service life	3 years

Additional technical information is included in the Technical Note, available online at my-mallya.com & www.solosmart.com

Symbols and Information on the Device and/or its Packaging and Labels

	Refer to the instruction manual / booklet. Follow instructions for use
www.solosmart.com	User manual / Operating instructions
	Manufacturer
FR	Date and country of manufacture
SN	Serial Number
#	Model Number
LOT	Batch Number
UDI	Unique Device Identification
A→B	Translation
REF	Product reference
REF SUPPLIER	Distributor reference
	Use by date
MD	Medical Device
	Type BF applied part (according to IEC 60601-1 continuous mode)
IP 22	Protection index IP22 (IEC 60529)
---	Direct current
	For indoor use only
	Moisture sensitive device
	Temperature limits to chich the device can be safely exposed
	Humidity limits to which the device can be safely exposed.
	Pressure limits to which the device can be safely exposed.
	Do not use if the packaging is damaged
	Waste from Electrical and Electronic Equipment (WEEE)
	Single patient, multiple use
IC	Canadian Radio Compliance Mark

Radio-communication statement

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). 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. This device complies with ISED radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.]

General Information and Contact Information

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