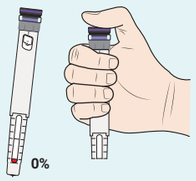
Transferring SoloSmart to a new pen : unmouting / mouting mode



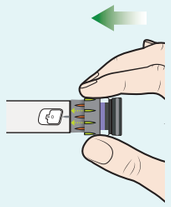
BEFORE removing SoloSmart from the empty pen, press firmly on the button for at least 5 seconds, until the **green** light turns **purple** then off.

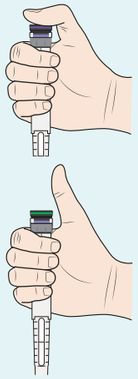
Remove SoloSmart from the empty pen, holding it by the wheel, and not pulling the button.

Put it vertically (button up) on a flat surface.

Discard the empty pen in an appropriate waste container (see the pen's IFU).

KEEP YOUR SOLOSMART





Install SoloSmart on the new pen as described in section 7.
Press firmly on the button for at least 5 seconds, until the light turns **purple**, then lift your finger: the light turns **green**.

Your new pen and SoloSmart are ready to be used together!

NOTE: *SoloSmart is reusable and can be transferred on a new pen when the previous disposable pen is empty.*

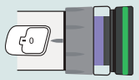
Activate the Unmounting/Mounting mode BEFORE removing Solosmart from the empty pen.
This mode stops dose recording, allowing handling operations.vide, ceci permet d'arrêter les mesures de doses lors des manipulations.

It is important to use this mode in order not to measure ghost doses during handling operations, and to have the app ask for confirmation that the same type of pen is still used. Not using this mode might lead to erroneous information.

The App detects the use of this mode and asks you to confirm the type of insulin pen used with your SoloSmart. In the case where the SoloSmart has been removed from the empty pen without using this mode, the App will keep using the previous type of insulin pen. Data will have to be manually modified, if necessary.

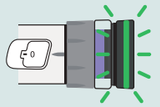
Use one SoloSmart per type of pen. If you use different pens (basal and bolus insulin for example), do NOT use the same SoloSmart for 2 different pens.

Light signals and meaning



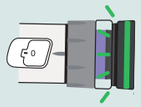
Green
Steady

SoloSmart is:
- properly installed and paired
OR
- during dose selection
OR
- injecting.



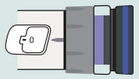
Green
Rapid flashing

SoloSmart is seeing the end of injection.
Keep the pressure on the button and the needle in your skin during all the time the light is flashing, or for the duration indicated in the pen's IFU.



Green
Slow, fading flashing

SoloSmart is plugged and charging.



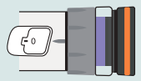
Blue

SoloSmart is ready to be paired.

Before SoloSmart has been paired, the light is **blue**, whatever the operation. No information is recorded.

Purple

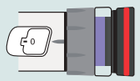
Unmounting / mounting mode, after a press hold of at least 5 seconds (pen change).



Orange

Low battery.

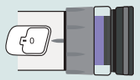
Plug and charge your SoloSmart (2h for a full charge).
The light is **orange** during injections if the battery is low.



Red

Steady **red**: SoloSmart is in error state.
Proceed to a reset, and pair it again with your phone.
If the problem persists, contact the Support service.

Flashing **red**, then off: after a reset.



No light

The light automatically turns off after an inactivity period (4 seconds). Press lightly on the SoloSmart button to wake it up and check its status thanks to the light color.
If the light does not turn on, press firmly on the button, the unmounting mode might have been activated.
If the light still does not turn on, despite a long and firm press on the button, the battery might be empty. Charge your SoloSmart.

Safe use 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.
- 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 mini.
- 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® 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.sanofi.com/) and in print, included in the SoloSmart box.

Cleaning

SoloSmart is not sterile and can be reused for a single patient only.
SoloSmart can be cleaned if necessary:
- If SoloSmart is plugged to a cable, unplug it.
- Wipe the external surfaces with a soft lint-free cloth, slightly damped with a small amount of neutral detergent if needed.
- Dry the surfaces with a soft cloth.

- 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.
- 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.sanofi.com/) and in print, included in the SoloSmart box.
- 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.

Technical specifications

Intended Patients	Insulin-dependent patients, using an injector pen for insulin treatment
Intended Users	Users aged from 18 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, 2A
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 5.2.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%; 800hPa / 1060hPa
Lifetime	2 years

Symbols and information on the device and/or its packaging and labels

	Danger
	Caution
	Refer to the instruction manual / booklet. Follow instructions for use
	Patient information website
	User manual / Operating instructions
	Manufacturer
FR	Country of manufacture
S N	Serial Number
#	Model Number
	Manufacturing date
LOT	Batch Number
UDI	Unique Device Identification
GTIN	International and unique item code (Global Trade Item Number)
	Translation
REF	Product reference
REF	Distributor reference
MD	Medical Device
	Class II device (double isolation) (according to IEC 60601-1 continuous mode)
	Type BF applied part (according to IEC 60601-1 continuous mode)
IP 22	Protection index IP22 (IEC 605229)
	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 use: reusable
	Disconnect the USB cable from the USB charging port and disconnect SoloSmart from the USB cable before using it.
CE	CE mark

Radio-communication 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.
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with FCC 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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63500 ISSOIRE
CEDEX – FRANCE
Tel : +33 4 73 55 70 50
www.biocorpsys.com

DISTRIBUTORS
(authorized dealers):
Distributor details are available on the back of the SoloSmart Mini box.