

TECHNICAL NOTE

SoloSmart™



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1. CURRENT SOLOSMART COMPATIBILITIES WITH PENS

SoloSmart is designed for Solostar® SANOFI injection pen platforms. SoloSmart is a class I medical device. The molecules and associated concentrations compatible with the SoloSmart device at the date of this Instructions For Use release are listed in the table below:

SOLOSMART MODEL	Insulin brand name	Concentration	Commercial names in launch country
SoloSmart designed for Solostar® SANOFI injection pen	Glargine	100 IU/mL	Lantus
		300 IU/mL	Toujeo Toujeo Doublestar
	Lispro	100 IU/mL	Insulin Lispro Sanofi
	Glulisine	100 IU/mL	Apidra
	Glargine and lixisenatide	100 IU/mL + 33mcg/mL	Soliqua 100/33
	Aspart	100 IU/mL	Insuline Asparte

2. RADIO AND EMC SPECIFICATIONS

2.1 LOSS OF CONNECTION

The SoloSmart module uses a Bluetooth Low Energy (BLE) connection to communicate with the user's smartphone. The BLE link between the SoloSmart module and the smartphone may break due to a variety of reasons.

However, the SoloSmart device will continue to track and record the history of all your injections. As soon as the smartphone reconnects to the SoloSmart module, the application will be able to request the injections it missed. The SoloSmart module has a storage capacity of 100 injections, in case more than 100 injections were done during the disconnection, the oldest injection is overwritten by the newest.

2.2 WIRELESS QUALITY OF SERVICE

Caution

Bluetooth communication limits:

The compatible application can inform you that Bluetooth communication has been interrupted. Indeed, if the compatible application and the SoloSmart device are used in a noisy environment (in terms of an electromagnetic signal close to 2.4 GHz), or are too far away, communication will no longer be possible between them and the connection will stop. However, the SoloSmart device will continue to track and record the history of all your injections. As soon as the disturbing factor disappears, or they come closer, the compatible application and the SoloSmart device will be able to communicate again, and the application will be able to request the injections it didn't transfer (up to 100 injections).

Bluetooth LE type	BLE v4.2 (Core Spec Bluetooth 4.2 - 2014)
Frequency band	[2400-2483,5] MHz
Spacing channel	2 MHz
Channel bandwidth	1 MHz
Antenna type	Integral
Max EIRP (Equivalent isotopically radiated power)	-6,18 dBm

2.3 WIRELESS COEXISTENCE

A key factor that may affect SoloSmart wireless medical device's performance is the limited amount of RF spectrum available, which can result in potential competition among wireless technologies for simultaneous access to the same spectrum. To avoid communication disturbances due to wireless coexistence, BIOCORP PRODUCTION recommends the following separation distances between the device and its intended companion:

In pairing mode:

Recommended separation distance	Less than 12 inches (30cm)
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In functioning mode:

Recommended separation distance	Less than 7 feet (2,15m)
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Caution

In case of wireless coexistence problems, the paired SoloSmart device will be unable to communicate with its companion application, but injections will still be tracked and recorded and can be retrieved at a later date by the companion application.

2.4 WIRELESS TRANSMISSION & CYBERSECURITY

BIOCORP PRODUCTION recommends that the user performs the pairing process in a private environment, e.g. at home, to avoid eavesdropping or potential attacks on the pairing process. Once the pairing process has been performed, the SoloSmart device has no particular security requirement.

2.5 ELECTROMAGNETIC COMPATIBILITY

2.5.1 GENERAL PRECAUTIONS AND WARNINGS

- 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.

SoloSmart has no essential performance. SoloSmart has no special security requirements. The device SoloSmart EFD3 was tested according to the recommendations of IEC TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

2.5.2 ELECTROMAGNETIC EMISSIONS

EMISSION	
RF emissions:	CISPR 11 / Group 1 Class B
Harmonic Distortion IEC 61000-3-2:	Not applicable
Voltage fluctuations and Flicker IEC 61000-3-3:	Not applicable

2.5.3 ELECTROMAGNETIC IMMUNITY

IMMUNITY		
Test	Requirements	Conformity Level
Electrostatic discharges (ESD) IEC 61000-4-2	± 8 kV contact discharges ± 2/4/8/15 kV air discharges	± 8 kV contact discharges ± 2/4/8/15 kV air discharges
Radiated RF EM fields IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM à 1kHz	10V/m 80MHz-2.7GHz 80% AM à 1kHz

IMMUNITY

Test	Requirements	Conformity Level		
Proximity fields from RF wireless Communications equipment IEC 61000-4-3	Frequency (MHz)	Modulation	Level (V/m)	Conformity Level (V/m)
	385	Pulse Modulation: 18 Hz	27	27
	450	Pulse Modulation: 18 Hz	28	28
	710 – 745 – 780	Pulse Modulation: 217 Hz	9	9
	810 – 870 – 930	Pulse Modulation: 18 Hz	28	28
	1720 – 1845 – 1970	Pulse Modulation: 217 Hz	28	28
	2450	Pulse Modulation: 217 Hz	28	28
5240 – 5500 – 5785	Pulse Modulation: 217 Hz	9	9	
Electrical fast transients / bursts IEC 61000-4-4	Supply: ± 2 kV I/O lines : ± 1 kV Repetition rate : 100 kHz	Not applicable		
Surges IEC 61000-4-5	Line-to-line: $\pm 0,5$ kV, ± 1 kV Line-to-ground $\pm 0,5$ kV, ± 1 kV, ± 2 kV	Not applicable		
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and radio-amateur band between 0,15 MHz and 80 MHz 80 % AM à 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and radio-amateur band between 0,15 MHz and 80 MHz 80 % AM à 1 kHz		
RATED power frequency magnetic fields IEC 61000-4-8	30 A/m	30 A/m		
Voltage Dips and Interruptions: IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0 % UT; 1 cycle at 0° 70 % UT; 25/30 cycles at 0° 0 % UT; 250/300 cycles	Not applicable		
Proximity magnetic fields IEC 61000-4-39	134,2 kHz / Pulse modulation 2,1 kHz / 65 A/m 13,56 MHz / Pulse modulation 50 kHz / 7,5 A/m 30 kHz / CW / 8 A/m	134,2 kHz / Pulse modulation 2,1 kHz / 65 A/m 13,56 MHz / Pulse modulation 50 kHz / 7,5 A/m 30 kHz / CW / 8 A/m		

3. MATERIALS

SoloSmart materials

PC, ABS, SEBS

4. DISTRIBUTOR ADDRESS

Manufactured by:
BIOCORP PRODUCTION

Imported & Distributed by:
sanofi-aventis Canada Inc., 1755 Steeles Avenue West, Toronto, ON, M2R 3T4