SO CONNECT+ V2

SO CONNECT+ 100

Ambulatory

Infusion Pump

User manual (English)

V001.03.02 – 2026/03/06

Table of Contents

About this manual

This user's manual is intended for you, who are a patient or a healthcare professional. It contains all the information required for the safe and effective use of SO-CONNECT+. Regardless of your experience of ambulatory infusion pumps, please read the whole manual carefully before you begin to use the SO-CONNECT+ pump.

This user's manual should be kept available for future use. If in doubt or if any of the information in this manual is not clear, please contact user support.

For the safe and correct use of SO-CONNECT+, please pay particular attention to the following points in this user's manual:


Comment

- The comments contain information for optimal and efficient operation of SO-CONNECT+.


Warning

- A warning message indicates safety information which, if ignored, may damage SO-CONNECT+, compromise the quality of the treatment or cause serious injury.

Introduction

The new version of SO-CONNECT+ pump has two references:

- SO-CONNECT+ V2 for use with SO-FILL 20-30-50 syringes,
- SO-CONNECT+ 100 for use with SO-FILL 100 and SO-FILL 20-30-50 syringes.

Version of the pump's software

This user's manual applies to all SO-CONNECT+ pumps equipped with the software in version 02.03.00 and higher.

Intended use

The SO-CONNECT+ V2 pump, when used in association with SO-FILL 20-30-50, is intended for the controlled subcutaneous administration of medications.
The SO-CONNECT+ 100 pump, when used in association with SO-FILL 100 or SO-FILL 20-30-50 syringes, is intended for the controlled subcutaneous administration of medications.

Intended users

The intended users are:

- Healthcare professionals trained to use the SO-CONNECT+ pump by the manufacturer or the distributor,
- Patients trained to use the SO-CONNECT+ pump by healthcare professionals,
- In cases where patients are unable to manage their treatment on their own, caregivers trained to use the SO-CONNECT+ pump by healthcare professionals,
- Maintenance staff trained to use the SO-CONNECT+ pump (maintenance and service functions are the responsibility of the manufacturer and are not described in this manual).

	Healthcare professionals	Patients	Caregivers	Maintenance staff
Gender	All genders			
Age	≥ 20 years old	≥ 18 years old	≥ 18 years old	≥ 18 years old
Job	Physician, nurse, etc.	Indifferent	Indifferent	Technician
User status	Yes	The healthcare professional should assess whether the patient has the physical and mental ability to use the pump. If not, the use of the pump should be reserved for a healthcare professional, caregiver or parent.	Yes	Yes
Knowledge of the disease	Yes	Yes	Yes	No

Indications

The SO-CONNECT+ ambulatory pump is indicated for the treatment of pathologies that require the subcutaneous infusion of medications.

Medical conditions

The SO-CONNECT+ ambulatory pump can be used in the case of:

- Primary Immune Deficiency (PID), Secondary Immune Deficiency (SID) and Chronic inflammatory demyelinating polyneuropathy (CIPD) that require subcutaneous infusion of SCIg (subcutaneous normal human immunoglobulin),
- Thalassemia, primary hemochromatosis not curable by bloodletting, secondary hemosiderosis, acute martial intoxication or aluminic intoxication in renal insufficiency dialysis patients that require subcutaneous infusion of Deferoxamine.

Target patient population

	Patient profile
Genre	All genders
Age	≥ 6 years old
Job	Indifferent
Disease	Pathology requiring continuous or occasional subcutaneous infusion of medications.
Knowledge of the disease	The patient is considered as a lay person. To be allowed to use the pump, the patient must be informed about the disease and trained by an HCP in the use and operation of the SO-CONNECT+ infusion pump.

Clinical benefits

The clinical benefits of SO-CONNECT+ ambulatory infusion pump are as follows:

- Allow the patient to keep a satisfying quality of life and to continue its daily activities.

Contraindications

Absolute contraindications
SO-CONNECT+ must not be used:

- in patients with severe cognitive impairment or
- in patients with psychotic symptoms or
- in patients physically incapable of receiving a subcutaneous infusion (due to paralysis, consequences of accidents or malformation), or
- in patients lacking the required maturity (very young children under 6 years of age).

The SO-CONNECT+ pump must not be used to administer medications by routes other than subcutaneous.

Relative contraindications
Eyesight or hearing issues cannot adequately enable to detect the audible and visual alarms of the pump. It is recommended to check this point with the patient before the beginning of the infusion.

Adverse effects

Irritations in case of repeated injections at the same site, injuries, or wounds in case of incorrect programming or inappropriate use.

The administration of large volumes during a subcutaneous infusion may result in local swelling that may cause discomfort.

Effects of overdosing and underdosing
In the case of deferoxamine:

- The administration of an overdose may be associated with hypotension, tachycardia and gastrointestinal problems. Sudden, transient loss of vision, aphasia, agitation, headaches, nausea, bradycardia and acute renal failure have also been reported. (Refer to the indications of the medication guide).
- Underdosage will keep the medication from having the intended effect.

In the case of immunoglobulins:

- The administration of an overdose does not have any known effect.
- Underdosage will keep the medication from having the intended effect.

Precautions for use

Comments

- For assistance if required with setting up or using SO-CONNECT+, please contact France Développement Électronique (contact details on back of this manual).
- Please contact France Développement Électronique (contact details on back of this manual) to report unexpected operation or events.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Warnings

Environment of use

- SO-CONNECT+ complies with the electromagnetic compatibility standard IEC 60601-1-2 and can therefore operate correctly with other medical devices that also comply with the standard. In order to avoid electromagnetic interference that could affect the working of SO-CONNECT+, do not use the pump close to powerful sources of electromagnetic interference. Electromagnetic interference can cause SO-CONNECT+ to malfunction and result in serious injury to the patient.
- Do not expose SO-CONNECT+ to therapeutic levels of ionizing radiation, as that could permanently damage its electronic circuits. It is preferable to disconnect SO-CONNECT+ during radiotherapy sessions. Exposure to ionizing radiation can cause SO-CONNECT+ to malfunction and result in serious injury to the patient.
- Do not use SO-CONNECT+ close to magnetic resonance imagery (MRI) equipment, because magnetic fields can affect its performance and result in serious injury to the patient.
- Do not use SO-CONNECT+ close to sources of heat, such as a fireplace or a radiator heater. Exposure to intense heat may cause malfunctions that could interrupt the administration of the medication and have serious consequences for the patient's health.
- Do not use SO-CONNECT+ close to sources of humidity, such as a kettle or a nebulizer. Exposure to high levels of humidity may cause malfunctions that could interrupt the administration of the medication and have serious consequences for the patient's health.
- Do not expose SO-CONNECT+ to excessive dust or fluff. These could get into the pump and cause it to malfunction and have serious consequences for the patient's health.
- Do not expose SO-CONNECT+ to intense sources of light, including sunlight. It could make the information displayed on the screen hard to read.
- In order to keep SO-CONNECT+ and its accessories safe from damage, keep them out of the reach of unattended children or pets. Damage to SO-CONNECT+ could cause malfunctions that could interrupt the administration of the medication and have serious consequences for the patient's health.
- SO-CONNECT+ is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Using SO-CONNECT+ in the presence of such mixtures may result in explosion or fire and have serious consequences for the patient's health.
- Use SO-CONNECT+ with a protective case to protect it in the event of impacts, falls or contact with liquids.
- 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.
- Do not use SO-CONNECT+ close to sources of electrostatic discharges. These could cause malfunction and have serious consequences for the patient's health.

Battery

- Incorrect handling of the battery by unqualified personnel may cause leaks, heating, emission of smoke, explosion or fire. It also may cause damage to the equipment or injury to the user.

Functions reserved for healthcare professionals.

- Healthcare professionals may not disclose to the patient the passwords or any other information likely to enable the patient to gain access to the configuration functions. Incorrect configuration may cause injury to the patient.

Training

- People using SO-CONNECT+ at home must be trained by a healthcare professional, qualified home caregiver or clinician.
- The functions reserved for healthcare professionals may only be used by healthcare professionals trained in the use of the pump. The use of these functions by an untrained user may cause serious injury to the patient.

Accuracy

- The SO-CONNECT+ pump does not measure any volume and flow rate at the syringe outlet. The values displayed by SO-CONNECT+ are the results of calculations performed by its software by counting the number of motor steps. The accuracy is based on product validation and is checked during manufacture.

Disposal

- Take care to dispose of the packaging, battery and any other electronic components in accordance with the applicable environment protection regulations.
- Do not dispose of the battery in or near fire. Doing so could cause it to explode and result in serious injury.

Hazards

- It is important to have an alternative solution and/or procedure to replace pump infusion if the pump is damaged. A good solution is to have a spare pump or an alternative system.
- During the infusion, regularly ensure that it is working properly by doing a visual check. In the event of malfunctions or unanticipated events, please contact France Développement Électronique (contact details on back of this manual).
- Regularly check the date and time of SO-CONNECT+. If you observe a significant deviation, correct these settings.
- Use only the accessories, spare parts and supplies described in this manual. Failing to do so could cause SO-CONNECT+ to malfunction and result in serious injury to the patient.

Emergency kit

Users are strongly advised to keep spare accessories and consumable supplies for emergencies. An emergency kit must contain the following:

- A SO-CONNECT+ infusion pump with a charged battery and a battery charger,
- A syringe and a sterile infusion line,
- The solution to be infused,
- A skin disinfectant.

Description of SO-CONNECT+

The features of SO-CONNECT+ have been designed to make treatment easier and keep the patient safe.

- **Screen with resistive touch panel**
  SO-CONNECT+ has a screen with a resistive touch panel that makes configuration and infusion control easier.

- **Programming mono and multi flow rates**
  In mono flow rate mode, the infusion rate (from 0 to 100 ml/h with SO-FILL 20-30-50, from 5 to 120 ml/h -or 300 ml/h depending if the respective option is enabled- with SO-FILL 100, in increments of 0.1 ml/h) or duration (from 0 to 24 hours in increments of 15 minutes) of SO-CONNECT+ can be configured.
- In multi flow rate mode, SO-CONNECT+ has up to 5 stages that can be configured for the flow rate (from 0 to 100 ml/h with SO-FILL 20-30-50, or from 5 to 120 ml/h -or 300 ml/h depending if the respective option is enabled- with SO-FILL 100, in increments of 0.1 ml/h) and for the duration (from 0 to 60 minutes in increments of 1 minute).

- **Changing the infusion rate or duration during infusion**
  SO-CONNECT+ allows the infusion rate or duration to be changed during infusion.

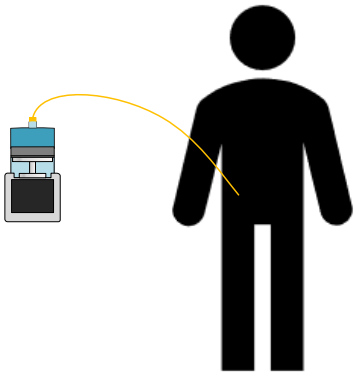
- **Saving of infusion configuration**
  The configuration of the last infusion is saved automatically even if the battery is changed.

- **Locking of configuration functions**
  An infusion cannot be programmed until a password has been entered.

- **Infusion accuracy**
  SO-CONNECT+ administers a dose dependent on the set infusion rate every 18 seconds.

- **Bluetooth Low Energy connection**
  A Bluetooth Low Energy connection is used for exporting the history.

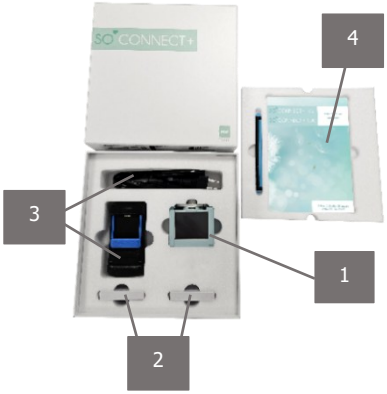
Connection of the pump to the patient



The patient is connected to the pump through the infusion needle set (in yellow) which is connected to the syringe. To choose the injection site(s), please refer to the instructions of your doctor or nurse.

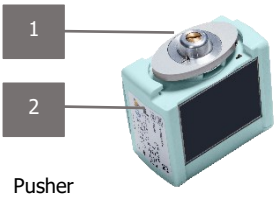
The syringe is clipped onto the pump. The pump's advancing mechanism (pusher) will push the syringe gasket to deliver the medication in a very precise manner.

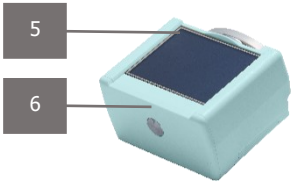
Contents of the box



1. SO-CONNECT+ V2 or SO-CONNECT+ 100 infusion pump
   (Ref. SO-CONNECT+ V2 or SO-CONNECT+ 100)
2. 2 VARTA EZPack XL batteries
   (Ref. SO-POWER+)
3. Battery charger and power cord
   (Ref. SO-CHARGE)
4. User's manual

Components of SO-CONNECT+

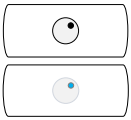




1. Pusher
2. Identification label
3. Battery compartment cover
4. Battery compartment
5. Touchscreen
6. Screen saver button

Screen saver button: switches the pump's screen ON and OFF. An indicator light is integrated in it to show the operating status of SO-CONNECT+.

- Indicator OFF: SO-CONNECT+ is on standby or not powered.
- Blue indicator: SO-CONNECT+ is active.



Comment

- When you are not using the screen, you can press on the screen saver button to turn it off without waiting for it to turn off automatically and thus save battery power.

The battery

SO-CONNECT+ can only operate when it is powered by a VARTA EZPack XL rechargeable battery supplied with the pump, sourced from France Développement Électronique only. The pump is supplied with two batteries. As a result, you can always have a charged spare battery that is ready for use.

The battery specifications are as follows:

Reference	VARTA EZPACK XL
Rated voltage	3.7 V
Capacity	2400 mAh typical
Watt hours	8.9 Wh
Number of cycles	> 500 cycles

Comment

- When you are not using a battery, charge it. This way, you will always have a battery ready to use.

Warning

- Do not use any other batteries than those supplied by France Développement Électronique. Using another type of battery may damage the pump and prevent the infusion from taking place.

The battery charger

The battery charger supplied with the pump allows to recharge VARTA EZPack XL batteries.

Model number	MASCOT Type 3745
Rated AC voltage	90 – 264 VAC 47/63 Hertz
Charging voltage	4.2 VDC
Charging intensity	1.5A
Dimensions	115 x 56 x 35 mm
Weight	175 g
Conditions of use	-25°C to +40°C
Storage conditions	-25°C to +85°C
Electrical safety	EN/IEC/ANSI 60601-1 ; EN/IEC 60335-1 et 60335-2-29 ; EN/IEC/UL 62368-1
Electromagnetic compatibility	EN 61000-6-1 et 61000-6-3 ; EN 60601-1-2 ; EN 55014-1 et 55014-2 ; EN 55024 ; EN 55032

Warnings

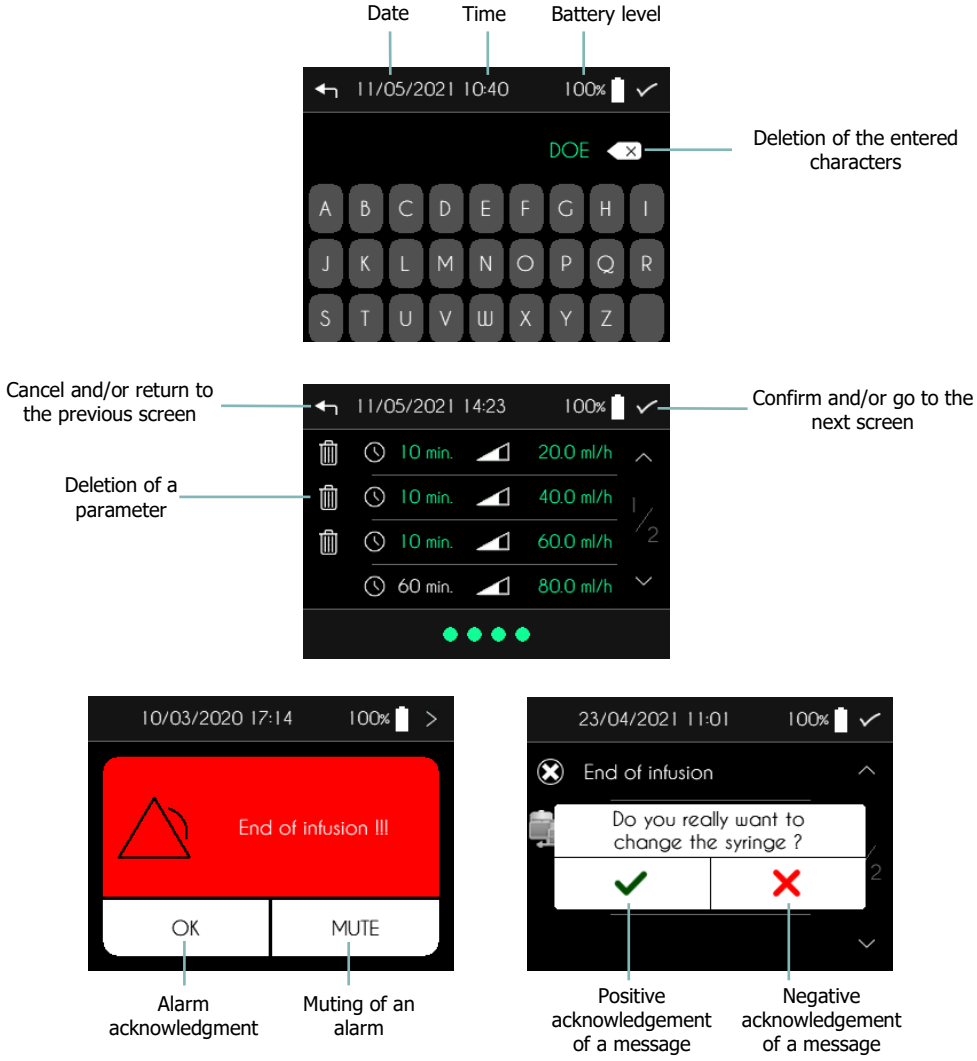
- Do not use any other charger than the one supplied by France Développement Électronique. Using another type of charger may damage the battery and compromise the continuation of the infusion.
- Do not attempt to recharge cells or batteries other than those supplied by France Développement Électronique. Doing so may damage the charger and prevent you from recharging the batteries of SO-CONNECT+.
- Do not use the charger if the cord is damaged or if the charger has been damaged. You may experience an electric shock or electrocution.

Using the screen

The touchscreen provides access to the various functions of the pump. This chapter introduces all the elements and icons that appear on the screen.

Comments

- In general, a parameter displayed in green can be selected and modified.
- If the screen displays incomplete characters, digits or symbols, or inaccurate information, remove the battery for a few seconds and put it back in place. If the problem persists, please contact France Développement Électronique (contact details on back of this manual).



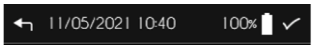
Using for the first time

Comment

- The batteries are delivered uncharged. You must therefore charge them completely before using them.

Charging the battery

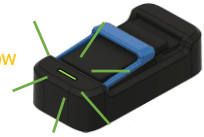
The battery level is visible on each page of the SO-CONNECT+, through a battery gauge and a percentage displayed on the top banner.



When charging a battery, please observe the following instructions:

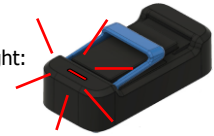
- First connect the power cord to the charger, then to a power socket.
- Insert the battery in the charger by carefully lifting the blue fastening system. The battery label must be turned towards the charger.
- If a problem occurs during charging, disconnect the charger from the wall socket immediately, in order to cut the current.
- Do not place the charger in areas that are very hot or cold, dusty or dirty, humid or subject to heavy vibrations.

Flashing or steady yellow light: charging underway.



Flashing green indicator light: battery disconnected

Steady green indicator light: battery charged

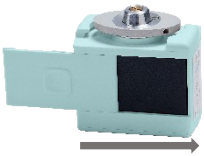


Flashing red light: error

Inserting the battery

1) Slide the battery compartment cover from right to left until it comes completely out of the groove.

2) Insert the battery in the compartment of the pump. Take care to insert the battery the right way: the + end of the battery must be at the + terminal of the pump, and likewise for the — end. The battery's label should be facing downwards, towards the bottom of the battery compartment.



3) Place the battery compartment cover back in the groove and slide the cover back into place, from left to right.

⚠ Warnings

- Do not use a knife, screwdriver or other pointed object to remove the battery compartment cover, as that could damage the pump.
- In order to keep water out of the housing of SO-CONNECT+, install the battery in a dry place.
- Make sure that the battery compartment cover is not damaged or missing and that the battery has been installed correctly.
- Incorrect handling of the battery by unqualified personnel may cause leaks, heating, emission of smoke, explosion or fire. It also may cause damage to the equipment or injury to the user.

Starting the pump

After inserting the battery, press on the screen saver button to turn the screen on.

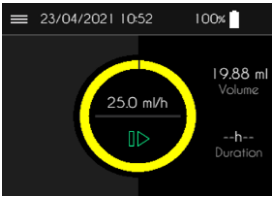
If no infusion is underway, SO-CONNECT+ displays a start screen for a few seconds with the reference "SO-CONNECT+ V2" or "SO-CONNECT+ 100"and the installed languages.

After the start-up screen is displayed, SO-CONNECT+ performs a self-test and moves the pusher to the removal position.

After the start screen, SO-CONNECT+ conducts a self-test and retracts the pusher. After this retraction, SO-CONNECT+ automatically displays the main screen.

If, while the battery is being changed, an infusion is underway, the pump displays the infusion screen.

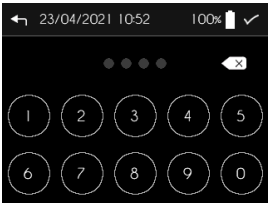
The infusion is automatically paused while the battery is being changed. Remember to restart it after.



Password

Warnings

- Healthcare professionals may not disclose to the patient the passwords or any other information likely to enable the patient to gain access to the programming and configuration functions of the SO-CONNECT+ pump. Incorrect programming may cause serious injury to the patient.
- The password must not be given to anyone not trained to use the pump.



Access to the functions reserved for healthcare professionals requires a password to be entered.

- After entering the password, press on the "✓" icon to validate and access the relevant function.

Comment

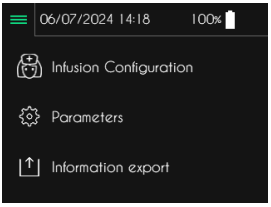
- If you forget the password, contact France Développement Électronique (contact details on back of this manual) or your distributor.

Main menu

The main menu provides access to the various functions of SO-CONNECT+.

- To open the main menu, press on the "☰" icon.

From the main menu, you can access the following functions:



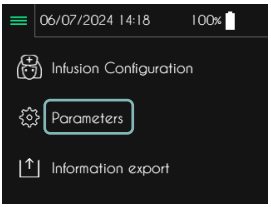
- "Infusion Configuration": Setting up an infusion. This function is reserved for healthcare professionals.
- "Parameters": Pump settings (date, time, language, etc.)
- "Information Export": Exporting the infusion history

Setting up the pump

Comments

- The different settings of SO-CONNECT+ are not available during an infusion.
- A change to any of the settings is applied immediately.

The SO-CONNECT+ setup function is available in the main menu by pressing on "Parameters".



Three tabs provide access to the various settings, by pressing on the corresponding icons.

Date, time and date format

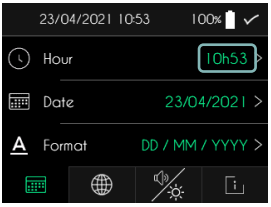
Language

Volume of the alarms and screen brightness

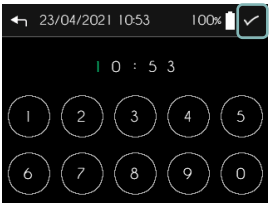
Software version

Setting the time

- Press on the hour to change it.



- Use the numeric keypad to enter the time.
- Press on the "✓" icon to confirm the input.



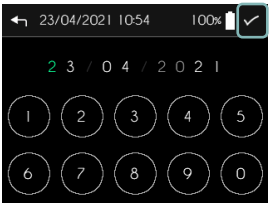
Comment

- It is crucial to set the correct time. The history of the infusions depends on this information.

Setting the date

- Press on the date to change it.

- Use the numeric keypad to enter the current date.
- Press on the "✓" icon to confirm the input.

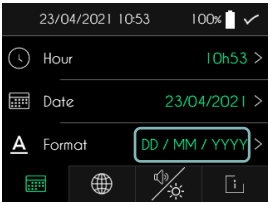


Comment

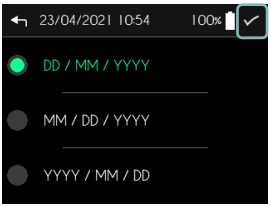
- Setting the correct date is crucial. The history of the infusions depends on this information.

Date format setting

- Press on the date format to change it.

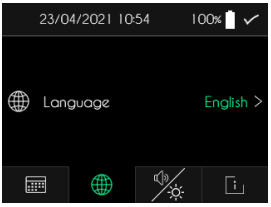


- Select the required date format by pressing on it.
- Press on the "✓" icon to confirm the selection.

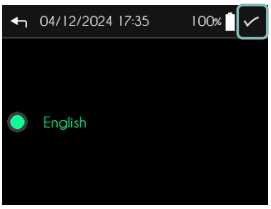


Language setting

- Press on the language to change it.



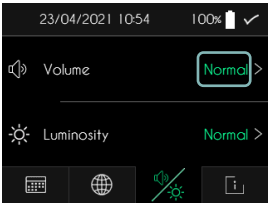
- Select the language you want to use.
- Press on the "✓" icon to confirm the selection.



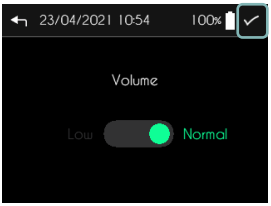
Setting the volume of the alarm

SO-CONNECT+ displays the screen for setting the volume of the alarms and the brightness of the screen.

- Press on the volume to change it.



- Select the sound level of the alarms (left: low volume; right: normal volume).
- Press on the "✓" icon to confirm the selection.



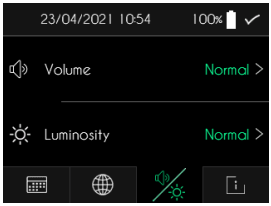
Comment

- The sound pressure levels of the audible alarms may be lower than the ambient noise level, in which case the operator may fail to recognize the alarms. The infusion may thus be stopped without the patient being informed.

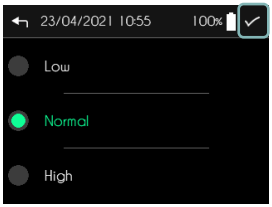
Setting the brightness of the screen

SO-CONNECT+ displays the screen for setting the volume of the alarms and the brightness of the screen.

- Press on the luminosity icon.



- Press on the brightness level you want to use.
- Press on the "✓" icon to confirm the selection.

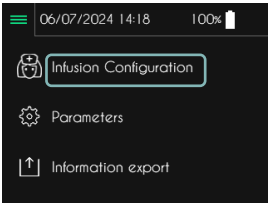


Software version display

SO-CONNECT+ displays the screen to view the version of the internal software, with the reference "SO-CONNECT+ V2" or "SO-CONNECT+ 100".

Setting up the infusion – Function reserved for healthcare professionals

- From the main menu, press on "Infusion Configuration"



Comment

- To simplify the process of setting up a new infusion, SO-CONNECT+ always displays the setup of the previous infusion.

The different infusion settings are summarized in the table below:

Setting	Values	Default value
Patient's last name	Up to 16 characters	[blank]
Patient's first name	Up to 16 characters	[blank]
Patient's date of birth	dd/mm/yyyy	00/00/0000
Name of the medication	"High viscosity" or "Low viscosity"	[High viscosity]
Type of syringe (SO-CONNECT+ V2)	20 ml / 30 ml / 50 ml	50 ml
Type of syringe (SO-CONNECT+ 100)	20 ml / 30 ml / 50 ml / 100 ml	100 ml
Volume to be infused	From 1 ml to 600 ml in increments of 1 ml.	50 ml
Type of infusion	Mono flow rate / multi flow rate	Mono flow rate
Number of infusion sites	1, 2, 3 or 4	1
Rate of the infusion (for 20 ml, 30 ml or 50 ml syringes)	From 0 to 40 ml/h for 1 infusion site From 0 to 80 ml/h for 2 infusion sites From 0 to 100 ml/h for 3 or 4 infusion sites In increments of 0.1 ml/h.	0 ml/h
Rate of the infusion (for 100 ml syringes) If 300 ml/h option is not enabled	From 5 to 40 ml/h for 1 infusion site From 5 to 80 ml/h for 2 infusion sites From 5 to 120 ml/h for 3 or 4 infusion sites 0 ml/h allowed In increments of 0.1 ml/h.	0 ml/h
Rate of the infusion (for 100 ml syringes) If 300 ml/h option is enabled	From 5 to 300 ml/h* for all infusion sites 0 ml/h allowed In increments of 0.1 ml/h.	0 ml/h

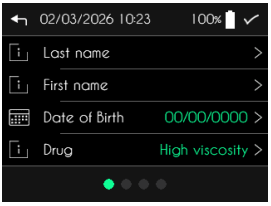
Setting	Values	Default value
Duration of the infusion	From X to 24 hours (X is a function of the maximum infusion rate). In increments of 15 minutes.	12:00 AM

*The manufacturer recommends the following infusion rate limits depending on the viscosity of the product to infuse and the gauge of the infusion set:

		Viscosity		
		Water	IgG 10 %	IgG 16.5 - 20 %
Infusion set gauge	G27	300 ml/h on 1 site	40 ml/h on 1 site	40 ml/h on 1 site 120 ml/h on 4 sites
	G26	300 ml/h on 1 site	100 ml/h on 1 site	60 ml/h on 1 site
	G24	300 ml/h on 1 site	300 ml/h on 1 site	100 ml/h on 1 site

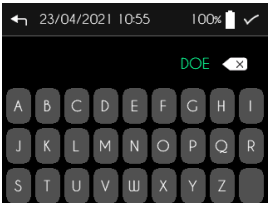
Entering the patient's information

SO-CONNECT+ has a function for saving patient information. This information is used while exporting the history of the infusions.



By default, the patient's information contains no data.

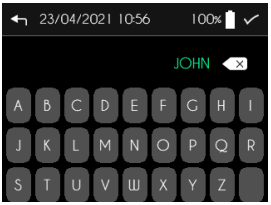
- Press on the information to be changed.



<u>Entering the surname</u>

It may have no more than 16 characters.

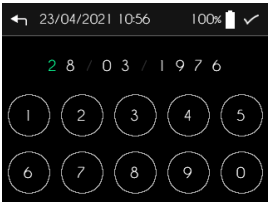
- Use the keyboard to enter the patient's last name.
- Press on the "✓" icon to confirm the input.



<u>Entering the first name</u>

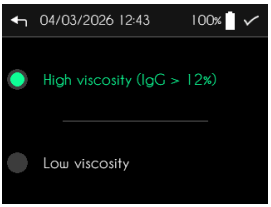
It may have no more than 16 characters.

- Use the keyboard to enter the patient's first name.
- Press on the "✓" icon to confirm the input.



Entering the date of birth

- Use the numeric keypad to enter the patient's date of birth.
- Press on the "✓" icon to confirm the input.



Selection of the viscosity of the drug

Two choices are available for the drug to be infused.

- Select the appropriate drug viscosity.
- Press on the "✓" icon to confirm the selection.

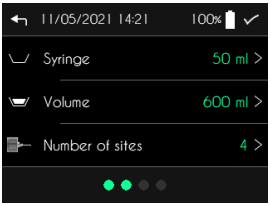
Comments

- The SO-CONNECT+ pump allows the infusion of drugs with different viscosities. For optimal performance, two modes are available: "High viscosity" and "Low viscosity".
- For immunoglobulins with a concentration greater than 12%, select the "High viscosity" mode.
- For other drugs, select the "Low viscosity" mode.

Selection of the type of syringe, entry of the volume to be infused and entry of the number of sites.

Comments

- Always make sure to select the correct type of syringe, corresponding to the one you are going to use for the infusion. The movements of the pump's pusher are calibrated to match the type of syringe.
- After the type of syringe has been changed, the volume to be infused is automatically programmed to the maximum volume.
- After the number of infusion sites has been changed, the rate is automatically reset to 0.

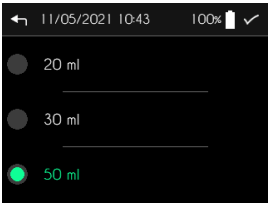


After the patient's information has been entered and confirmed, SO-CONNECT+ shows the screen for selecting the type of syringe and for entering the volume to be infused.

- Press on the setting to be changed.

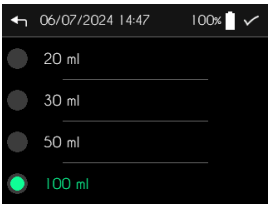
Selection of the type of syringe (for SO-CONNECT+ V2)

- Select the type of syringe used for the infusion.
- Press on the "✓" icon to confirm the selection.



Selection of the type of syringe (for SO-CONNECT+ 100)

- Select the type of syringe used for the infusion.
- Press on the "✓" icon to confirm the selection.

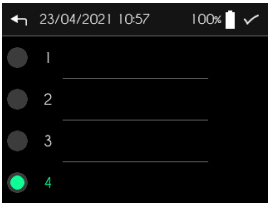


Entering the volume to be infused

- Press on the syringe icon to set the volume and on the "+" and "-" icons to adjust the value.
- Press on the "✓" icon to confirm the input.

Entering the number of infusion sites

- Select the number of infusion sites by pressing on it.
- Press on the "✓" icon to confirm the input.



Setting up the infusion mode (MONO / MULTI)

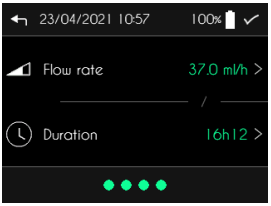
SO-CONNECT+ is designed to offer the following two operating modes for infusion:

- In MONO mode, you can configure only one infusion rate.
- In MULTI mode, you can configure up to 5 infusion rates in the form of stages that are reached by the pump automatically, in order.

After the validation of the type of syringe and the volume to be infused, SO-CONNECT+ displays the screen for entering the infusion mode. By default, the infusion mode is MONO.

- Select the relevant operating mode by pressing on "Mono" or on "Multi".
- Press on the "✓" icon to confirm and go to the infusion rate setting screen.

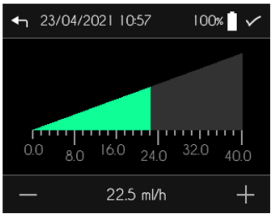
Entering the infusion rate or duration in mono flow rate mode



Once the infusion mode has been validated, SO-CONNECT+ displays the screen for entering the infusion rate or duration.

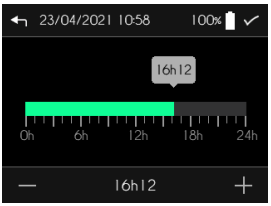
By default, the infusion rate is 0 ml/h.

- Press on the setting to be changed. When one setting is changed, the other is automatically changed.



Entering the infusion rate

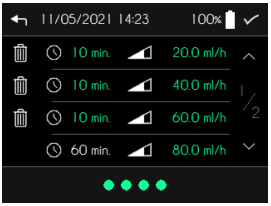
- Press on the graph to set the infusion rate and on the "+" and "-" icons to adjust the value.
- Press on the "✓" icon to confirm the input.



Entering the infusion duration

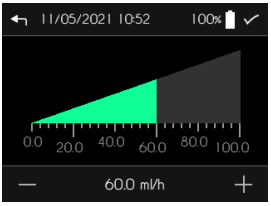
- Press on the graph to set the infusion duration and on the "+" and "-" icons to adjust the value.
- Press on the "✓" icon to confirm the input.

Entering the infusion rate or duration in multi flow rate mode



Once the infusion mode has been validated, SO-CONNECT+ shows the screen for setting up the infusion stages.

- Press on the setting to be changed.



Entering the infusion rate of a stage

- Press on the graph to set the infusion rate and on the "+" and "-" icons to adjust the value.
- Press on the "✓" icon to confirm the input.

Entering the duration of a stage

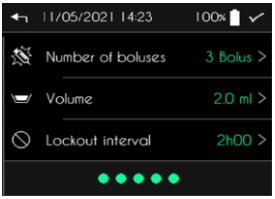
- Press on the graph to set the duration of the stage and on the "+" and "-" icons to adjust the value.
- Press on the "✓" icon to confirm the input.

Entering the bolus configuration (if option enabled)

Comment

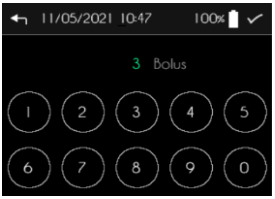
- By default, the bolus features are disabled and do not appear on the screen.

In case the bolus function is enabled, after validation of the flow rates and infusion time, SO-CONNECT+ displays the bolus settings screen.



By default, the bolus settings are all set to 0.

- Press the setting you want to change.

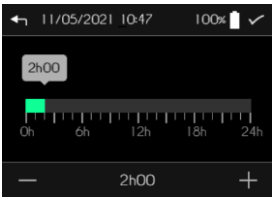


Entering the number of boluses

- Press the numbers to enter the number of boluses.
- Press on the "✓" icon to confirm the input.

Entering the volume of a bolus

- Press the graph to set the volume of a bolus and the "+" and "-" icons to adjust the value.
- Press on the "✓" icon to confirm the input.



Entering the refractory period

- Press the graph to set the refractory period and the "+" and "-" icons to adjust the value.
- Press on the "✓" icon to confirm the input.

Infusion

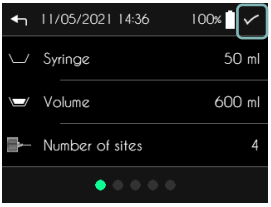
> ⚠ Comment
>
> - Before starting a new infusion, check that the date and time are correct. The flow rates and data of the histories are saved based on this information.

- Press on "New Infusion" on the main menu to start an infusion.

Displaying the infusion configuration

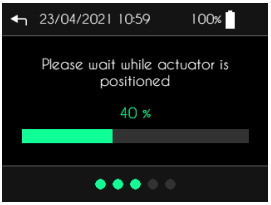
Before starting an infusion, SO-CONNECT+ displays the infusion configuration.

- After checking the settings, press on the "✓" icon to go to the next screen.



Positioning the pusher

Once all the settings have been checked, SO-CONNECT+ automatically positions the pusher. This positioning is calibrated to match the type of syringe and the volume to be infused. This operation can take several minutes.

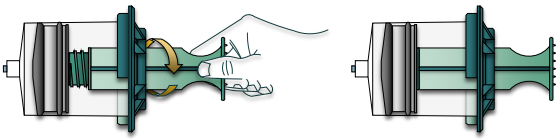
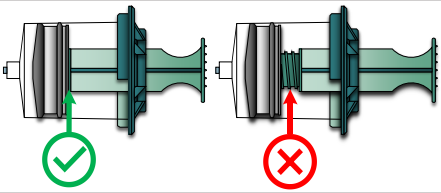
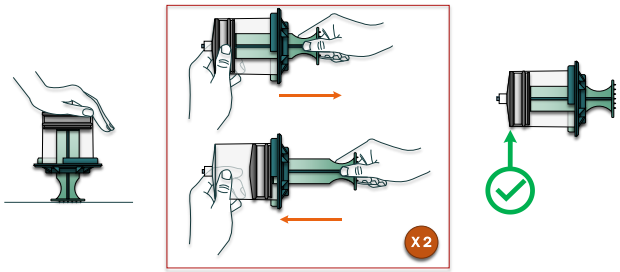
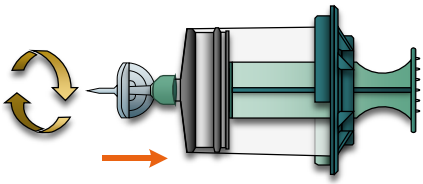
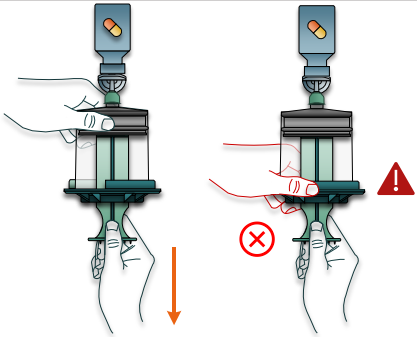


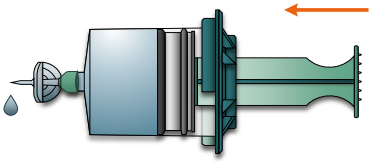
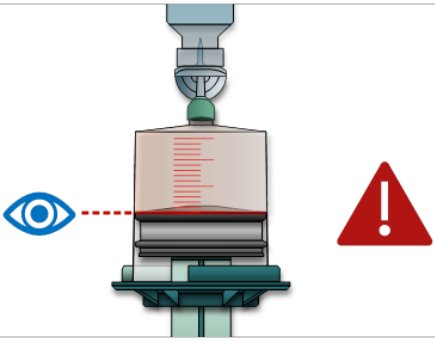
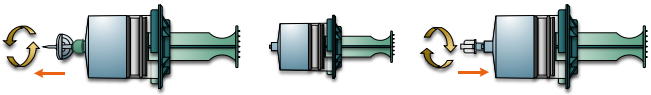
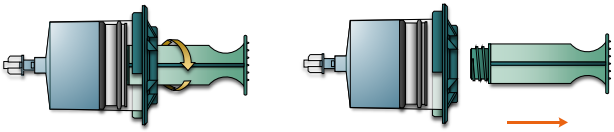
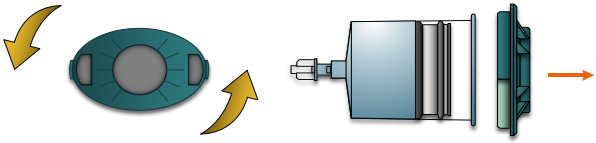
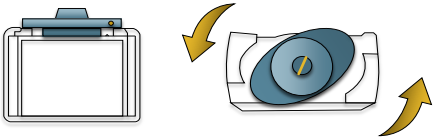
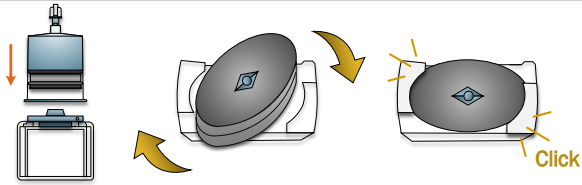
> Comment
>
> - Do not block the movement of the pusher. This could trigger an occlusion alarm.

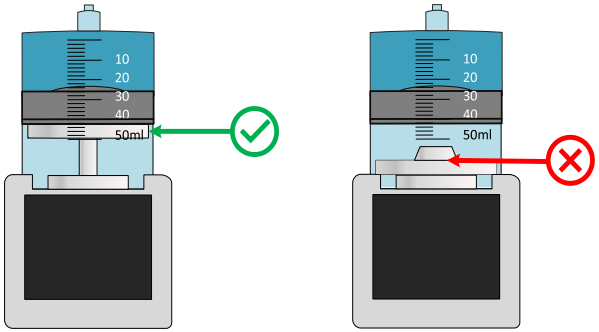
Syringe filling and installation on the pump (only for SO-FILL 20-30-50)

After the pusher has been positioned, SO-CONNECT+ shows a screen requesting to install the syringe.

Before placing the syringe on the pump, fill it according to the instructions below.

1		Unscrew and screw the plunger so that it can be unscrewed easily after filling the syringe.
2		Check the correct "tightening" between the plunger and the piston.
3		Push the plunger back and forth to uniformly lubricate the silicone inside the body of the SO-FILL syringe.
4		To fill the SO-FILL syringe, you can use an adapter or a spike. Take the chosen option and screw it clockwise a quarter turn onto the prepared syringe.
5		Fill the SO-FILL syringe by sucking up the liquid slowly. During filling, SO-FILL syringe must be held by the upper part and not by the side.

6		Drain the syringe, without forcing, to avoid air bubbles.
7		Verify that the quantity of liquid does not exceed the capacity of the SO-FILL syringe or the defined volume.
8		Unscrew the adapter or spike counterclockwise. Insert the Luer Lock cap by screwing it clockwise to avoid loss of medication.
9		Unscrew the plunger counterclockwise and set it aside.
10		Repeat the previous operation with the plunger flange.
11		Turn the pump head slightly counterclockwise.
12		Place the SO-FILL syringe on the pump and turn it clockwise until you hear a slight click.

13		Check if the pusher is in contact with the syringe gasket. If not, go back and redo the infusion placement procedure.

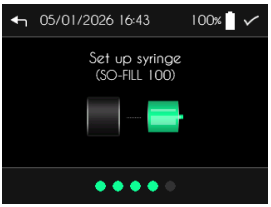
- Press on the "✓" icon after the syringe has been positioned.

Comments

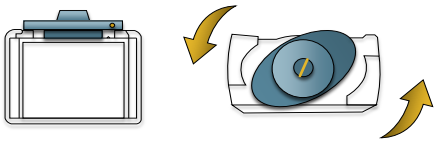
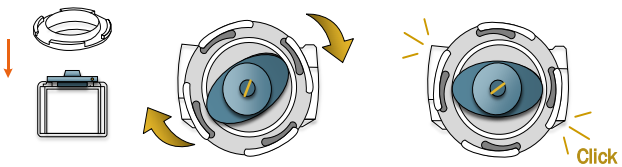
- Do not fill the syringe too close to the pump to avoid splashing on the pump.
- Tests carried out on SO-FILL syringes have demonstrated the compatibility and stability of immunoglobulin and Deferoxamine over a 24-hour period.

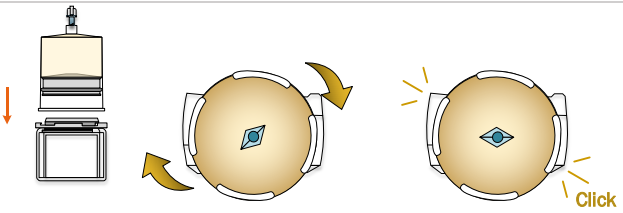
Syringe filling and installation (only for SO-FILL 100)

After the pusher has been positioned, SO-CONNECT+ 100 shows a screen requesting to set up SO-FILL 100 syringe.



Before placing the elements on the pump, fill it according to the SO-EASY+ instructions.

1		Turn the SO-CONNECT+ 100 pump head slightly anti-clockwise.
2		Place the SO-ADAPT 100 adapter on the pump and turn it clockwise until you hear a slight click.

3		Place the SO-FILL 100 syringe on the SO-ADAPT 100 and pump assembly and turn it clockwise until you hear a slight click.

- Press on the "✓" icon after SO-ADAPT 100 and the syringe has been positioned.

Comments

- Do not fill the syringe too close to the pump to avoid splashing on the pump.
- Tests carried out on SO-FILL syringes have demonstrated the compatibility and stability of immunoglobulin and Deferoxamine over a 24-hour period.

Installing the infusion set

Infusion sets with the following characteristics should be used:

- Luer Lock connection
- Small internal tube volume (optimum 0.1 ml, maximum 0.62 ml);
- Tube that does not exceed 90 cm length;
- Anti-throttle tube.

The infusion set is to be put in place as follows:

1) Remove the adhesive tape.
2) Remove the needle guard.
3) Pinch the skin with one hand and insert the infusion set vertically.
4) Press the adhesive to fix the infusion set on the skin.

The absorption capacity of the subcutaneous tissue must be taken into account when choosing the infusion site, with priority given to positioning on the abdomen, and then on the thighs, for example. Alternatively, other catheterization sites that may be used are:

- The lateral abdominal walls, outside of the periumbilical area;
- The antero-external area of the thighs, at the junction between the middle and lower thirds;
- The outer arms;
- The subclavicular region, three finger-breadths below the middle of the collarbone (avoid if patient has a pacemaker or implantable port);
- The subscapular region of the back, when the patient is agitated.

For the flow rates to be used depending on the infusion set, please refer to the table in chapter "Setting up the infusion".

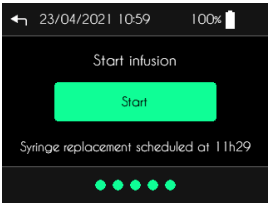
Warnings

- The use of an unsuitable infusion set may make the pump malfunction, e.g. it may take longer to report an occlusion.
- Before putting the infusion set in place, manually prime the infusion set in order to remove all air from it.
- Before using patient tubing accessories or connecting SO-CONNECT+ to other infusion systems, contact France Développement Électronique (contact details on back of this manual) to identify

the procedure to be followed. Connecting the pump to other infusion systems may make the infusion rate inaccurate.

- Users are strongly advised against the use of infusion sets with gauges above G27. Otherwise, the viscosity of the infused product will give rise to excess pressure, and lead to deformations and a risk of product leakage.

Starting the infusion



Starting the infusion

- Press on the "Start" button to start the infusion.

Comment

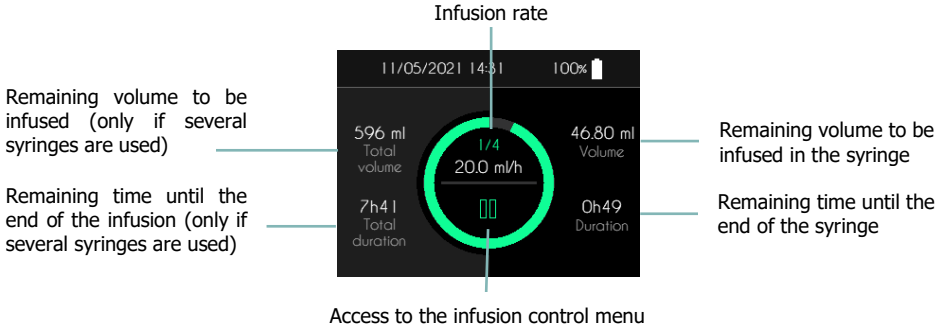
- The start screen of the infusion indicates the time at which the user must change the syringe, if necessary.

Warnings

- When the infusion starts, the pump emits an audio signal. If you don't hear the audio signal, this means that the alarm system may be defective. In that event, contact user support. Malfunctioning of the pump's buzzer can result in serious injury to the patient.
- Check that the pusher is in contact with the syringe's gasket before starting the infusion. If the pusher is not in contact with the syringe's gasket, go back and redo the infusion set-up procedure. If the pusher does not move during priming, change the pump and contact France Développement Électronique (contact details on back of this manual).

Infusion control screen (using SO-FILL 20-30-50)

During the infusion, SO-CONNECT+ displays information about its status.



Comment

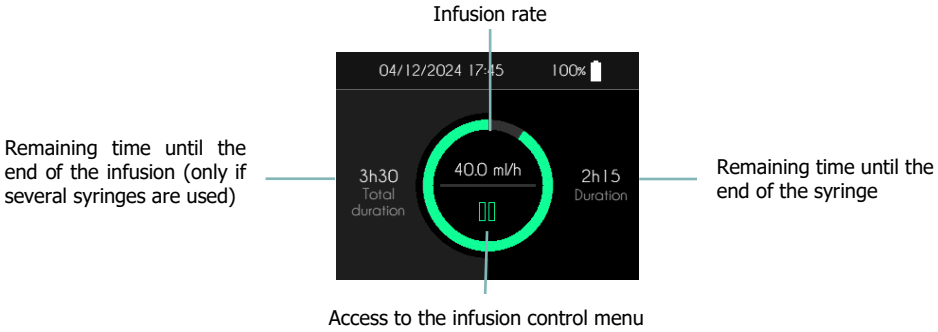
- For the safe use of the pump during infusions, the various buttons and icons must be pressed and held for 2 seconds in order to function.

Warning

- During the infusion, check the working of the pump from time to time. If you observe any malfunctioning or poor performance, pause the infusion and contact France Développement Électronique (contact details on back of this manual).

Infusion control screen (using SO-FILL 100)

During the infusion, SO-CONNECT+ 100 displays information about its status.



Comment

- For the safe use of the pump during infusions, the various buttons and icons must be pressed and held for 2 seconds in order to function.

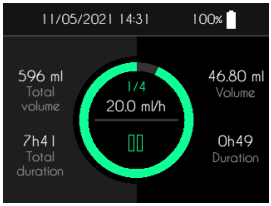
Warning

- During the infusion, check the working of the pump from time to time. If you observe any malfunctioning or poor performance, pause the infusion and contact France Développement Électronique (contact details on back of this manual).

Infusion control menu

From the infusion screen, you can access various functions in the infusion control menu.

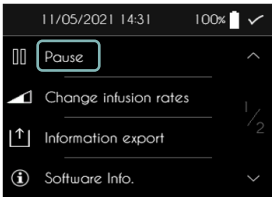
- Press for 2 seconds on the "⏸" or "▶" icon to reach the infusion control menu.



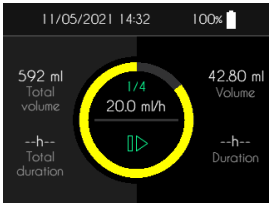
SO-CONNECT+ will display the infusion control menu.

Pausing the infusion

- In the infusion control menu, press for 2 seconds on "Pause".

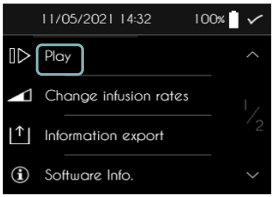


SO-CONNECT+ displays the infusion paused screen. The green circle flashes yellow.

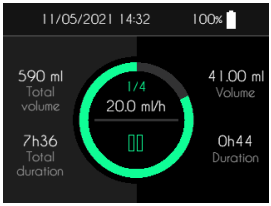


Restarting the infusion

- In the infusion control menu, press for 2 seconds on "Play".



SO-CONNECT+ displays the Infusion underway screen.

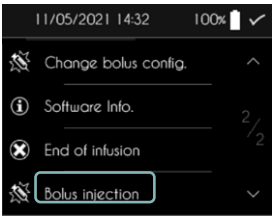


Bolus injection (if option enabled)

Comment

- By default, the bolus features are disabled and do not appear on the screen.

- In the infusion control menu, press for 2 seconds on "Bolus injection".



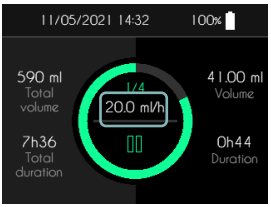
If a refractory period is configured, this button is not accessible for the duration of the refractory period following a bolus injection.

Also, if the number of boluses allowed has already been infused, the button will not appear.

Displaying the configuration in multi flow rate mode

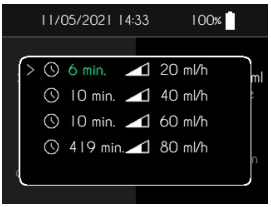
From the infusion screen, you can display the configuration of the flow rates in multi flow rate mode.

- Press for 2 seconds on the current infusion rate (for example, 20.0 ml/h on the figure opposite).



SO-CONNECT+ displays the configuration of the stages.

- Press on the screen to return to the infusion screen.



Modifying the infusion rate or duration of the infusion – Function reserved for healthcare professionals

- In the infusion control menu, press for 2 seconds on "Change infusion rates".

Changing the infusion rate or duration is done in the same way as during the infusion programming process.

Comments

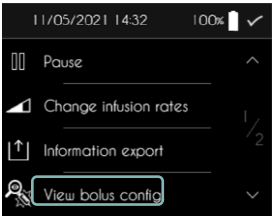
- The infusion is paused automatically while the infusion rate or duration is being changed. Remember to restart it after.
- Any changes made apply immediately.

Visualization of the bolus configuration (if option enabled)

Comment

- By default, the bolus features are disabled and do not appear on the screen.

- In the infusion control menu, press for 2 seconds on "View bolus config.".



The bolus configuration is displayed but cannot be edited.

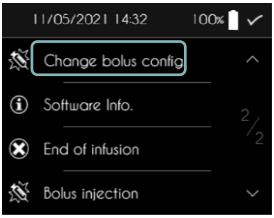
- Press on the "✓" icon to return to the infusion screen.

Modifying the bolus configuration (if option enabled) - Function reserved for healthcare professionals

Comments

- By default, the bolus features are disabled and do not appear on the screen.
- The infusion is paused automatically while the bolus configuration is being changed. Remember to restart it after.
- Any changes made apply immediately.

- In the infusion control menu, press for 2 seconds on "Change bolus config.".



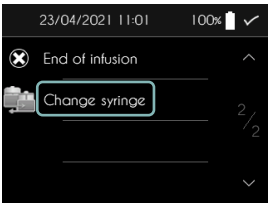
Changing the bolus configuration is done in the same way as during the infusion programming process.

Exporting the history

- In the infusion control menu, press <u>for 2 seconds</u> on "Information Export".

For more information on this function, go to the "Exporting the history" section.

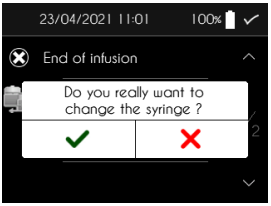
Changing the syringe



<u>Changing the syringe early</u>

At any time, you can change the syringe from the infusion control menu.

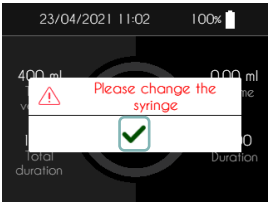
- Press on "Change syringe" <u>for 2 seconds</u>.



SO-CONNECT+ displays a message requesting to confirm that you want to change the syringe.

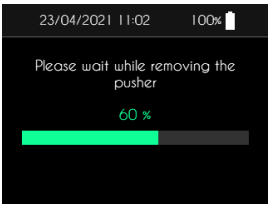
- Press on the "✔" button <u>for 2 seconds</u> to confirm the changing of the syringe.
- Press on the "✘" button <u>for 2 seconds</u> to cancel the changing of the syringe.

<u>Automatic syringe change</u>



At the end of the syringe, SO-CONNECT+ beeps and displays a message requesting that the user change the syringe.

- Press on the "✔" button <u>for 2 seconds</u> for starting the change of syringe process.

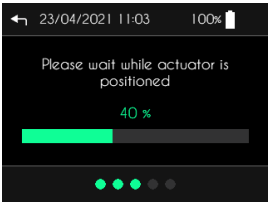


<u>Retraction of the pusher</u>

At the end of the infusion, SO-CONNECT+ retracts the pusher. This operation can take several minutes.

<u>Removal of the syringe</u>

After the pusher has been retracted, SO-CONNECT+ displays the screen requesting that the syringe be removed. Press on the "✓" button once the SO-FILL syringe has been removed.



Positioning the pusher

The SO-CONNECT+ pump positions the pusher automatically. This positioning is calibrated to match the type of syringe and the volume to be infused. This operation can take several minutes.

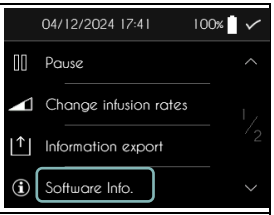
Setting up the new syringe

After the pusher has been positioned, SO-CONNECT+ shows a screen requesting that the syringe be installed.

- Press on the "✓" icon after the new syringe has been set up.

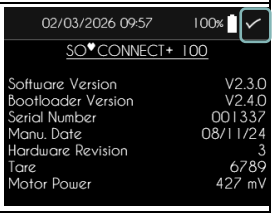
Display of the software's internal information

- In the infusion control menu, press for 2 seconds on "Software Info.".



SO-CONNECT+ displays the pump's internal information screen, with the reference "SO-CONNECT+ V2" or "SO-CONNECT+ 100".

- Press on the "✓" icon to return to the infusion screen.

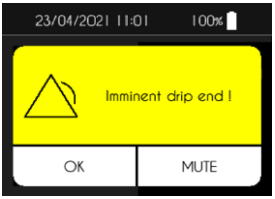


End of infusion

Imminent end of infusion

Shortly before the end of the infusion, SO-CONNECT+ triggers an alarm to warn of the imminent end of the infusion.

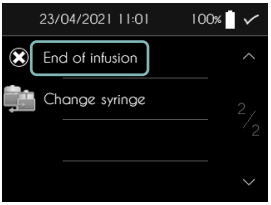
For more information about this alarm, refer to the section on alarms in this user's manual.



Ending the infusion early

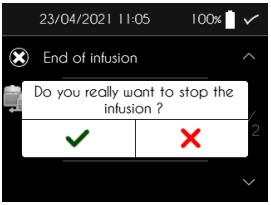
At any time, you can end an infusion from the infusion control menu.

- Press on "End of infusion" for 2 seconds.



SO-CONNECT+ displays a message requesting you to confirm that you want to end the infusion.

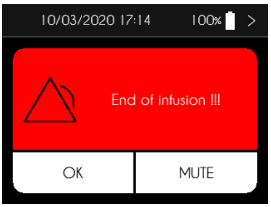
- Press on the " ✔ " button <u>for 2 seconds</u> to confirm the end of the infusion.
- Press on the " ✘ " button <u>for 2 seconds</u> to cancel stopping of the infusion.



<u>Automatic end of the infusion</u>

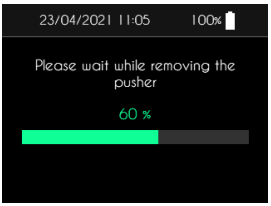
At the end of the infusion, SO- CONNECT+ generates an alarm. While this alarm is being emitted, SO-CONNECT+ automatically retracts the pusher.

For more information about this alarm, refer to the section on alarms in this user's manual.



<u>Retraction of the pusher</u>

At the end of the infusion, SO-CONNECT+ retracts the pusher. This operation can take several minutes.



<u>Removal of the syringe</u>

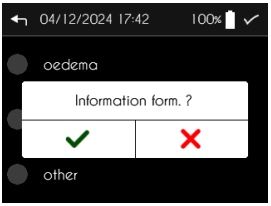
After the pusher has been retracted, SO-CONNECT+ displays the screen requesting that the syringe be removed. Press on the "✓" icon once the SO-FILL syringe has been removed.

End of infusion form (if option enabled)

At the end of the infusion, SO-CONNECT+ asks you to enter information in the "End of infusion form".

After the pusher has been retracted, SO-CONNECT+ asks if you want to fill in the "End of infusion form".

- Press on the " ✔ " button for 2 seconds to go to the form.
- Press on the " ✘ " button for 2 seconds to go straight to the main screen.

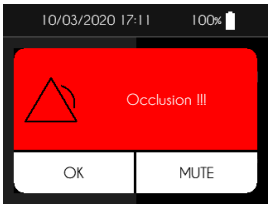
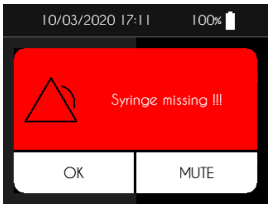
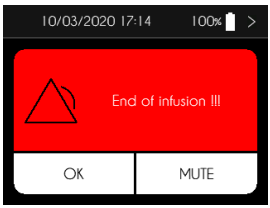


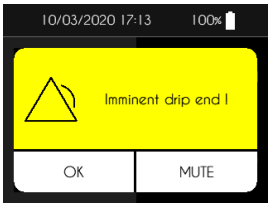
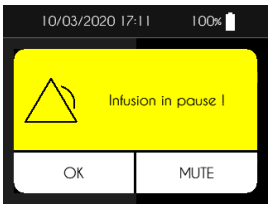
- Select the incident(s) or event(s): presence of oedema, redness, or other incident during the infusion.
- Press on the "✓" icon to confirm and return to the main screen.

Alarms

Alarm system description

The table below summarizes all the conditions in which the different alarms are generated.

Alarm	Visual	Priority	Conditions of triggering	Triggering period
Device failure		High	Failure of a printed circuit board component detected by the internal software of the pump Or Mechanical failure	1 min. and 30 sec.
Occlusion		High	Motor blocked during infusion, due to excessively high pressure in the tubing.	See section "Time required for reporting an occlusion"
Missing syringe		High	Detection of missing syringe during the infusion by the internal software of the pump with each injection.	54 sec.
End of infusion		High	End of the infusion.	Immediate
Low battery		Low	Remaining battery life less than 30 minutes.	1 minute

Infusion about to end		Low	Time remaining before the end of the infusion: between 5 and 35 minutes.	Immediate
Infusion paused		Low	The infusion has been paused for 5 minutes.	Immediate

When two or more alarm conditions are met, the alarms are generated in the following descending order of priority:

- Device failure,
- Occlusion,
- Syringe missing,
- End of infusion,
- Low battery,
- Infusion about to end,
- Infusion paused.

If several alarms are generated at the same time, each alarm must be acknowledged individually.

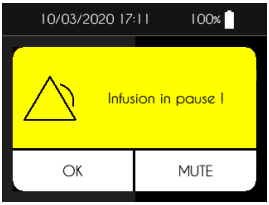
High priority alarms are indicated by a message displayed on a flashing red background and a sound signal made up of 10 beeps every 10 seconds.

When a high-priority alarm occurs, the infusion is paused automatically.

Low priority alarms are indicated by a message displayed on a steady yellow background and a sound signal made up of 2 beeps every 20 seconds.

When a low-priority alarm occurs, the infusion is not paused.

Alarm acknowledgment



The alarm screens offer two buttons:

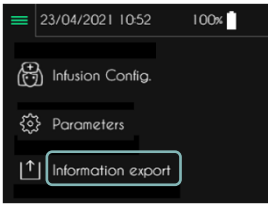
- Press the "OK" button for 2 seconds to acknowledge the alarm.
- Press the "MUTE" button for 2 seconds to switch off the sound alarm for 2 minutes. The icon  is displayed in the bar at the top of the screen.

⚠ Warnings

- If the device fault alarm occurs, remove the battery and contact France Développement Électronique (contact details on back of this manual).
- If the syringe missing alarm is triggered, you need to contact the healthcare professional in charge of your treatment to know the measures that need to be taken to restart infusion.
- The occlusion alarm activates when the pump detects high pressure in the infusion line. The high pressure must be eliminated to prevent the administration of a post-occlusion bolus, which may cause serious injury.
- If the occlusion alarm is triggered, you need to contact the healthcare professional in charge of your treatment to know the measures that need to be taken.

Exporting the history

The history export is accessible from the main menu but also from the infusion control menu.



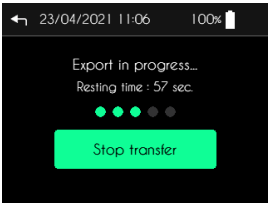
From the main menu

- From the main menu, press on "Information export".

From the infusion control menu

- From the infusion control menu, press for 2 seconds on "Information export".

SO-CONNECT+ activates the Bluetooth Low Energy interface to export the history of the infusions.



- Press on "Stop Transfer" or on the " ↩ " icon to end the connection.

Problems

If you have any problems, follow the instructions given below. If the problem is not solved, contact France Développement Électronique (contact details on back of this manual).

Problem	Possible cause(s)	Solution(s)
SO-CONNECT+ won't turn on.	The battery is not installed.	Insert the battery as indicated in the "Using for the first time" section.
	The battery is not inserted correctly.	Check the battery and insert it as indicated in the "Using for the first time" section.
	The battery is depleted.	Recharge the battery completely and insert it as indicated in the "Using for the first time" section.
SO-CONNECT+ displays an error message while starting.	Software integrity error	Remove and reinsert the battery. If the problem remains, contact France Développement Électronique.
The indicator on the screen saver button is flashing.	The pump is in update mode.	Press on the screen saver button again.
The infusion settings are not saved when the battery is changed.	The internal battery is depleted.	Contact France Développement Électronique.
SO-CONNECT+ is emitting a fault alarm.	Fault of an internal component	Remove the battery and then reinsert it. If the problem persists, contact France Développement Électronique.
SO-CONNECT+ is emitting a syringe missing alarm.	The syringe is disconnected from the pump.	Put the syringe back in place and restart the infusion.
	The syringe detection switch is blocked by dust or fluff.	Stop the infusion. Clean the pump as indicated in the "Maintenance, Support, Disposal" section.
SO-CONNECT+ is emitting an occlusion alarm.	The infusion set is tangled, twisted or pinched.	Check the entire length of the infusion set.
	There is a clamp on the infusion set.	
The SO-CONNECT+ display is malfunctioning or no longer responding	Electronic malfunction	Remove and reinsert the battery. If the problem remains, contact France Développement Électronique.
	The screen is broken following an impact.	

Associated products

Reference	Description	
SO-FILL 20-30-50	Empty SO-FILL 20 ml, 30 ml et 50 ml syringe to be filled with the treatment	
SO-FILL 100	Empty SO-FILL 100 ml syringe to be filled with the treatment	
SO-ADAPT 100	Adapter to fix a SO-FILL 100 syringe on a SO-CONNECT+ 100 pump	
SO-EASY+	System for easy filling of SO-FILL 100 syringe	
FBLUE+	Blue nylon case with window for 20ml, 30ml and 50ml SO-FILL syringe	
L50WBLACK+	Black imitation leather case with window for 20ml, 30ml or 50ml SO-FILL syringe	
FBLUE100	Blue nylon case with window for 100 ml SO-FILL syringe	

Using the protective case

The protective case protects the SO-CONNECT+ pump from splashing liquids and impacts when it is in use. It also protects the syringe. The protective case does not have a shelf or storage life.

Warning

- It is preferable to wear the protective case on your waist or shoulder. In the event of a fall, the strap could cause strangulation if it is around the neck.

1) Insert SO-CONNECT+ into the protective case.

2) The pump and the syringe must be inserted all the way into the protective case.

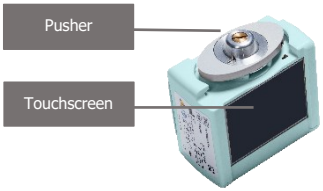
3) Close the protective case.

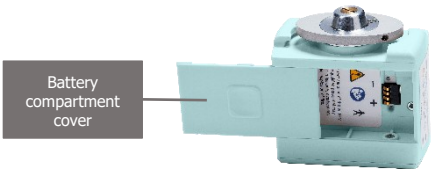
Maintenance, support, disposal

Cleaning and disinfecting the pump

Before assigning the pump to another patient, please clean and disinfect the pump.

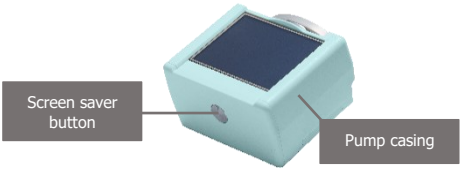
All the visible parts of the device shown in grey by the pictures below must be cleaned and disinfected.





To clean and disinfect the pump:

- Make sure that there is no syringe connected to the pump. If there is one, remove it.
- Clean the pump body with a soft, damp cloth.
- Turn on the screen.
- Program a new infusion with a syringe of 20 ml and a volume to be infused of 1 ml.
- Wait for the pusher to be positioned.
- Once the pusher is in position, remove the battery.
- Disinfect the parts shown on the previous pictures (and SO-ADAPT 100 for SO-CONNECT+ 100) with a cloth dampened with an enzymatic disinfectant, as Pursept AF. Alternatively, you can use a disinfectant wipe for non-immersible medical devices, such as Mikrozid AF Wipes.
- Wait for the disinfectant solution to be completely dry before handling the pump.



Warnings

- Do not use solvents or inorganic acids. Avoid disinfectants that are very oxidizing such as the hypochlorite sodium (NaOCL).
- Before any use, be sure that the cleaning solution is compatible with the pump which is made of ABS and aluminium.
- FDE recommends using soft, lint-free cloths to wipe the device.
- Aerosol disinfecting sprays should not be used because the droplets can infiltrate in the system and inhibit the device's safety features to function appropriately. Aerosol disinfecting sprays can damage the electronic components and are potentially flammable.
- In order to avoid causing the pump to malfunction, which could result in serious injury to the patient, the following instructions must be followed:
  - Never clean the pump during an infusion;
  - Do not use household or industrial cleaning solutions, chemicals, solvents, bleach, scouring pads or sharp instruments;
  - Always remove the syringe and the battery while cleaning the pump.
  - Make sure not to press too hard on the screen of SO-CONNECT+ while cleaning it.
  - Ensure that the product used cannot seep inside the pump.
  - The pump must not be sterilized.
  - Do not use cleaning and disinfection products other than those recommended in this manual.

Pump inspection

It is crucial for the pump to be in good working order to guarantee correct administration of medication. Check the pump screen at regular intervals during the day and when you go to bed, especially if you are unable to hear the sound signals for any reason.

Check your pump every day:

- Make sure that the pump housing, screen and the syringe do not show any damage or cracks and that the screen does not display incomplete or abnormal letters or symbols. If that does happen, contact user support.
- Inspect the syringe carefully. Check that the actual quantity of fluid to inject in the syringe is indeed the quantity displayed on the screen.
- Inspect every component of the pump and the infusion device at regular intervals during the day and before you go to bed. If you detect any leakage of fluid, replace the component responsible for the leak immediately.
- Check that the battery cover is fastened and correctly positioned, level with the pump housing.
- Make sure that the infusion system is primed, free from air bubbles and correctly connected.
- Check that the infusion device is inserted according to the instructions for use. The infusion site must be safe, not lead to any discomfort and not show any signs of irritation or infection.
- Check that the time and date are correct.

Maintenance

SO-CONNECT+ does not require any special maintenance. In the event of a malfunction, please contact France Développement Électronique (contact details on back of this manual).

⚠ Warnings

- No modification of this equipment is allowed.
- The pump must be repaired by qualified, trained technicians only.
- Unauthorized modifications may adversely affect the operation of the pump and result in serious injury to the patient.

Operating history

SO-CONNECT+ has an operating history enabling France Développement Électronique to carry out detailed diagnostics during assessments.

The operating history tracks all the operations carried out by the user (healthcare professional or patient) over the past 15 days of the pump's use: changes of the settings or the infusion setup, actions carried out during infusions, alarms that occurred and alarms that were cleared.

The operating history is saved even if the battery is changed, with no time limit.

The operating history may be retrieved by France Développement Électronique through the Bluetooth Low Energy interface.

Testing the alarm system

The alarm system should be tested at least once a month.

The alarm system is tested with the missing syringe detection alarm. To do so, follow the procedure below:

1. Start an infusion.
2. While the pump is running, remove the syringe.
3. After a maximum of 18 seconds, SO-CONNECT+ must generate a syringe missing alarm.

⚠ Warning

- Before you test the alarm system, take care to disconnect the pump from the patient.
- If no alarm is emitted, contact France Développement Électronique (contact details on back of this manual).

Pump damage in the event of a fall or impact

The pump may be damaged in the event of a fall or impact. Remember to use the case that has been designed especially for SO-CONNECT+, which will help avoid falls and protect it from impacts.

⚠ Warnings

- Inspect the pump immediately in the event of a fall or impact to ensure it is operating properly.
- Do not use the pump if you see any cracks or other damage. Water, dust, infusion fluid or other foreign material could enter into the pump and lead to malfunctioning.
- If you have any questions or are in doubt about possible damage to the pump, contact France Développement Électronique (contact details on back of this manual).

Pump coming in contact with water

If your pump comes in contact with water, please follow the instructions below:

- Pause the infusion, disconnect the pump and inspect it.
- Wipe the outside of the pump with a soft, dry cloth and check to see if any water has entered the battery compartment. If the battery compartment is wet, turn the pump over to let the water drain out, and leave it to dry.
- Do not use hot air to dry the pump. For example, do not use a hair dryer. This could damage the pump's housing.
- Do not reinsert the battery until the compartment is completely dry.

It is crucial to verify the pump immediately if it comes in contact with other liquids or chemicals, such as:

- Cleaning liquids,
- Alcohol,
- Beverages,
- Oil or grease.

Clean your pump immediately if it has come into contact with such materials.

⚠ Warnings

- Avoid putting the pump in contact with medicines or hygiene products (e.g. antiseptic, antibiotic cream, soap, scent, deodorant, body lotion or any other cosmetics). Such substances could discolor the pump or damage the screen.
- SO-CONNECT+ is not sealed. Use the case supplied with your pump to protect it from accidental splashing with water.
- Avoid all contact with water. Remember to disconnect and remove it before you have a bath or a shower, enter a Jacuzzi or go swimming.
- Avoid excess humidity (e.g. sauna), which could damage the pump.

Storing the pump

If you do not intend to use the pump for a long period of time, store it in an appropriate manner to avoid any subsequent malfunctioning.

To store the pump:

- Remove the battery to conserve it,
- Put the cover back on the battery compartment,
- Store the pump in its original box.

Comment

- Please initialize the pump if it is stored for several weeks, in order to conserve the life of the pump's internal battery.

Warning

- A battery leak could damage the SO-CONNECT+ pump. This is why the battery must be removed if the pump will not be in use for long periods.

Disposal

When it is in use, the pump is liable to come in contact with blood and could thus be a risk of infection. As a result, it is not within the scope of the European Directive 2002/96/EC and cannot be disposed of with other electronic devices. If necessary, return the pump to France Développement Électronique for disposal.

Under international regulations, medical devices such as infusion pumps require controlled destruction. Please act in compliance with local rules.

Take care not to dispose of batteries and charger with household waste and recycle them at the existing collection points.

Pump service life

SO-CONNECT+ has a life of 5 years from the date of purchase. For safety reasons, it may not be used after that time.

Warning

- If the pump is used beyond its service life, you expose yourself to risks, as the safety and performance requirements of the device are no longer guaranteed.

Technical Specifications

Compliance and classification

This manual has been prepared in accordance with the requirements of standard IEC 60601-2-24 relating to medical electrical equipment – Part 2-24: Particular requirements for the safety of infusion pumps and controllers. The data stated in this part are based on the specific test conditions defined in that standard. Actual performance data may differ from the stated data depending on other external factors, particularly variations in counter-pressure, temperature, use of the infusion kit, viscosity of the solution or a combination of these factors.

SO-CONNECT+ is classified as follows:

- Class IIb medical device
- Accessible parts: pump body, screen saver button, screen, pusher
- Type BF applied part: syringe
- Classified for continuous operation
- Electrical protection class: 3

SO-CONNECT+ has an IPX2 protection rating:

- No protection against solid objects.
- Protected from dripping water when tilted at 15° maximum.

Pump specifications

Dimensions of the pump	74 x 72 x 40 mm
Weight of the pump	200 g (battery included)
Battery	VARTA EZPack XL 3.7V 2400 mAh 8.9 Wh The battery is charged in a separate charger (see "Charging the battery" section)
Battery life	10 infusions (1)
Battery lifespan	> 500 cycles (>70% of initial capacity)
Disposable syringe	SO-FILL 20 ml / SO-FILL 30 ml / SO-FILL 50 ml / SO-FILL 100 ml (SO-CONNECT+ 100 only)
Volumes that can be administered	Programmable from 1 ml to 600 ml in increments of 1 ml.
Flow rates (for 20 ml, 30 ml or 50 ml syringes)	Programmable from 0 to 40 ml/h for 1 infusion site Programmable from 0 to 80 ml/h for 2 infusion sites Programmable from 0 to 100 ml/h for 3 or 4 infusion sites Increments of 0.1 ml/h
Flow rates (for 100 ml syringes) If 300 ml/h option is not enabled	Programmable from 5 to 40 ml/h for 1 infusion site Programmable from 5 to 80 ml/h for 2 infusion sites Programmable from 5 to 120 ml/h for 3 or 4 infusion sites 0 ml/h allowed Increments of 0.1 ml/h
Flow rates (for 100 ml syringes) If 300 ml/h option is enabled	Programmable from 5 to 300(3) ml/h for all infusion sites 0 ml/h allowed Increments of 0.1 ml/h
Infusion rate accuracy	5% (2)
Bolus injection speed	135 ml/h
Maximum infusion pressure	5 bars
Occlusion pressure	5 bars
Occlusion reporting time	See the section "Time required for reporting an occlusion"

Post-occlusion bolus	1.1 ml using SO-FILL 20-30-50 4 ml using SO-FILL 100
Memory	The infusion settings are saved, even if the battery is removed.
Screen	TFT 2.4" RGB 320 x 240 pixels with resistive touchscreen
Motor	Stepping motor with magnetic encoder
Locking of reserved functions	Via password entry.
Degree of protection	IPX2
Pump operating condition	Temperature: +5°C to +40°C Relative humidity: 15% to 90% without condensation Atmospheric pressure: 700 hPA / 1060 hPA
Pump transport and storage condition	From -25°C to +70°C under the following conditions: • -25°C to +5°C • +5°C to +35°C if relative humidity up to 90% without condensation • > +35 to +70°C at a water vapour pressure up to 50hPa
Acoustic range of sound alarm	44 dB(A) for high-priority alarms 38 dB(A) for low-priority alarms
Maximum volume infused in first fault condition	0.5% of the infusion rate/hour
Bluetooth Low Energy interface	Frequency band: 2.4 GHz Radio power: -24 dBm Software version: v002.04.00 (SoftDevice S130 v2.0.0-7)

(1) The autonomy of the battery has been checked in the laboratory under the following operating conditions:
- 50 ml infusion at a rate of 20 ml/h
- 50 ml infusion at a rate of 5 ml/h

(2) The accuracy is based on product validation and is checked during manufacture.

(3) For the flow rates to be used depending on the number on infusion sites, please refer to the table in chapter "Setting up the infusion".

Performances

Essential performances	Description
Infusion accuracy	The advancing mechanism (pusher) of the SO-CONNECT+ pump acts directly on the gasket of the SO-FILL 20-30-50 syringe, which allows for very precise drug delivery. The SO-CONNECT+ pump delivers a dose every 18 seconds, depending on the programmed flow rate. The accuracy of the infusion flow rate for the SO-CONNECT+ pump is ±5%.
Occlusion pressure	5 bars
Post-occlusion bolus volume	1.1 ml using SO-FILL 20-30-50 4 ml using SO-FILL 100
Protection against unintended bolus volumes	To prevent unintended bolus volumes after an occlusion, the pusher moves back a few steps.
High priority alarm signals	In case of high priority alarm condition, the infusion is stopped, and the pump emits an alarm: ▪ Failure of the device, ▪ Occlusion, ▪ Missing syringe, ▪ End of infusion.

Time required for reporting an occlusion

The time required for reporting an occlusion is the time interval between the start of the occlusion and the detection of that condition by the pump. That value depends on the infusion rate.

The table below provides the time required for reporting an occlusion depending on the infusion rate.

Infusion rate	Time required for reporting an occlusion
50 ml/h	3 minutes with SO-FILL 20-30-50 20 minutes with SO-FILL 100

Comments

- The time for activating the occlusion alarm depends on the infusion rate. The lower the infusion rate, the longer the pump will take to activate an occlusion alarm.
- The precision and the time required for reporting an occlusion may vary from the values indicated in this user's manual depending on the components that make up the infusion line.

Post-occlusion bolus

The occlusion alarm activates when the pump detects high pressure in the infusion line. The high pressure must be eliminated to prevent the accidental administration of a post-occlusion bolus to the patient, which may cause serious injury. The volume of the post-occlusion bolus of the pump is 1.1 ml with SO-FILL 20-30-50, and 4 ml with SO-FILL 100.

Comment

- The volume of the post-occlusion bolus administered after an occlusion can increase depending on the components that make up the infusion line.

Trumpet curves and infusion rate curves

The graphs and curves below have been calculated from the pump precision verification procedures described in standard IEC 60601-2-24.

The tests were conducted in normal ambient temperature conditions (23°C) using a pump, a 50 and a 100 ml syringe, and an infusion set (part: Neria™ from Unomedical) with different rates required by the standard:

- Intermediate rate: 50 ml/h using SO-FILL 50, and 80 ml/h using SO-FILL 100,
- Minimum rate: 1 m/h using SO-FILL 50, and 5 ml/h using SO-FILL 100.

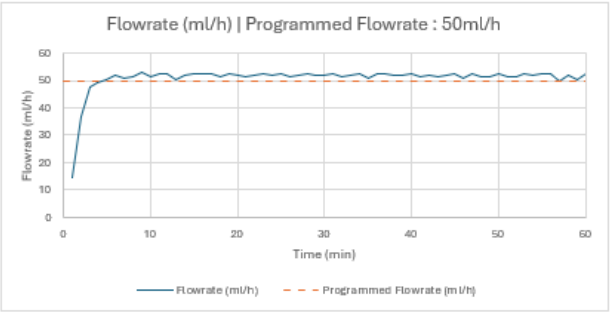
The normal conditions for optimum precision are:

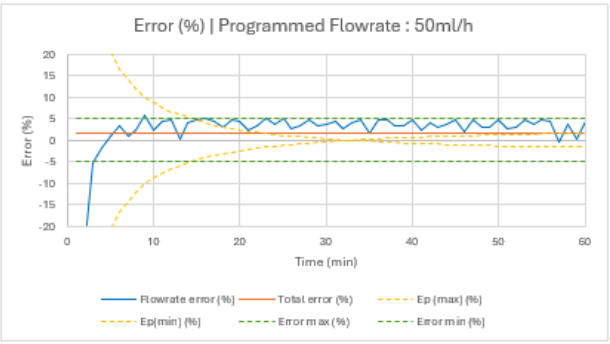
- No counter-pressure due to the size of the catheter or a height difference between the pump and the infusion site
- Ambient temperature (23°C),
- Atmospheric pressure at sea level
- Medication with liquids with characteristics similar to water.

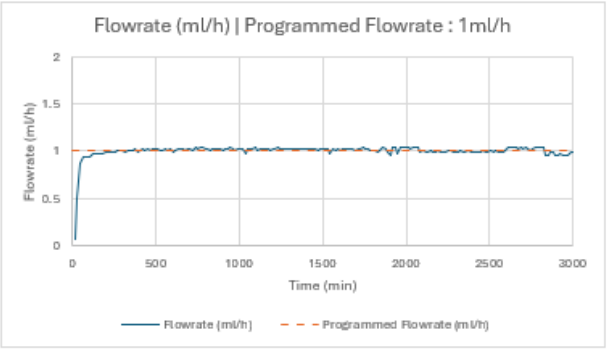
External factors can lead to fluctuations in the precision of the infusion rate. These factors are particularly:

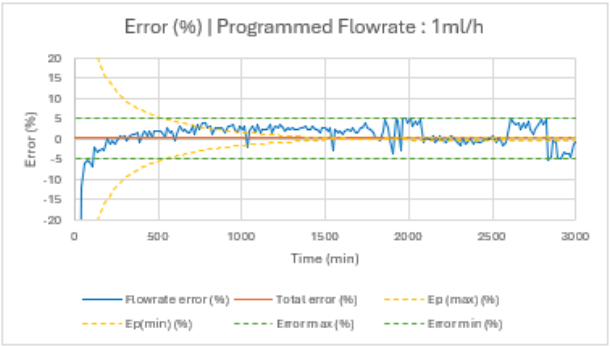
- Liquids with characteristics different from those of water, namely density, viscosity and homogeneity,
- Ambient temperature above or below 23°C,
- Atmospheric pressure above or below 101 kPa.

With SO-FILL 50:

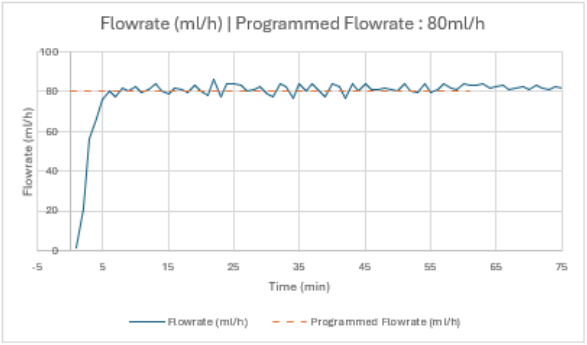


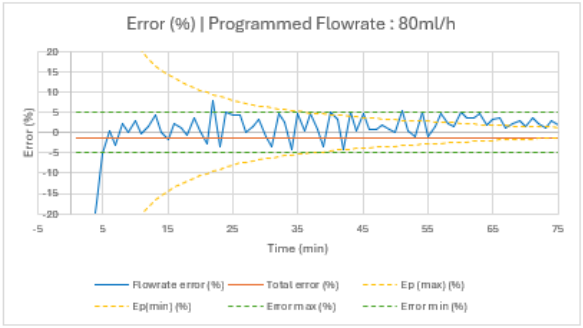


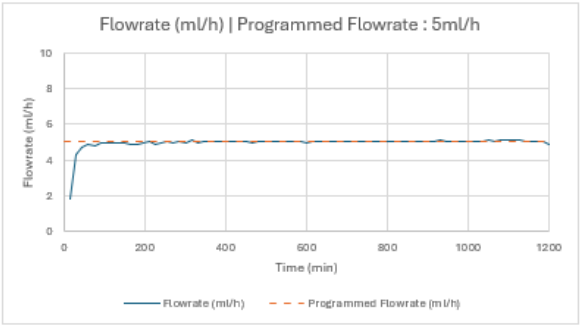


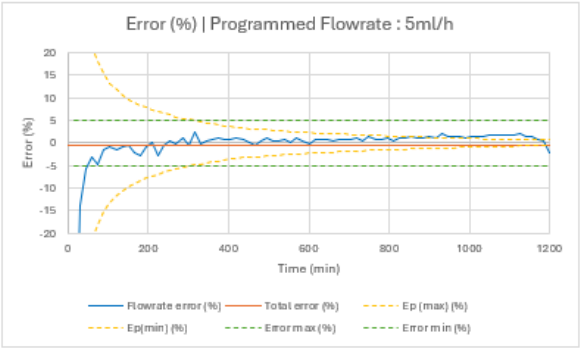


With SO-FILL 100:









Electromagnetic compatibility

The information contained in this section is provided as recommendations for the proper operation of the pump with respect of electromagnetic compatibility. The tables presented in this section refer to the criteria of the standard IEC 60601-1-2.

⚠ Warnings

- 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of SO-CONNECT+, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Advice and declaration of the manufacturer: electromagnetic emissions

SO-CONNECT+ is intended for use in the electromagnetic environment specified below. The user of the SO-CONNECT+ pump must make sure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - Tips
RF CISPR 11 emissions	Group 1	SO-CONNECT+ only uses RF energy for its internal working. As a result, its RF emissions are very low and not liable to interfere with electrical equipment in the vicinity.
RF CISPR 11 emissions	Class B	SO-CONNECT+ is suitable for use in all establishments, including homes, with the exception of installation close to high-frequency electrosurgical equipment and close to the controlled access zone of a magnetic resonance system, where the intensity of electromagnetic interference is high.
Harmonic emissions IEC 61000-3-2	Not applicable	Not applicable

Advice and declaration of the manufacturer: electromagnetic immunity

SO-CONNECT+ is designed for use in the electromagnetic environment specified below. The user of SO-CONNECT+ must make sure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - Tips
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV (contact) ±8 kV (in the air)	± 8 kV contact ± 15kV air	Floors finished in wood, concrete or tiles. If the floors are in synthetic material, the relative humidity must be at least 30%.
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2.5 GHz	10 V/m	Note (1)

Note (1): Portable and mobile RF communication devices may not be used at a distance from the components of the SO-CONNECT+ pump that is below the recommended distance, calculated on the basis of the equation applicable to the frequency of the emitter.
Recommended distance:

- $d = (3/3.5)\sqrt{P}$
- $d = (3/3.5)\sqrt{P}$ from 80 MHz to 800 MHz
- $d = (7/10)\sqrt{P}$ from 800MHz to 2.5GHz

where P is the maximum rated output power of the emitter, in watts (W) as indicated by the emitter manufacturer and d is the recommended distance in meters.

The intensities of the fields from fixed RF emitters as determined by the electromagnetic reading on the site must be below the compliance level in each reference range. Interference may occur close to equipment bearing the symbol: 

Warning

- When the SO-CONNECT+ pump is subjected to electromagnetic interference, the essential performance of the following functions can be lost or adversely impacted:
  - The precision of the infusion rate
  - The functioning of the alarm system.

  A loss or alteration of essential performance can result in serious injury to the patient.

Recommended separation distances from mobile/portable RF communication equipment

SO-CONNECT+ has been designed for use in an electromagnetic environment where the emitted RF interference is controlled.
The user of the SO-CONNECT+ pump can limit electromagnetic interference by keeping a minimum distance between the pump and mobile and portable RF communication equipment as recommended below, depending on the maximum power of the emitting equipment.

Maximum rated power of the emitter (W)	Separating distance in meters (m) depending on the emitter frequency		
	150 KHz to 80 MHz $d = 1,2\sqrt{p}$	80 MHz to 800 MHz $d = 1,2\sqrt{p}$	800 MHz to 2.5 GHz $d = 2,1\sqrt{p}$
0.01	0.12	0.12	0.21
0.1	0.38	0.38	0.66
1	1.2	1.2	2.1
10	3.8	3.8	6.64
100	12	12	21

If the maximum output power of the transmitter is not indicated in the table, the recommended separating distance d in meters (m) may be calculated with the help of the equation applicable to the frequency of the transmitter, where p is the maximum output power in watts (W) according to the emitter manufacturer.

At 80 MHz and 800 MHz, the distance is applied to the highest frequency range.

These indications are not universal. Absorption and reflection by structures, objects and individuals affect electromagnetic propagation.

Meaning of the symbols

Symbol	Description	Location
	Reference in the manufacturer's catalogue	▪ Pump body ▪ Pump packaging ▪ User manual
	Serial number	▪ Pump body ▪ Pump packaging
	Date of manufacture	▪ Pump body ▪ Pump packaging
	Manufacturer	▪ Pump body ▪ Pump packaging ▪ User manual
	Unique Device Identification	▪ Pump body ▪ Pump packaging
	Caution! Refer to the accompanying documentation for safety instructions.	▪ Pump body ▪ Battery compartment
	Refer to the instructions for use.	▪ Pump body ▪ Battery compartment ▪ Pump packaging
	Disposal of Waste Electrical and Electronic Equipment (WEEE). This symbol shows that waste batteries and electronic equipment may not be disposed of with household waste, but collected separately.	▪ Pump body
	Type BF medical device (insulated from the patient, not protected from defibrillation)	▪ Pump body
CE 0459	CE mark	▪ Pump body ▪ Pump packaging ▪ User manual
MD	Medical device	▪ Pump body ▪ Pump packaging
IPX2	Protection rating	▪ Pump body
	Store in a dry place, away from humidity.	▪ Pump body ▪ Pump packaging
	Fragile	▪ Pump packaging
	Storage temperature range	▪ Pump packaging
	Storage humidity range	▪ Pump packaging
	Information website	▪ User manual

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