CRONO S-PID 50

Ambulatory infusion pump

NEW MODEL

CANE

MEDICAL TECHNOLOGY

SECTION 12

SECTION 13

APPENDICES

SYMBOLS AND CONVENTIONS

To assist you in using the manual, the following symbols and conventions have been used:

Triangle containing an exclamation mark
This "**WARNING**" icon indicates something that must always be taken into consideration for safe use of the pump.

Notepad
This icon indicates "**NOTES**" containing additional information or useful tips about the use of the pump.

Flashing symbol
The graphic symbol shown in the manual above the pictures of the pump display, indicates that the information below it is flashing.

This manual is divided into 5 parts:

Part 1 (red): sections 1 to 7, general information, technical specifications and warnings.

Part 2 (blue): sections 8 to 10, which describe the functions of the *CRONO S*-PID 50 device.

Part 3 (orange): section 11, which describes the *reservoir*, the preparation and insertion of the *reservoir* into the pump, the infusion sites and the preparation for an infusion.

Part 4 (purple): sections 12 and 13, giving general warnings and a description of the accessories supplied, as well as discussing maintenance, disposal and support. It also details the guarantee and the declaration of conformity.

Appendices: Pages 69 to 86.

INTRODUCTION

Thank you for having chosen the ambulatory infusion pump, model: *CRONO S*-PID 50.

This manual has been prepared to enable you to make the best use of the *CRONO S*-PID 50 pump, supplying information on the settings, safe use and maintenance of the device.

If any of the information is not clear, or if you have any doubts or questions, please contact the Customer Support Service of CANÈ S.p.A.

Incorrect use of the pump, or the failure to follow the instructions and warnings provided in this manual could cause serious injury.

The instructions provided herein are exclusively with respect to the ambulatory infusion pump, model: *CRONO S*-PID 50 and are intended for use by the medical and paramedical personnel who need to set up the pump initially, and subsequently by patients who are capable of managing their therapy autonomously, or persons who are caring for patients.

The pump has a settings locking system (see page 24) which stops the settings from being modified by accident. The information relating to the locking/unlocking of the settings lock is supplied at the back of this manual on a plastic card.

The purpose of the settings lock is to avoid accidental or unauthorised modification of the selected parameters. If it is considered inappropriate that the patient should be aware of how to unlock the settings lock, the doctor and/ or other person who is assisting the patient should not supply this information.

The instructions in this manual are essential for the safe and correct use of the pump. You are advised to read the whole manual before starting to use the device and to keep the manual handy for future reference.

The pump does not need to be installed, tested and/or activated.

CANÈ S.p.A. reserves the right to modify the hardware and software specifications described in this manual at any time and without notice.

NOTES

- CANÈ S.p.A. reserves the right to modify and/or update this manual at any time and without notice.

- In order to make this manual as complete and accurate as possible, please report any errors or omissions to the following e-mail address: service@canespa.it.

WARNING: PRECAUTIONS FOR USE

This pump is not recommended for independent use by patients who are unable to follow and understand the instructions supplied in this manual or unable to perform the basic operations and the regular maintenance of the pump.

INFORMATION

For further information about the *CRONO S*-PID 50 pump, contact:

Customer Support Service
CANÈ S.p.A. Medical Technology
Via Cuorgnè, 42/a 10098 Rivoli (Turin) - Italy
Tel. +39.011.9574872 Fax +39.011.9598880
Internet: www.canespa.it   e-mail: service@canespa.it

INTENDED USE

The *CRONO S*-PID 50 ambulatory infusion pump is designed for the subcutaneous infusion of immunoglobulins and drugs in general.

CANÈ S.p.A. disclaims all responsibility for the administration of drugs by other methods.

NOTE

The manufacturer holds itself liable for the safety and the correct functioning of the device, provided that it is used in accordance with these instructions and that any required repairs and/or modifications are carried out exclusively by the said manufacturer.

WARNINGS

The use of incorrect settings and/or incomplete understanding of the operational functionality and of the alarms could cause serious harm to the patient.

Before using the pump, evaluate whether its use is appropriate for the need and for the patient, paying close attention to the following aspects:
- The technical specifications of the pump
- The infusion sets which will be used
- Whether you will be using multiple tube sets and *clamps* in the infusion line
- The cognitive and psycho-physical condition of the patient.
With respect to the clinical procedural aspects, which are the responsibility of the medical or paramedical personnel, the above list is supplied for example purposes only and is not exhaustive.

The device must be used:
- Under the control of a doctor
- Adopting appropriate procedures and adequate measures when dealing with patients who could suffer serious consequences (injury or death) in the event of accidents and/or breakdowns which cause an interruption of the administration of the pharmaceutical.

Do not *prime* the infusion line when it is connected to the patient, because this could cause an overdose of the pharmaceutical.

Before beginning an infusion, inspect the infusion line to ensure there are no folds, *clamps*, or other occlusions in the line, and expel any air bubbles.

The level of precision and amount of time needed to detect an occlusion could differ from the values indicated in this manual, depending on the type of catheter, the infusion set and all the elements which comprise the infusion line.

If you have any suspicion that the pump has been in any way damaged, for example by fluid penetration or having been dropped, contact the Customer Support Service to check that the pump is functioning correctly. Do not use a damaged pump.

If you have any doubts about the functioning of the pump and/or an error or anomaly occurs, stop using the device and contact the Customer Support Service.

CANÈ S.p.A. does not supply a replacement service for the pump during the period needed for any repairs; such service should be supplied by the relevant medical structure or the local distributor.

Any liquid on the pump casing must be removed immediately with absorbent paper.

It is important to establish a procedure and/or alternative to pumped infusion, in case the pump malfunctions. A valid alternative could be to have both a second pump and an alternative backup system.

It is recommended that the people who assist and/or live with the pump user know how the pump works and are aware of the information in this user guide.

It is important to stop using the device after the indicated service life has expired and follow the instructions for its correct disposal.

Do not administer immunoglobulins intravenously; if they are accidentally administered to a blood vessel or capillary the patient could suffer an anaphylactic shock or thromboembolic events. Always check this before continuing with an infusion.

PUMP DESCRIPTION

CRONO S-PID 50 is an ambulatory infusion pump for controlled subcutaneous administration of immunoglobulins and drugs in general.

CRONO S-PID 50 is a union of high technology and innovative design. Its reduced dimensions and weight make it ideal for home use, giving the patient the freedom to engage in everyday activities during the therapy.

CRONO S-PID 50 uses 50 ml dedicated reservoirs.
The pump's standout features are:
- the ability to choose between time or flow rate programming modes:
- the ability to divide the drug volume contained in the syringe over several infusion sites (feature only available in flow rate mode).
The pusher mechanism, which operates directly on the rubber piston of the reservoir, enables the pump to combine high delivery pressure with excellent precision while administering the drugs.

CRONO S-PID 50 is provided with a liquid crystal display (LCD) which shows practical information to the doctor and patient about the settings, operations and diagnostics of the pump.

INFUSION SYSTEM

The pump administers micro doses (shots), the volume and interval of which depend on the flow rate and the configured delivery time. By shot, we mean the quantity administered for every rotation of the motor.

TECHNICAL CHARACTERISTICS

Pump dimensions	3.31 x 2.17 x 1.65 in (84 x 55 x 42 mm).
Weight	139 g (126.72 g.), including battery.
Battery	Lithium CR 123A 3V (battery life about 60/80 infusions).
Dedicated* single use *reservoir	with a 50 ml capacity and a "*Luer-Lock*" universal security attachment.
Partial volume	Selectable, from 1 to 50 ml in 1 ml increments
Time Mode (delivery time)	Selectable, from 30' to 500 h.
Flow rate Mode	Selectable, from 0.1 ml/h to 100 ml/h.
Setting of the number of infusion sites (only in Flow rate Mode)	Selectable, from 1 to 5 sites.
Available *priming* volume	1.5 ml.
Flow rate precision	+/-3%.
Occlusion pressure	3.0 bar +/-1.5
Shot volume	20 microlitres (shot: quantity administered for every rotation of the motor).
Time needed to signal an occlusion	See APPENDIX 4.
Post-occlusion bolus	About 1.8 ml.

Settings memory	All settings are automatically stored in a flash memory which is retained even if the device is left without a battery
Display	Liquid Crystal Display (LCD - 0.43 x 1.0 in; 11 x 28 mm).
Motor	Coreless DC motor, the rotation of which is controlled by an infrared system.
Settings lock	Two configurable levels.
Electronic circuit with twin microcontrollers	Ensures a more reliable and safer infusion system.
Safety circuits	These check that the device is functioning correctly, intervening in the event of any anomaly with sounds and messages on the display.
Ingress protection rating	IP 42
Pump operating conditions	+10°C / +45°C. 30% / 75% RH. 700 hPa / 1060 hPa.
Pump storage conditions	-10°C / +60°C. 10% / 85% RH. 500 hPa / 1060 hPa.

EQUIPMENT SUPPLIED

1. CRONO *S- PID 50 ambulatory infusion pump*.
2. Pump carry-case (Code: VAL/05).
3. Elastic belt (Code: CM/01).
4. Fabric case (Code: CM/06).
5. Collar strap (Code: CM/18D).
6. 2 Batteries (one of which is already inserted in the pump) (Code: CR/123A).
7. Battery-cover opening tool (Code: CA/02).
8. User Guide.

PUMP PARTS

Attachment for the *reservoir wings*

LED

Supporting eyelets of the supporting cord

Display

Buttons

Pusher

Anti-slip grooves

Battery compartment

Serial No.

Quick reference

CE marking
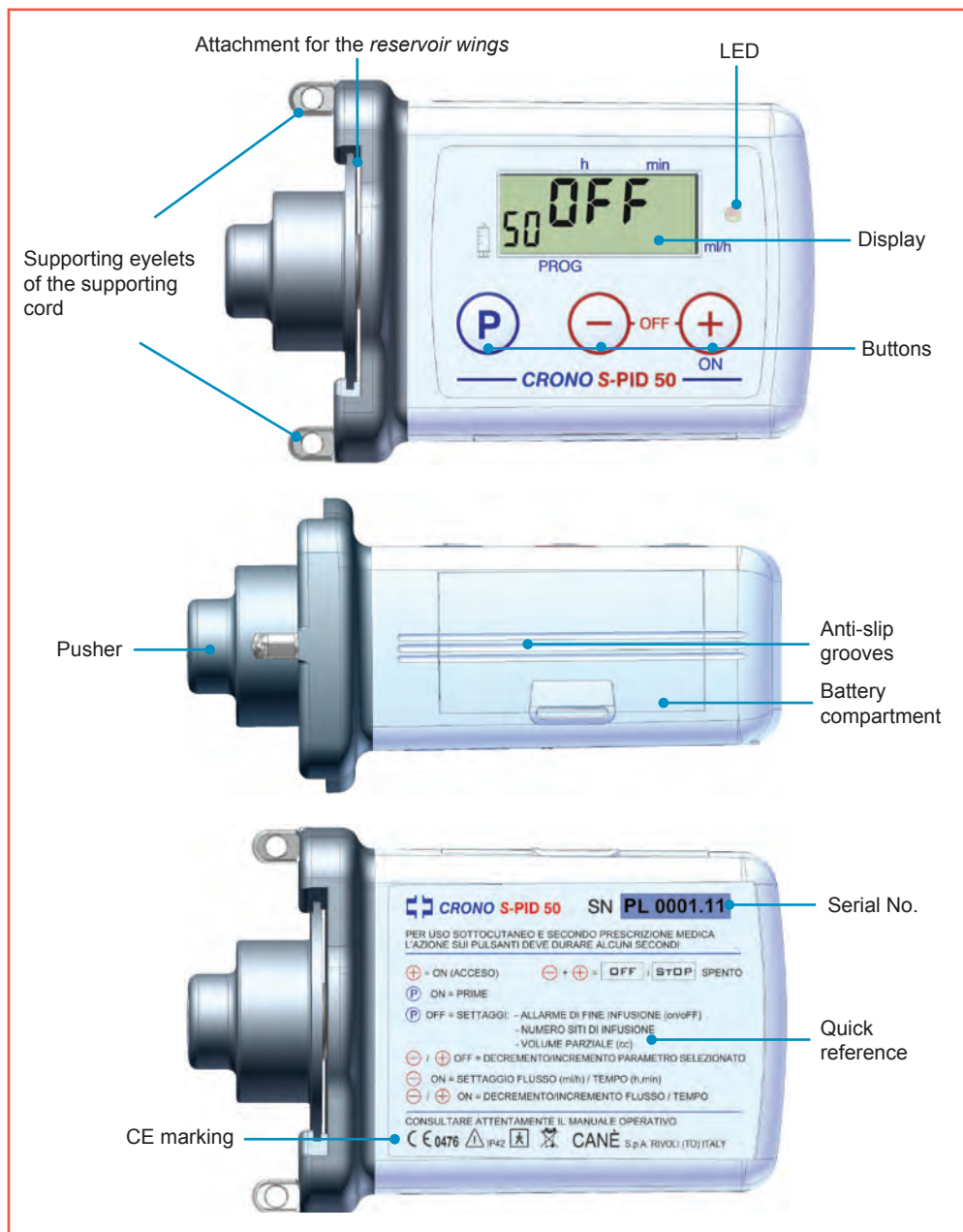
CONTROL BUTTONS

There are 3 control buttons.
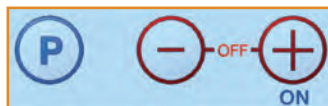
The buttons have a built-in safety delay: you must keep them pressed for several seconds before the command takes effect. Use only your fingertips; do not use sharp objects.

The buttons make a ticking sound when pressed.

A brief acoustic signal confirms that a command is being executed.

WARNING

The buttons have different functions according to which of the following conditions the pump is in when they are pressed:

- **OFF**

- **StoP**

- **ON**

The functions of the buttons in the various different conditions mentioned above are described in the quick reference instructions on pages 30-32 and in Section 10.

LED

The red LED to the right of the display is switched on in the following circumstances:

1 - When the battery is inserted during the pump verification checks, see page 33.

2 - When an error has occurred, see pages 25-26.

LIQUID CRYSTAL DISPLAY (LCD)

The liquid crystal display uses text messages and icons to display useful information about the settings, the operation being performed and any error situations.

Four principal digits

Arrow icons

Lock indicator

Two secondary digits

Low battery indicator

Drop icon
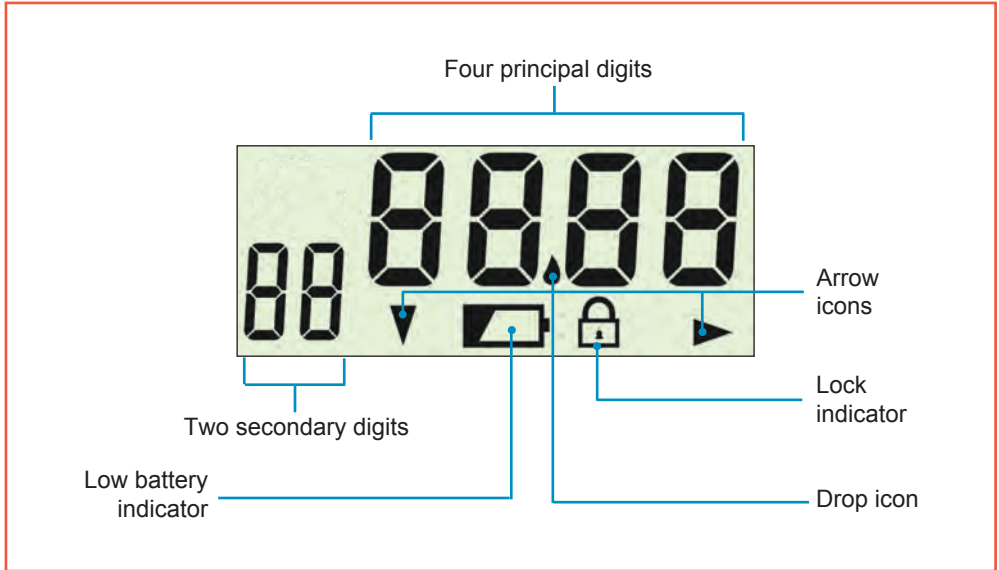
Four principal digits of the display
Display principal information related to the values of the settings, error information, etc.

Two secondary digits of the display
Display:
- The remaining drug volume contained in the *reservoir*;
- Information related to the setting being displayed in the four main digits;
- The unit of measurement of the setting being displayed.

"Low Battery" indicator:
Displayed when the battery is nearly dead (see related section on page 21).

"Drop" icon:
Steady: the decimal point indicator.
Flashing: the hour and minute separator.

"Arrow" icons:
• A downward arrow indicates that the settings of the pump are being programmed.
• A flashing right arrow indicates that the setting shown is a flow which is expressed in ml/h.

PROG   ml/h

"Minute" indicator:
Flashes when the remaining delivery time is expressed in minutes (time left is less than 60 minutes).

"Lock" indicator:
Indicates that the settings are locked (**L 1**); i.e. they can be viewed but cannot be changed.

LOW BATTERY INDICATOR

The presence of the "**LOW BATTERY**" indicator (not flashing) on the display indicates that the battery is nearly low.

If the indicator remains displayed for several consecutive infusions, the "**LOW BATTERY**" message is displayed, accompanied by a beep repeated approximately every 10 seconds.

In these circumstances the pump can no longer be used and the battery must be replaced.

During battery replacement, when in the **OFF** or **StoP** states, the pump retains the current settings and the position of the pusher in its memory.

If the battery needs to be changed during an infusion the pump must be in the **StoP** state.

If the battery is removed with the pump in the **ON** state, the pump is automatically re-initialized, i.e. the pusher is withdrawn until it reaches the "machine zero" position (pusher in contact with the syringe support) and, then repositioned to start an infusion, displaying **OFF** on the display.
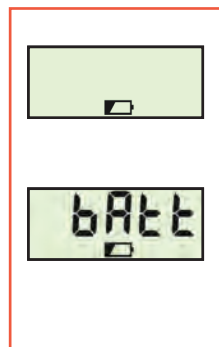
WARNINGS

- Do not use rechargeable batteries.
- Using other types of battery than lithium CR 123 A batteries could cause the pump to malfunction.
- The battery life can be influenced by the age and the temperature and circumstances of its use and storage.
- Ensure you always have a replacement battery available for use.
- If the pump is left inactive for long periods (1-2 months), you are advised to remove the battery.

NOTES

- After you have inserted the battery, the pump runs a self-diagnosis test during which it will emit brief audio signals and display all of the icons and indicators.

- When you have finished changing the battery, check that the compartment is properly closed.

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BATTERY REPLACEMENT

Use a 3 Volt Lithium battery, model 123 A.

To replace the battery, ensure that the pump is switched off (the display showing **OFF** or **StoP**), and then proceed as follows:

1. Open the cover of the battery compartment with the appropriate tool supplied, or by using a paper clip

2. Pull back the cover

3. Use the small ribbon strap (which lies under the battery) to facilitate the removal of the battery.

4. Remove the discharged battery and discard it properly, using the appropriate containers.

5. Wait 10 seconds before insert the new battery checking that it is in the correct position (see picture below) and that the ribbon strap is under the battery.

6. After you have inserted the battery, close the compartment cover.

NOTES

In the event that it is not possible to remove the battery using the ribbon strap, do not use an object to lever out the battery, but proceed as follows:

• Hold the pump and the compartment cover firmly in your right hand;
• Strike the palm of your other hand with the pump, to jolt the battery from the compartment.
• The cover is supplied with a gasket which must remain in position as indicated in the illustration.

Gasket
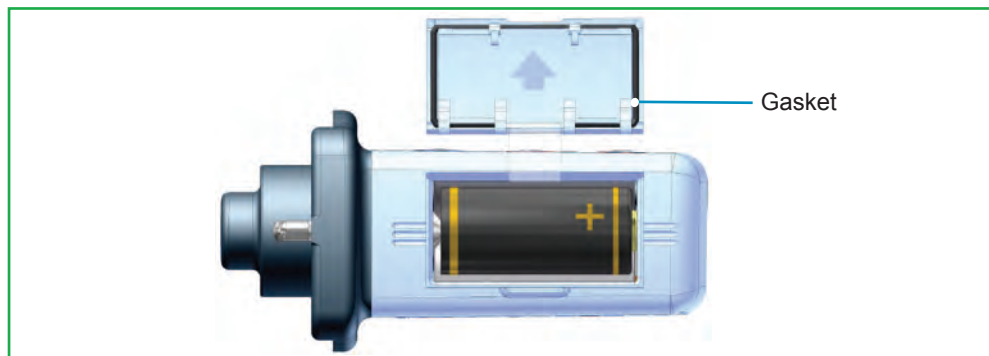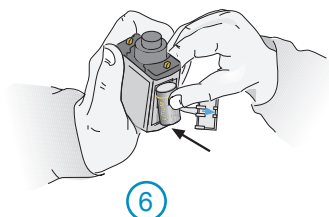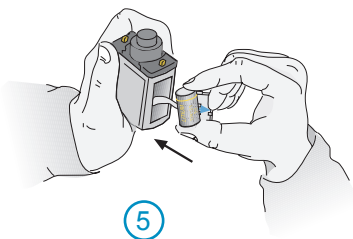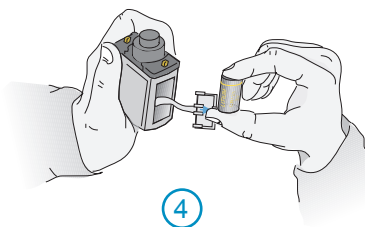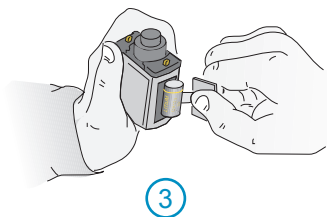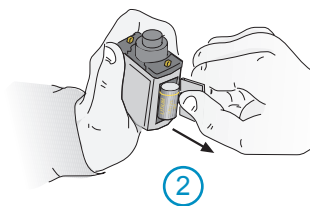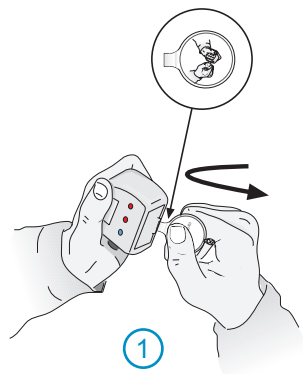
SETTINGS LOCK

The *CRONO S*-PID 50 pump has 2 access configurations:

- **L 0 (unlocked)**: in this configuration you can use the control buttons to access all of the settings and parameters and control all of the operational functions

- **L 1 (locked)**: in this configuration you can use the control buttons to control the operational functions (switching on, priming and switching off) but cannot modify any of the settings. When the pump is set to **L 1** the display shows the lock indicator 🔒.

Before attempting to modify any of the settings, ensure that the selected access level of the pump is **L 0** (OFF 🔓 symbol).
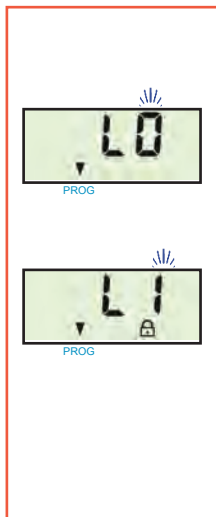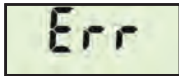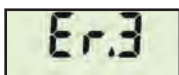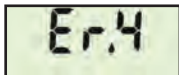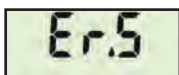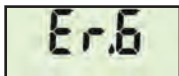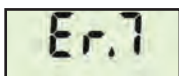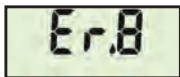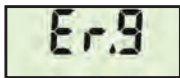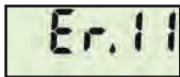
WARNINGS

- This access level for the functions remains in the memory even if the battery is removed.

- When the settings access is **L 1** (locked), any attempt to access the locked options will cause the pump to beep intermittently and display the "lock" indicator.

- The information relating to the locking/unlocking of the settings lock is supplied at the back of this manual on a plastic card and is only for use by a doctor.

ERRORS AND ANOMALIES

DISPLAY	ACOUSTIC SIGNAL	ERROR DESCRIPTION	CORRECTIVE ACTION
Err	Brief beep.	Operation not allowed	---
Er.2	Continuous acoustic signal and flashing LED.	Critical problem in the safety system.	Press the button. ⊕
Er.3	Intermittent acoustic signal repeated approximately every 10 seconds.	Anomaly in the motor circuit.	Press the button. ⊕
Er.4	Intermittent acoustic signal repeated approximately every 10 seconds.	Mechanism of the pusher blocked while withdrawing (could be caused by a foreign body preventing its movement).	Eliminate the cause and initialize the pump.
Er.5	Intermittent acoustic signal repeated approximately every 10 seconds.	Pusher mechanism blocked.	Press the button. ⊕
Er.6	Intermittent acoustic signal repeated approximately every 10 seconds.	Motor anomaly.	Initialize the pump.
Er.7	Intermittent acoustic signal repeated approximately every 10 sec. (possibly accompanied by flashing LED).	Communication error between the two microcontrollers.	Press the button. ⊕

DISPLAY	ACOUSTIC SIGNAL	ERROR DESCRIPTION	CORRECTIVE ACTION
Er.8	Intermittent acoustic signal repeated approximately every 10 seconds.	When a battery is inserted and at the start of every infusion, the pump performs a check of the settings in the memory. If an error is found, the value in error is replaced by the default value, the pump motor is locked and the error is indicated both on the display and audibly.	Initialize the pump.
Er.9	Intermittent acoustic signal repeated approximately every 10 seconds.	Anomaly in the safety circuit which drives the pump motor. If an error is found, the pump locks and the error is indicated.	Initialize the pump.
Er.11	Intermittent acoustic signal repeated approximately every 10 seconds.	Anomaly in the pusher mechanism.	Initialize the pump.
OCCL	Intermittent acoustic signal repeated approximately every 10 seconds.	Mechanism blocked because of an occlusion in the infusion line.	Eliminate the cause and press the ⊕ button. See page 28.

WARNINGS

• Following the display of error message **Er,8** and the successive initialisation, the system reverts to the factory settings (see page 29): in this event **the pump settings prescribed by the doctor should be re-entered**.

• Error messages **Er,2** and **Er,7** are accompanied by the flashing red LED.

NOTES

• The displayed error messages (from **Er,2** to **Er,11** and **OCCL**) are accompanied by an acoustic signal and the system stops.

• To initialize the device, remove the battery when the pump is in an error state or the **ON** state and reinsert it after 10/15 sec. If the error is detected again after the corrective action or initialisation of the device, contact the CANÈ S.p.A. Technical Support Service.

INFUSION SET OCCLUSION

The pump is designed to recognize when the administration of a pharmaceutical has been interrupted by external means, such as, for example, the kinking of the infusion set tube and consequent occlusion. In these circumstances, the pump stops the infusion: the display indicates that there is an occlusion, accompanied by a brief acoustic signal. The pump then continues beeping every 10 seconds. While the system is still occluded, the drug is not administered: to recommence the infusion, press the ⊕ button, after having removed the cause of the occlusion.

NOTES

- The cause of the occlusion is to be found along the infusion line and at the point of injection.
- To avoid or reduce the incidence of occlusions, you are advised to use an infusion set with *anti-kinking* tubes.

POST-OCCLUSION BOLUS

The occlusion alarm is given when the pump detects excessive back pressure in the infusion line. This back pressure must be removed without accidentally releasing a post-occlusion bolus, which could cause serious harm to the patient. The volume of a CRONO S-PID 50 post-occlusion bolus, considering only the combined volume of the pump and the-*reservoir* is about 1.8 ml.

WARNINGS

- The volume of the bolus released after an occlusion can vary, depending on the type of catheter, the infusion set and all the other components that comprise the infusion line.
- Another element that could affect the volume of the released bolus after an occlusion is the presence of any air in the system.
- After the occlusion alarm is given, disconnect the infusion set from the patient to avoid a post-occlusion bolus being administered to the patient.

FACTORY SETTINGS

The pump is supplied with the following default settings:

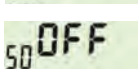|	
Delivery time	**10 h**
End of infusion acoustic signal	**AL on (active)**
Partial volume	**50 ml**
Access level	**L 0 (unlocked)**
Number of infusions	**0**

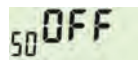In flow rate mode the pump is supplied with the following settings:

Flow rate	**5 ml/h**
End of infusion acoustic signal	**AL on (active)**
Number of infusion sites	**IP,1**
Partial volume	**50 ml**
Access level	**L 0 (unlocked)**
Number of infusions	**0**
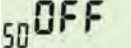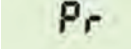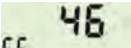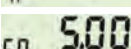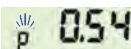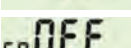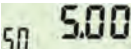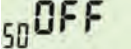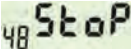
QUICK REFERENCE

The buttons have a built-in safety delay: you must keep them pressed for several seconds before the command takes effect.
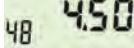
These quick reference instructions are not an alternative to reading the information in this manual, but give a basic and rapid summary of the pump's functions.

	BUTTONS	ACTIVATION	DISPLAY
BATTERY INSERTION	(P) (−)	• Show all display segments • Show the type of programming (flow rate/time) • Access the flow rate/time selector (only possible with **L 0** access level). • Change the flow rate/time setting • Automatic positioning of the pusher at the start of the infusion • Switching off the pump	

	BUTTONS	SETTINGS	DISPLAY
PUMP SET TO OFF	(P) 1st press (P) 2nd press (P) 3rd press (−) / (+)	• The pump is switched off with **L 0 access level** • Access the end of infusion alarm selector • Access the number of infusion sites selector - **IP** from **1** to **5** - (only in "**F"**mode). • Access the partial volume selector • Change the value of the preceding settings	

	BUTTONS	SWITCHING ON	DISPLAY
PUMP SET TO ON	⊕ ⊕	• Switching on the pump • Priming *phase* • Displaying the partial volume (if it has been set) • Displaying the number of infusion sites (only in "F" mode) • Start of infusion	50 **OFF** **Pr** cc **46** IP **2** 50 **5.00**
	PRIMING		
	(P) keep pressed ⊖ and ⊕ press contemporaneously	• Priming *dose* (max 1.5 ml) • Switching off the pump	**Pr** P **0.54** **Pr** 50 **OFF**
	SETTING THE DELIVERY TIME		
	⊖ ⊖ / ⊕	• Delivery time • Setting the delivery time ("**t**" mode) • Decrease / Increase the delivery time	50 **5.00** t **4.00** PROG
	FLOW RATE PROGRAMMING		
	⊖ ⊖ / ⊕	• Flow rate • Flow rate programming • Decrease / Increase of flow rate	50 **10** ml/h F **10** ml/h PROG
	SWITCHING OFF THE PUMP		
	⊖ and ⊕ press contemporaneously	• Switching off the pump	50 **OFF** 48 **StoP**

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		EARLY WITHDRAWAL OF THE PUSHER / NUMBER OF INFUSIONS	
PUMP SET TO OFF	**P** and **−** press contemporaneously / **−** press for 4 seconds	• Interruption of an active infusion, withdrawing the pusher to the start position of the infusion / • Number of infusion (**PC**: Partial Counter)	End ⊦--- ₅₀OFF / PC 0123

	BUTTONS	**START OF INFUSION**	**DISPLAY**
PUMP SET TO ON	⊕	• Start of infusion	IP 2
		• When the pump is in action, the display shows the delivery time.	48 4.50
		• Display the flow rate setting	48 10 ml/h
		• If a number of infusion sites from 2 to 5, for example 2, has been set the pump will proceed as follows:	
		- 50% of the drug volume contained in the syringe will be administered in the first site of infusion;	
		- At the end of the partial administration, the display will show **End** alternating with **1-2**. Now it is possible to change the infusion site;	End / IP 1-2
	⊕	- Restart the infusion administering the remaining 50% of available drug;	IP 2
		- At the end of the partial administration, the display will show **End** and, after a few seconds, the pusher is withdrawn to the infusion start position.	End

	BUTTONS	**END OF INFUSION**	**DISPLAY**
END OF INFUSION		• End of the infusion	End
		• Automatic withdrawal of the pusher	⊦----
		• Switching off the pump	₅₀OFF

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PUMP INITIALISATION

If the battery is removed when the display shows **OFF** when you reinsert the battery the pump runs the initialisation sequence, during which it:

1. Runs a self-diagnosis test, emitting a series of brief acoustic signals, flashing the red LED and displaying all the indicators and icons on the screen.

2. The display shows the previously selected programming mode.

3. The display shows **OFF**.
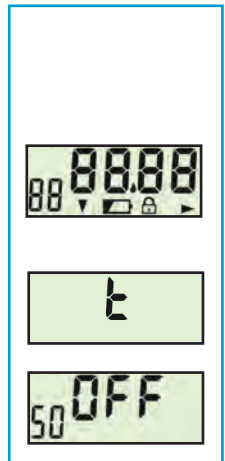
NOTES

• The pump is supplied with a new battery already inside the pump.

• For instructions on how to install the battery, see page 22.

• You are recommended to initialize the pump if it is left unused for a long period (more than 1 - 2 months) and the battery is not removed.

• If the battery is removed when the display shows **StoP**, when you reinsert the battery the pump runs a self-diagnosis test (as shown in Step 1) and then the display will show **StoP**.

WARNING

The setting of the pump is the responsibility of the doctor, who will choose the parameter values best suited to the therapy required for the patient.

PUMP SETTINGS WHEN INSERTING BATTERY

If the battery is removed when the display shows **OFF** when you reinsert the battery you can set the programming mode of the pump:

1 - by flow rate, expressed in ml/h if you select "**F**" or,
2 - by time, expressed in hours and minutes if you select "**t**".

Procedure:

1 - Remove the battery when it is in the **OFF** state and reinsert it.

2 - The display shows all the symbols.

3 - At the same time, the device carries out an auto-diagnosis during which it emit acoustic signals.

4 - The display will then show the programming mode "**F**" (flow rate) or "**t**" (time): pressing the (P) button makes the symbol flash for 9 seconds; you can move from one option to the other using the (−) button.

5 - Not pressing these buttons for 9 seconds will mean that the device will memorise the mode that has been selected.

6 - Then, the display shows **OFF**.
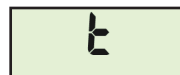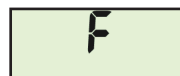
NOTE

Setting the programming mode is only possible with the **L 0** access level and only at the start of the infusion.

WARNING

Choosing whether to program the pump by flow rate or by time is the responsibility of the doctor, who will decide on the most suitable method.

PUMP SETTINGS SEQUENCE WITH THE PUMP OFF CONDITION

When the device is set to **OFF**, the following parameters can be set:
1 - End of infusion acoustic signal.
2 - Number of infusion sites (feature available only in flow rate mode).
3 - Partial volume.

In the **OFF** state, the parameters can only be selected in the following conditions:
- Settings lock unlocked
- At the start of a new infusion (partial or total).

To access the settings, press the ⓟ button for about 3 seconds: the display shows the setting of **end of infusion acoustic signal**. You can change the parameter setting (activate/de-activate) while the display is flashing using the ⊖ and ⊕ buttons.

Press the button once more and ⓟ the display will show and allow setting the **number of infusion sites (IP = Infusion Point)**. You can change the parameter setting (activate/de-activate) while the display is flashing using the ⊖ and ⊕ buttons.

Press the ⓟ button again to display and set the **partial volume**. You can change the parameter setting (activate/de-activate) while the display is flashing using the ⊖ and ⊕ buttons.
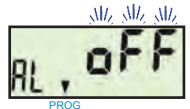
NOTE

When the settings lock is on (**L 1**), if any attempts are made to change the parameter then the display will show the flashing lock symbol and beep several times.

SETTING OF END OF INFUSION ACOUSTIC SIGNAL

1. In the **OFF** state, by pressing the (P) button: the pump starts the mode for selecting the end of infusion acoustic signal.

2. When the value flashes, select a new value using the (−) and (+) buttons.
Selecting **OFF** disables the warning and the end of infusion acoustic signals; selecting **on** activates the warning of end of infusion acoustic signals, which will go off 5 mins. and 10 mins. before the end of the infusion, and the end of infusion acoustic signal.

3. Do not press any button for 10 seconds, and the setting phase will end. The flashing displayed value becomes fixed and then **OFF** is displayed.

4. Press the (P) button before the **OFF** indication is displayed (while the value of the end of infusion acoustic signal is still flashing) to pass to the setting of the successive parameter (this function is active and is displayed only if the pump is being programmed in flow rate mode; if the pump has been programmed in time mode you will go straight to the next step): **SETTING THE NUMBER OF INFUSION SITES** (see page 37).

5. Press the (P) button while the value of the previous setting is still flashing to pass to the setting of the next parameter: **SETTING THE PARTIAL VOLUME** (see page 39).
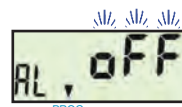
NOTES

• When the settings lock is on (**L 1**), if any attempts are made to change the parameter then the display will show the flashing lock symbol and beep several times.
• The end of infusion acoustic signal can be set also in the **StoP** state.

SETTING THE NUMBER OF INFUSION SITES

This function is active only if the pump has been set in flow rate mode.

In case it is required to administer a drug volume by dividing it in multiple infusion sites, called *Infusion Points* (**IP**), the pump allows you to select up to 5 sites and make partial delivering in succession.

To set this parameter, press the (P) button again.

You can select the number of infusion sites **IP** (while the number of sites is flashing) in which the drug volume is to be administered; the selection is done using the (−) and (−) buttons; select the number of sites from **1** to **5**:

- Select **1** to administer the drug contained in the syringe at one single infusion site;
- Select **2** to administer 50% of the drug contained in the syringe at one site and then, the other 50% at another infusion site;
- Select **3** to administer the drug contained in the syringe at 3 different infusion sites (33% at each site) and so on. Select **4** (25% at each site) and **5** (20% at each site).

By selecting a number of infusion sites from 2 to 5, for example 4, the pump will run the administration as follows:

1 - The first fraction of the drug volume contained in the syringe will be administered at one infusion site. Then, the pump will stop and the display will show **End**, and it will emit, at the same time, an intermittent acoustic signal indicating the end of partial infusion until the start of the next fraction.

2 - Then, the display will show **End** alternating with **1-4** (fraction 1 out of 4 administered).
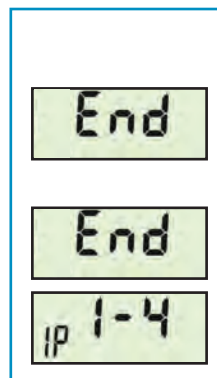
3 - In this phase, the patient can replace the infusion set, start the pump again by pressing the ⊕ button, perform the *priming*, change the infusion site and continue with the infusion.

4 - The pump will proceed in the same manner described above with the next infusion sites, showing **End** alternating with **2-4**, **End** alternating with **3-4** and eventually **End**. Dosing of infusions will end and the pusher will be withdrawn to the infusion start position.
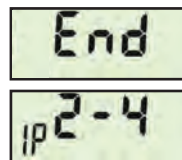
NOTES

- The function is available only if the pump is programmed according to flow rate mode "**F**".

- At the start of the administration of each ***Infusion Point*** the *priming* function is available again.

- At the end of the administration of each ***Infusion Point*** the device emits an intermittent acoustic signal which can be switched off by pressing the ⊖ button.

WARNING

Using aspiration with a normal syringe, verify that the needle is not inserted into a vein or a capillary at every change of the infusion site (refer to your general practitioner for more information on the procedure to be used).

SETTING THE PARTIAL VOLUME

The partial volume function is used when the therapy requires an infusion with less than 50 ml.

The partial volume can be set from 1 cc to 50 cc in increments of 1 cc.
To set this parameter, press the (P) button again while the previous setting is flashing.
The partial volume function can only be set before the start of a new infusion, either partial or complete (50 ml).

Proceed as follows:

1. The display shows a flashing value for the volume, preceded by **cc**, which indicates the unit of volume (1 cc = 1 ml)

2. Press the (−) button to decrease the value, and the (+) button to increase it. Each change is indicated by a beep.

3. Do not press any button for 10 seconds and the setting phase will end. The display will show **P,cc**.

4. The pusher is automatically positioned at the configured partial volume value. An intermittent beep is emitted while it does so, and the pump displays -- in real time -- the actual volume corresponding to the pusher position.

5. When the pusher is in the correct position the display changes to **OFF**.

NOTES

- The partial volume setting is automatically stored in the pump's memory.

- At the end of the infusion, the pusher returns to the position corresponding to the partial volume setting.

- The partial volume setting can be interrupted by pressing the ⊖ and ⊕ buttons simultaneously.
- If the pusher is still advancing, the pump switches off (the display shows **StoP**) and the pusher remains where it was when the infusion was interrupted: the partial volume setting is not stored and the previous value remains in memory
- If, however, the pusher was in the process of being withdrawn, the display alternates between **OFF** and **P,cc**. The only possible operation is to continue the withdrawal of the pusher, by pressing the ⊕ button. The pusher withdraws to the position of the partial volume setting.

- Press the ⊖ and ⊕ buttons simultaneously while **P,cc** it is shown to cancel the storing of the partial volume.

WARNINGS

- This operation must not be carried out with the infusion set connected to the patient.
- A partial volume cannot be set while an infusion is in progress.
- The partial volume setting remains in the pump's memory even if the battery is removed.
- If the battery is removed when the pump is set to **OFF/StoP**, the partial volume remains in the memory and the pusher is not withdrawn.
- If the battery is removed when the pump is set to **ON**, the pusher returns to the infusion start position for recalibration, and then repositions itself at the stored partial volume.

MAKING SETTINGS IN THE ON STATE

When the device is set to **ON** the following parameters can be set:
1 - Delivery time (if time mode has been selected upon battery insertion).
2 - Flow rate (if flow rate mode has been selected upon battery insertion).

SETTING THE DELIVERY TIME

This function is available only if the "**t**" (time) function has been selected upon battery insertion.

Time value can be set from 30' to 500 h
- From 30 minutes to 1 hours in increments of 5 minutes
- From 1 hours to 50 hours in increments of 15 minutes
- From 50 hours to 500 hours in increments of 120 minutes (2 hours).

You can change the time parameter during an infusion.

Procedure:
1 - Switch on the pump by pressing the ⊕ button.

2 - Press the ⊖ button and the pump allows setting the infusion delivery – the time display begins to flash.

3 - You can change the parameter using the ⊖ or ⊕ buttons while the value is flashing.

4 - Not pressing these buttons for about 9 seconds or pressing the Ⓟ button will mean that the device will memorise the parameter that has been selected and the infusion recommences.
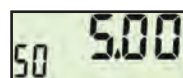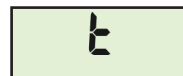
NOTES

• If the settings lock is active the delivery time setting is not accessible; if any attempts are made to change the parameter then the display will show the flashing lock icon and the device will give an intermittent acoustic signal.
• If you keep pressing either the ⊖ or the ⊕ buttons, it is possible to change delivery time quickly.

WARNING

If a partial volume is used, the pump can run an infusion in less time compared to the minimum time specified (30 minutes).

SETTING THE FLOW RATE

This function is available only if the "**F**" (flow rate) function has been selected upon battery insertion.

Flow rate value can be set from 0.1 ml/h to 100 ml/h
- From 0.1 ml/h to 1 ml/h in increments of 0.01 ml/h;
- From 1 ml/h to 10 ml/h in increments of 0.1 ml/h;
- From 10 ml/h to 100 ml/h in increments of 1 ml/h.
You can change the flow rate parameter during an infusion.

Procedure:
1 - Switch on the pump by pressing the ⊕ button.

2 - The display shows the selected number of infusion sites and then the delivery time or the flow rate.

3 - Press the ⊖ button and the pump allows setting the flow rate: the display shows the flashing value of the flow rate.

4 - You can change the parameter using the ⊖ or ⊕ buttons while the value is flashing.

5 - Not pressing these buttons for about 9 seconds or pressing the Ⓟ button will mean that the device will memorise the parameter that has been selected and the infusion recommences.
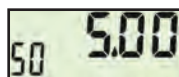
NOTES

- When the settings lock is on the flow rate setting is not accessible; if any attempts are made to change the parameter then the display will show the flashing lock symbol and beep several times.
- If you keep pressing either the ⊖ or the ⊕ buttons, it is possible to change the flow rate quickly.
- If you press the ⊕ button, the display toggles between the delivery time and the flow rate and vice versa.

SWITCHING ON THE PUMP

From the **OFF** state, press the ⊕ button. The pump will give a brief beep and display:

- **Pr** (*priming* function) the display shows **Pr**. There are three options (see page 44);
- Having carried out the *priming,* or if the pump is turned on to resume the infusion from the **StoP** state, the display shows the following in sequence:

- The partial volume value (if it has been set)

- The number of infusion sites (in flow rate mode only)

- The value of delivery time or flow rate
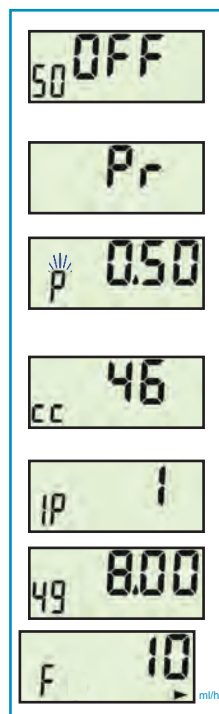
THE PUMP IN ON CONDITION

When the pump is in action, the display shows the flow rate value in ml/h or the delivery time in hours and/or minutes:

- From 500 h to 100 h the delivery time decreases hour by hour

- From 99.59 h to 1 minute the delivery time decreases minute by minute.
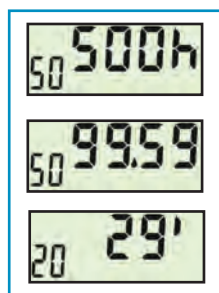
WARNINGS

Before starting an infusion:
- Inspect the infusion line to ensure there are no folds, *clamps* or other occlusions in the line
- Expel any air bubbles.

PRIMING THE INFUSION LINE

The *priming* function allows filling the infusion line with the drugs contained in the reservoir.

The volume available for *priming* is 1.5 ml.

The *priming* function is enabled when you switch on the device and the pusher is in the infusion start position or at the start of an infusion fraction (***Infusion Point***), regardless of whether the settings lock is on.

The priming procedure *is* as follows:

1. Turn on the device by pressing the ⊕ button.

2. The display shows **Pr**. There are three options:

> **a.** Postpone the *priming*.
> **b.** Cancel the *priming*.
> **c.** Carry out the *priming*.

a. Postpone the *priming*
Wait 10 seconds, the pump will turn off automatically.
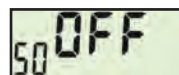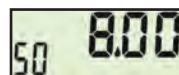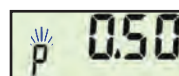
b. Cancel the *priming*
Press the ⊕ button: the pump begins the infusion and the display shows the time remaining until the end of the infusion.

c. Carry out the *priming*
Press and hold down the ⓟ button: the pump delivers the *priming dose* until you release the button. The display then shows a flashing letter **P** in the secondary digits, followed by the number of ml delivered. When the button is released, the display shows **Pr**. The procedure can be repeated up to a maximum release of 1.5 ml.
Proceed until the infusion set is completely full and a few drops of the drugs leak out of it.

NOTES

- If you keep the (P) button pressed, the pump delivers the *priming dose*, giving an acoustic signal every consecutive delivery of 0.5 ml (i.e. 0.5 – 1.0 – 1.5 ml).

- If, after the *priming* indication is displayed, the buttons are not pressed again for 10 seconds, the display shows **OFF**.

- The *priming* function can be interrupted by releasing the (P) button. The display shows **Pr** again , and you again have the choice of postponing, cancelling or performing the *priming* function as described above.

- At the start of the administration of each ***Infusion Point*** the *priming* function is available again.

WARNINGS

- Do not *prime* the infusion set with the tube connected to the patient.

- The *priming* function must only be performed with the *reservoir* attached to the infusion set before inserting the needle into the infusion site.

- Before beginning an infusion, check that there are no air bubbles in the infusion line, expelling any that are found. Alternatively, use a vented filter.

END OF INFUSION

Ten minutes before the end of the infusion (only if **AL** is active), the device gives an intermittent acoustic signal lasting 2 seconds. This signal is repeated twice at 5 minutes from the end of the infusion and at the end of it: the display shows the **End** message.

After a few seconds, the pusher starts withdrawing until it reaches the start position of the infusion.

When the withdrawal is complete, the display shows **OFF** and the pump is ready for a further infusion.

NOTE

The withdrawal time for a 50 cc syringe is about 6 minutes and is proportionately less for lower volumes.

WITHDRAWING THE PUSHER

1. Stopping an infusion before the end
This function allows the interruption of an active infusion, withdrawing the pusher to the start position of the infusion.

To carry out a withdrawal, proceed as follows:

- Turn off the pump by pressing the ⊖ and the ⊕ buttons simultaneously.

- Press the Ⓟ and the ⊖ button simultaneously: the display shows **End** for 10 seconds and then begins to withdraw the pusher.
- During the 10 seconds that the display shows **End** you can cancel the withdrawal request by pressing the ⊖ and the ⊕ buttons together.

2. Withdrawal of the pusher at the end of the infusion
At the end of the infusion the display shows the **End** message and the pump will emit an acoustic signal for a few seconds.

The pusher remains stationary at the end-infusion position for around 10 seconds, after which it begins to withdraw until it reaches the start-infusion position.

When the withdrawal is complete, the display shows **OFF** and the pump is ready for a further infusion.

Pusher in motion
While the pusher is in the process of being withdrawn, the display shows the "**pusher continuous withdrawal**" indication.

NOTE

The function to withdraw the pusher can be interrupted by pressing the ⊖ and ⊕ buttons together. The display then alternates between **End** and **OFF**. At this point only the ⊕ button is active. When you press again the pump recommences the withdrawal of the pusher.
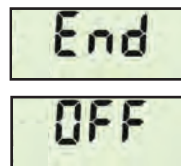
WARNING

Do not remove the *reservoir* until the pusher has been withdrawn to the infusion start position.

SWITCHING OFF THE PUMP

To switch off the pump during an infusion, press the ⊖ and the ⊕ buttons simultaneously; the display will show **StoP**.

If the pump is switched off during an infusion, the device will emit a series of 10 short beeps every 10 seconds, and the display will flash the **StoP** message. To interrupt the audible signals, press the ⊖ button. These indications will be repeated each time the pump is switched off during an infusion.
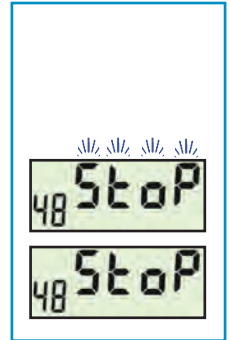
DISPLAYING THE SETTINGS

This function displays the settings of the pump from when it was programmed. To display the pump settings, the pump must be set to **OFF** or **StoP**.

If the settings are displayed when the settings lock is set to **L 0** (settings lock off) the settings flash and can be modified. If the settings are displayed when the settings lock is set to **L 1** (settings lock on, with the display showing the "lock" symbol), the settings do not flash and cannot be modified.

The procedure is as follows (pump in flow rate mode):

1. Press the Ⓟ button for approx. 1 second: the display will show the menu for selecting **the end of infusion alarm**.

2. Press the Ⓟ button for approx. 1 second: the display shows **the number of infusion sites**.

3. Press the Ⓟ button again and the display will show **the selected partial** volume.

4. Do not press any button for 9 seconds, and the setting phase will end. The display will show **OFF** or **StoP**.
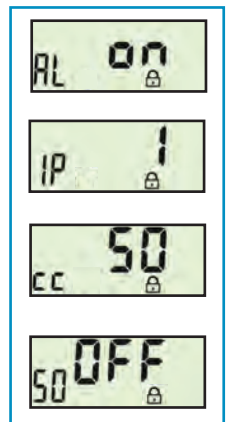
RESETTING THE NUMBER OF PARTIAL INFUSIONS

The device contains two infusion counters: one which is partial and can be reset and another which shows the total number.

To reset the number of partial infusions, proceed as follows:

1 - Press the ⊖ button for approx. 4 seconds, until the display shows the counter of infusions **PC** (Partial Counter)

2 - Without releasing the ⊖ button, press the Ⓟ button. the displayed partial counter of infusions begins to flash

3 - By pressing the Ⓟ button once more you can enter the programming phase (appearing from the downwards arrow)

4 - By pressing the ⊖ o ⊕ button you can reset the number of partial infusions, while pressing the Ⓟ button once more you can see the total number of infusions **tC** (Total Counter).

5 - Press the Ⓟ button again to display the firmware release **rE** (release).

6 - If you do not press anything for approx. 10 seconds or press the button again, Ⓟ the display changes to **OFF**.
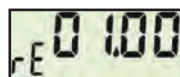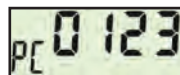
RESERVOIR PARTS

The *CRONO S*-PID 50 pump uses dedicated 50 ml *reservoir*, model: CRN® CRONO® Syringe.

The *reservoirs* are: single-use, non-pyrogenic and only to be used if the packaging is undamaged.

Reservoir *body*   Piston   *Luer-Lock* cap   Stem

Needle

Needle cover   Labyrinthine cap
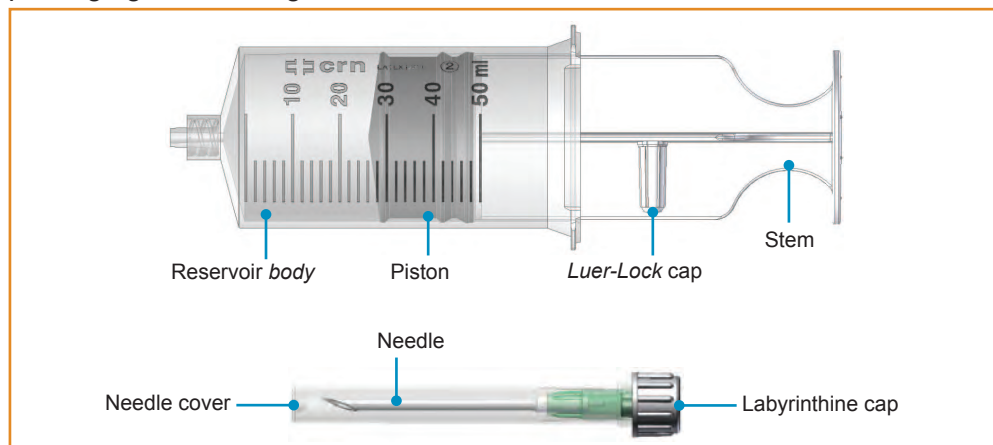
WARNINGS ⚠️

- For safety reasons, you are recommended to use the original CRN® CRONO® Syringe reservoir.
- The use of any other type of *reservoir* could damage the pump and harm the patient.
- CANÈ S.p.A. disclaims all responsibility if the device is used with a non-original *reservoir* different from that recommended.

LUER-LOCK CAP FUNCTIONS

- After the *reservoir* has been filled, it facilitates the unscrewing of the stem from the piston, avoiding spillage of the drug
- It facilitates the correct connection between the pump pusher and the rubber piston of the *reservoir;*
- It protects the drug inside the *reservoir* in case it is not used immediately.

Luer-Lock cap

The Luer-Lock cap is connected to the stem of the reservoir from which it should be separated by applying a light pressure.
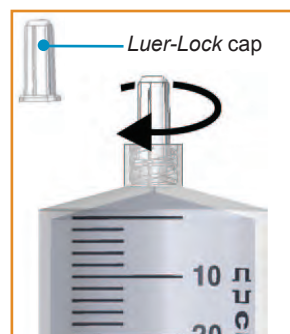
INFUSION SET

You are recommended to use an infusion set with the following characteristics:
• Low internal volume of tube (ideally 0.1 ml, maximum 0.62 ml)
• Tube length not more than 11.43 inch (90 cm)
• Anti-kink tubing.

INFUSION SET PARTS
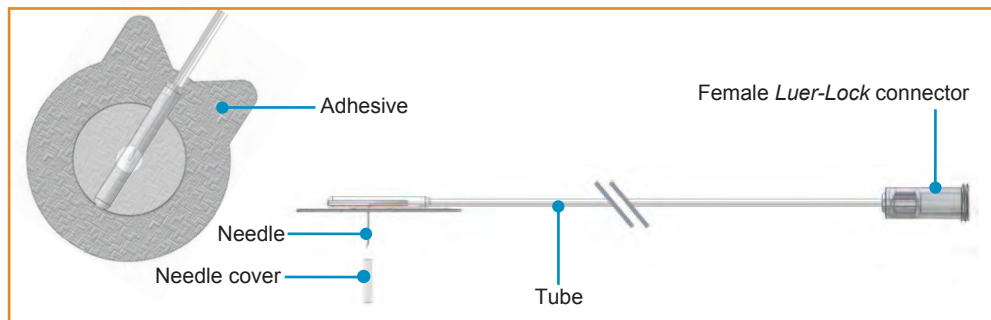
NOTE

The images show the Neria™, infusion set from Unomedical, a Convatec Company.

WARNING

Refer to the user guide supplied with the device for information about using the infusion sets.

Y-SET

Using a Y-SET you can infuse the drug in two different infusion sites at the same time.
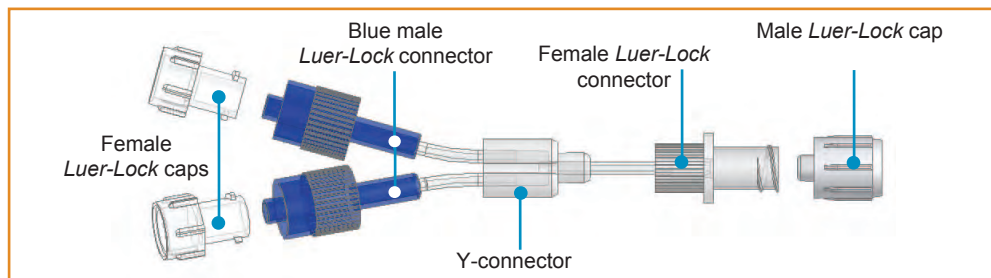
WARNINGS

- The Y-SET does not guarantee that the drug is equally distributed in both infusion sites.

- Refer to the product sheet supplied with the device for information about using the Y-SET.

MULTIPLE INFUSION SET

You can use a two-way or multiple infusion set as an alternative to the Y-SET.

MULTIPLE INFUSION SETPARTS

Female *Luer-Lock* connector

Tube

Adhesive
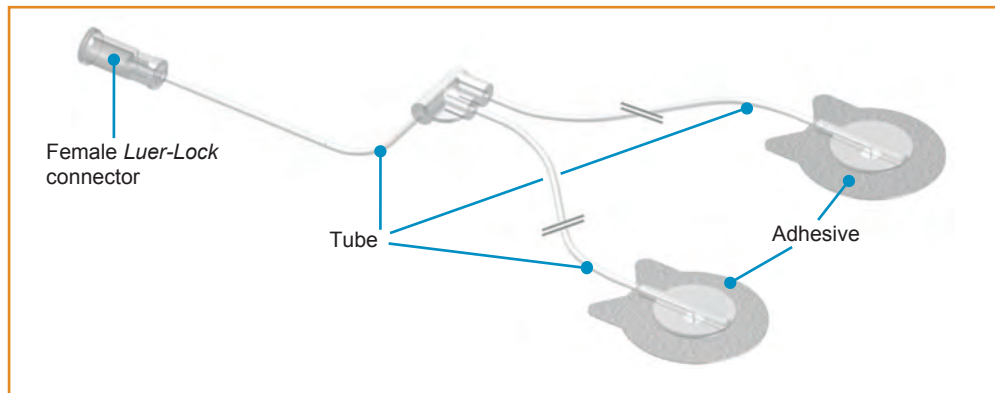
NOTE

The images show the Neria™ multi, infusion set produced by Unomedical, a Convatec Company.

WARNING

Refer to the user guide supplied with the device for information about using the infusion sets.

PREPARATION OF THE *RESERVOIR* AND CONNECTION TO THE PUMP

1. Screw the needle into the *reservoir* in a clockwise direction and remove the needle cover;

2. Fill the *reservoir*, aspirating the liquid slowly and checking that the quantity of the drug does not exceed its capacity or any partial volume you may have set;

3. Screw the *Luer-Lock* cap to the *reservoir* (a) and then unscrew the stem, rotating it counter-clockwise (b) with a fairly rapid movement;

4. Insert the *reservoir* into the pump; the rubber piston will be inserted into the pusher. Rotate it clockwise through 90° and it will click and engage with the pusher;

5. Insert the cone of the infusion set over the *reservoir*.

INSERTION OF THE *RESERVOIR* INTO THE PUMP

Insert the dedicated CRN *reservoir* into the pump and engage it by rotating it 90° clockwise; a click confirms it has engaged.

Front view
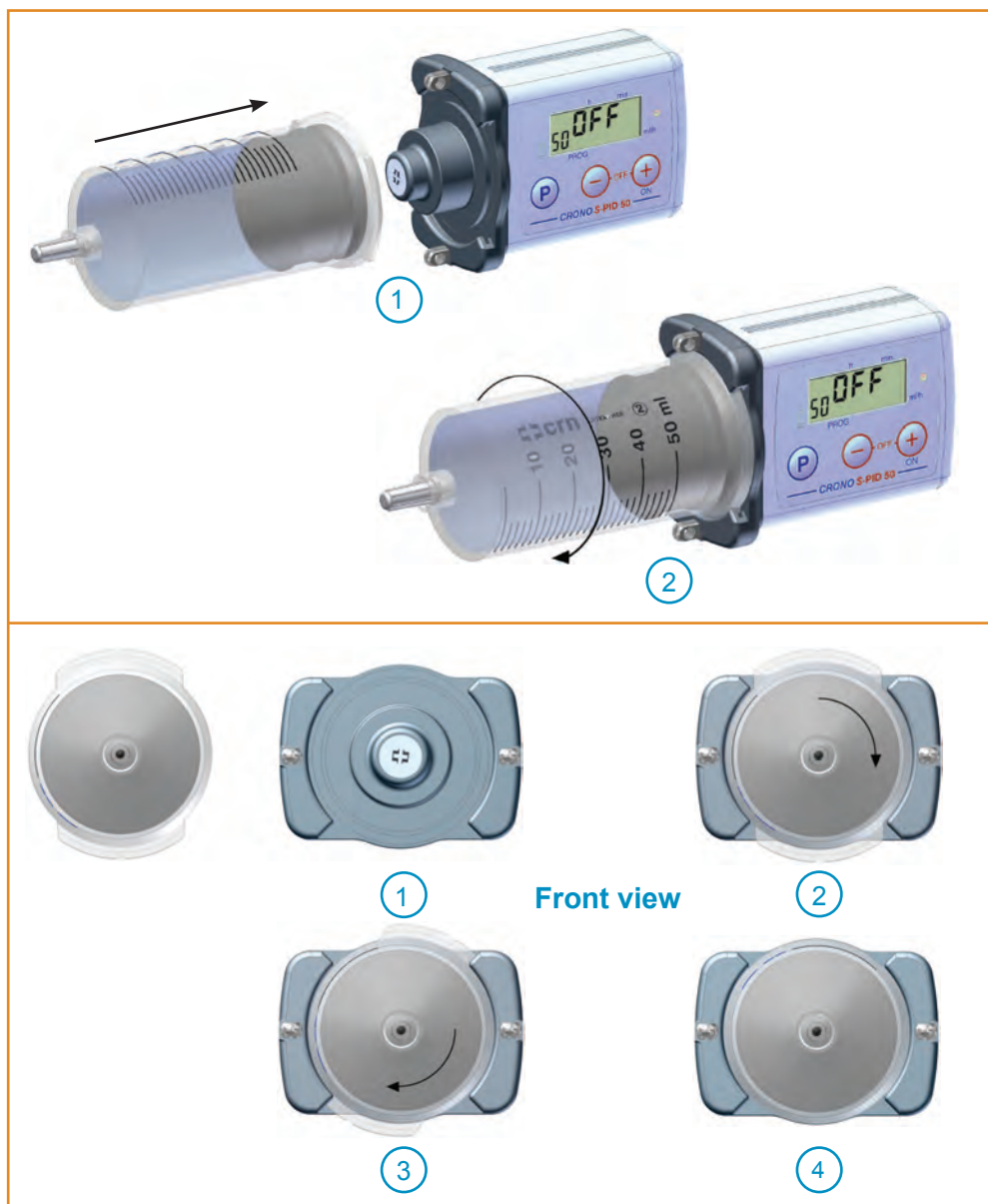
WARNING

• **Before filling the *reservoir***
Unscrew and screw back the piston rod to facilitate its unscrewing after you have filled the *reservoir*.
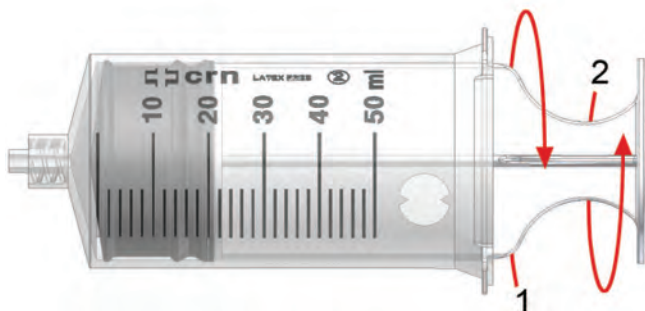
• **Filling the *reservoir***
The liquid must be aspirated slowly.
Do not fill the *reservoir* more than the maximum level allowed.
The rod must be unscrewed with a fairly rapid movement.

• **Insertion of the *reservoir* into the pump**
To avoid any leakage of the pharmaceutical while the *reservoir* is being inserted into the pump you can use the infusion set, as an alternative to the *Luer- Lock* cap indicated on page 51.

When making the connection, avoid exerting any pressure on the *reservoir* walls, because this could cause liquid to leak past the piston rings.

While filling the *reservoir* and inserting it into the pump, a small leakage might occur between the first and second rings on the rubber piston. This does not compromise either the correct working of the *reservoir* or the delivery of the drug.

PUMP CONFIGURATION IMAGES FOR INFUSIONS AT MULTIPLE SITES:

1 - Y-SET PUMP

2 - TWO-WAY SET PUMP

INFUSION SITES

The figures below indicate the recommended infusion sites.
You are recommended to change the injection site after every infusion to avoid skin irritations.
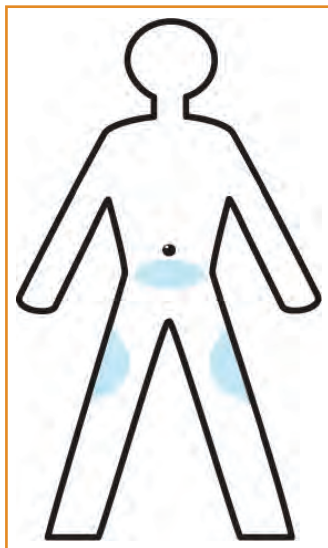
PREPARING FOR THE INFUSION

Before preparing for the infusion, you are recommended to adopt the following precautions:

1. Wash your hands

2. Prepare a clean working environment.

WARNING

Always carry out the infusion in antiseptic conditions, to reduce the risk of infection to the minimum.

The images refer to the Neria™ infusion set from Unomedical, a Convatec Company.

Disinfect the infusion site following the instructions of the relevant medical personnel. Ensure that the area of the infusion site is dry before inserting the subcutaneous needle.

Connect the infusion set to the *reservoir*.
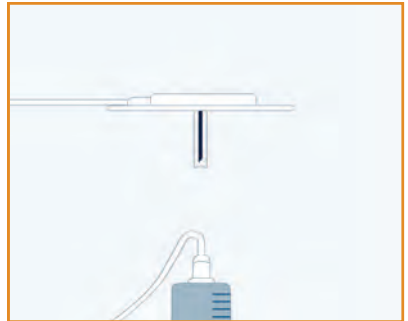
Hold the infusion set by the wings. Prime the infusion line manually or use the *priming* function of the pump. Ensure there are no air bubbles in the infusion line.

WARNING

When you are priming the infusion line and are preparing to insert the needle below the skin, hold the set with the needle pointing downwards to ensure that none of the drug can come into contact with the protecting adhesive paper.

Remove the protective adhesive paper.
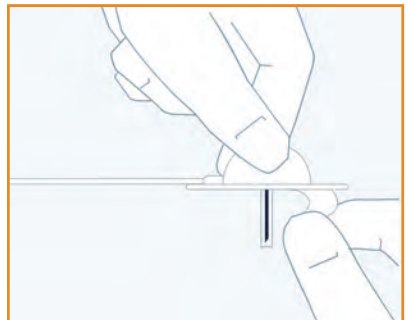
Remove the needle cover, extracting it with care, before inserting the needle.

WARNING

Be careful not to touch the Neria™ needle when you remove the protection.
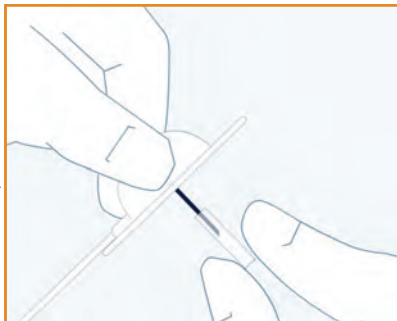
It is important to lift a fold of skin, to reduce the risk of positioning the needle in a muscle. Pinch the skin with your fingers at the chosen infusion site before inserting the needle, which you do by taking the protective wings of the infusion set with the other hand and inserting the needle vertically.
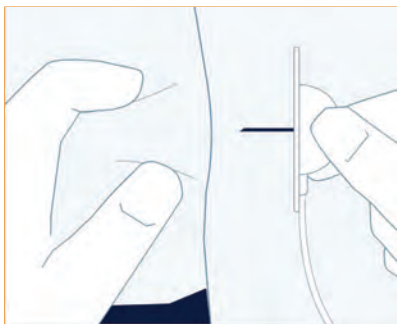
WARNING

Do not administer immunoglobulins intravenously; if they are accidentally administered to a blood vessel or capillary the patient could suffer an anaphylactic shock or thromboembolic events. Always check this before continuing with an infusion.
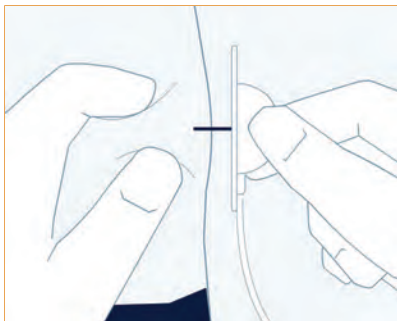
Press firmly on the adhesive to fix it to the skin. Check the infusion site frequently to ensure that the needle remains in the correct position.
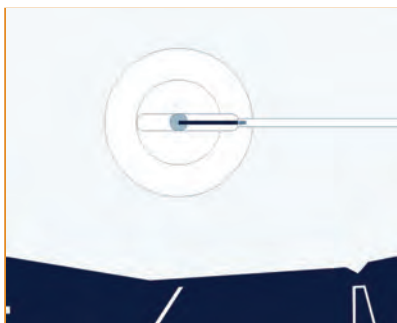
HOW TO USE THE ACCESSORIES SUPPLIED

The following figures give an indication of how to use the standard equipment supplied with the pump.

PUMP CARRIED AROUND THE NECK

The pump worn with a collar strap and a fabric case.
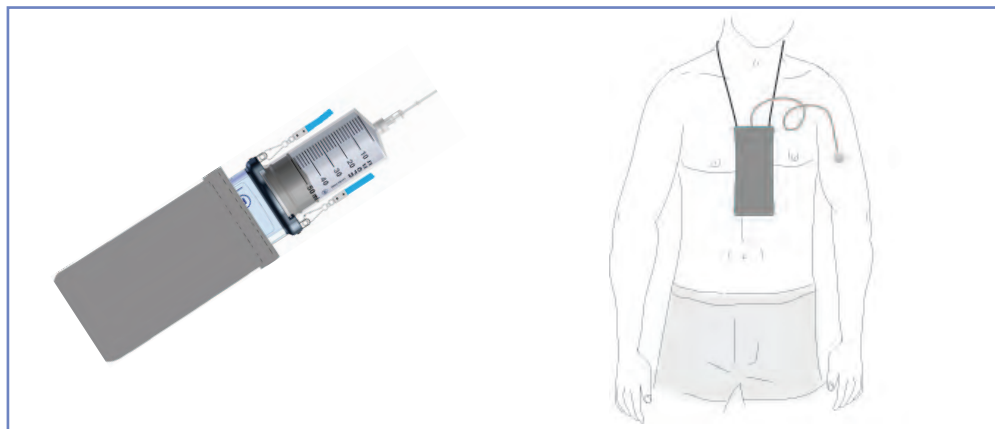
PUMP ATTACHED AT THE WAIST

The pump worn with an elastic belt and a fabric case.
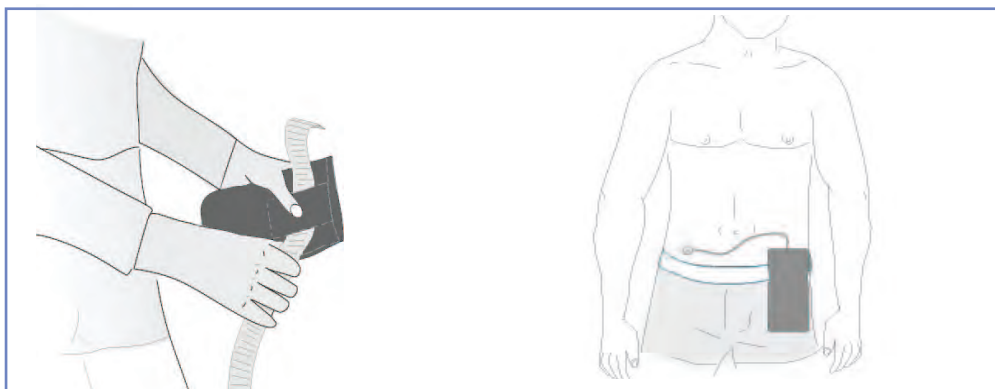
GENERAL WARNINGS

The device can be damaged by liquid, so it must not be kept on while in the bath or the shower, etc. If the device is accidentally made wet, (for example, drops of the drugs, or overnight bedwetting), you must ensure it is checked by the CANÈ S.p.A. Service Centre

The device must be kept away from:
- Sources of heat (radiators, gas rings, stoves, etc.)
- Direct sunlight
- Strong electro-magnetic fields (magnets, loudspeakers, mobile devices)
- Details are given in APPENDIX 6.
- Ionising radiation
- Ultrasound devices
- MRI devices.

The device does not need sterilising.

Do not freeze the CRN *reservoir* with the drug still in it.

The device must not be placed in a fridge or freezer.

The device must not be placed in an oven or microwave oven.

Reservoirs, infusion sets, needles, filters and all consumable materials must be disposed of in an appropriate way, using containers designed for the purpose.

If you do not observe the above warnings, the device could malfunction, with potentially serious consequences for the user.

MAINTENANCE

The technical characteristics of the device make it extremely simple to maintain.

If the device is damaged, you are recommended to have it checked by the CANÈ S.p.A. Customer Support Service, before re-using it.

The external surfaces can be cleaned with a lightly dampened soft cloth, using a mild detergent or disinfectant.

GENERAL WARNINGS

- Do not immerse the pump in detergent solutions or water.
- Avoid getting liquids inside the pump. If the device gets wet, immediately try to dry it with absorbent paper.
- Do not clean the pump with acetone, solvents or abrasive detergents.
- Do not sterilise the pump.

STORAGE

If the device is not used for more than one or two months, you are recommended to remove the battery and put the pump away in its case in a dry place at room temperature.

DISPOSAL

At the end of the expected life of the pump, contact the CANÈ S.p.A. Customer Support Service, which will provide you with instructions about the disposal of the device.

Reservoirs, infusion sets, needles, filters and all consumable materials must be disposed of in an appropriate way, using containers designed for the purpose.

EXPECTED PUMP LIFE

The pump is expected to last for 4 (four) years from its purchase date. For safety reasons you should not continue to use it after this period.

SUPPORT

The device must only be repaired by the CANÈ S.p.A. Customer Support Service. You are recommended, before sending the device, to contact:

- **Servizio Assistenza Clienti (Customer Support Service)**
  CANÈ S.p.A. Medical Technology
  Via Cuorgnè, 42/a
  10098 Rivoli (Turin) - Italy
  Tel. +39 011 957 4872
  Fax +39 011 959 8880

- **CANÈ S.p.A. Online**
  Internet: www.canespa.it - E-mail: service@canespa.it

GUARANTEE

CANÈ S.p.A. guarantees the product from any material or manufacturing defects for a period of 2 (TWO) YEARS from the original date of purchase.

If, in the course of this guarantee period, any material or manufacturing defects are identified, CANÈ S.p.A. will repair or substitute the defective components according to the terms and conditions herein, without any charge for labour or parts; the Customer is responsible for the costs of sending the pump to the CANÈ S.p.A. Customer Support Service.

CANÈ S.p.A. reserves the right to vary the characteristics or model of its devices, without being under any obligation to make corresponding modifications to devices already manufactured and sold.

Conditions:
1. The guarantee is valid only if the defect is reported within the period of the guarantee.

2. This guarantee does not extend to any costs and / or defects following modifications or adaptations made to the product, without prior written authorisation by CANÈ S.p.A.

   CANÈ S.p.A. disclaims all responsibility either to the purchaser or to third parties for damage that occurs to persons or things as a result of improper operation of the device, for uses of the device for which it was not designed and for the non-observance of the instructions provided in the instruction manual. The purchaser undertakes to indemnify CANÈ S.p.A. from any claims by third parties with respect to the above.

3. This guarantee is not valid if the model number and serial number of the product have been modified, erased, removed or have in any way been made illegible.

4. The following are excluded from the guarantee:
• Periodic maintenance
• Damage consequent to improper use, including but not limited to:
- Incorrect power supply
- Use of the product for purposes other than those for which it is designed
- Repairs performed by unauthorised personnel or by the Customer
• Accidental and unintentional events, such as liquid spills and falls
• Natural events and malicious or negligent acts
• The standard accessories supplied with the pump.

5. CANÈ S.p.A. undertakes to perform repairs on the device for a period of not more than 4 (four) years from the date of purchase.

After that period, CANÈ S.p.A. has no further obligations to make repairs. CANÈ S.p.A. disclaims all responsibility either to the purchaser or to third parties for damage that occurs to persons or things as a result of the use of the device after 4 (four) years from the date of purchase.

6. After the guarantee period is expired, support will be provided by CANÈ S.p.A. with the customer bearing the subsequent costs of replaced parts, labour and transport in effect at the time.

7. The company disclaims any liability with respect to the patient and / or third parties for any health problems and / or inconvenience resulting from the period when the device is being repaired.

8. The company disclaims any liability with respect to the patient and / or third parties for any problems and / or delays associated with the shipping of the device.

DECLARATION OF CONFORMITY

$$C \epsilon$$
0476

The company CANÈ S.p.A. with headquarters in Via Cuorgnè, 42/a 10098 Rivoli (Turin) - Italy, manufacturer of the medical electrical equipment *CRONO S*-PID 50 ambulatory infusion pump with "reservoir" for drug administration,

Serial No.

declares that the device conforms to the essential requirements of Appendix I of Directive 93/42/EEC, modified by Directive 2007/47/EEC, as per certificate MED 9813 provided by the Notifying Body No. 0476 according to Appendix II of the same Directive and is released to the market in compliance with the corresponding laws of the individual European member states.

Rivoli, 09/05/2012

The Chairman

ENCLOSURES

ICONS USED ON THE PUMP

SN	**Serial No. of the pump**
IP 42	**IP protection rating** 1st digit (4) = protection from solid objects larger than 1 mm. 2nd digit (2) = protection from water droplets sprayed at an angle (up to 15º degrees from the vertical).
CE 0476	**CE marking**
人	**Medical electrical equipment** Electrical classification: Type BF.
⚠	**Warning: read instructions before use**
🗑	**Separated waste collection of electrical and electronic equipment** **Pursuant to article 13 of Legislative Decree 151 of 25 July 2005 "Implementation of the Directives 2002/95/EC, 2002/96/EC and 2003/108/EC concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment, as well as the disposal of waste".**

The symbol of the crossed out waste bin on the product and its packaging indicates that at the end of its useful life, the product must be disposed of separately from other waste. Sorted waste disposal of products at the end of their useful life is organised and managed by the manufacturer. Users wishing to dispose of this device must therefore contact the manufacturer (or the appropriate local distributor) and use the system which has been devised to allow for the separate disposal of devices at the end of their useful lives. A proper differentiated collection system for devices destined for recycling, treatment and environmentally compatible disposal helps reduce the potentially negative impacts on the environment and health, and facilitates the re-use or recycling of the materials from which the device is constructed. The illegal disposal of a product is punishable according to the laws currently in force.

Note: The symbol displayed on the product label is, for obvious reasons of space, reduced and simplified with respect to the specifications in the reference standard CENELEC EN50419.

ICONS USED ON THE *RESERVOIR* BLISTER PACK

	Read the instructions
CE 0123	**CE marking**
	Recyclable
	Use only once
PYROGEN	**Non-pyrogenic**
	Keep dry
	Keep away from sunlight
	Expiry date
STERILE EO	**Sterilised with ethylene oxide**
PP	**Polypropylene**
LOT	**Batch code**
REF	**Reference No.**
NEEDLE	**Needle size**

OPTIONAL ACCESSORIES AVAILABLE ON REQUEST

1. Vertical leatherette case, similar to a mobile phone case.

Detail of belt clip
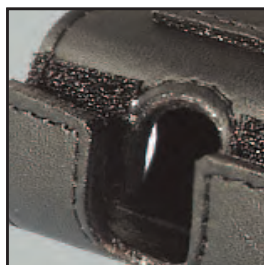
Detail of opening system with aperture for infusion set

Item code: CM/17/A

Colour: black

Dimensions: approx. 6.30 x 2.2 x 1,57 inch (16 x 5.5 x 4 cm)

Weight: about 60 g

2. Horizontal leatherette case, similar to a spectacle case.
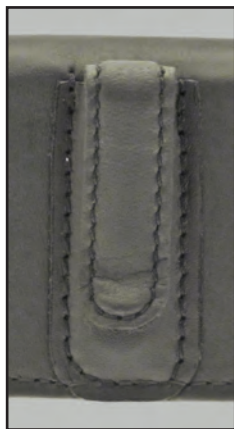
Detail of belt clip

Item code: CM/22/A

Colour: black

Dimensions: 6.3 x 2.2 x 1.57 inch
(16 x 5.5 x 4 cm)

Weight: Approx. 50 g

PRECISION TESTS

The tests have been performed according to IEC 60601-2-24, Electro-medical devices, Part 2: Particular requirements for the safety of infusion pumps and controllers. The following graphs show the precision of the pump during the administration of the pharmaceutical.

1.1 – Start-up flow
Flow rate setting: 1 ml/h.
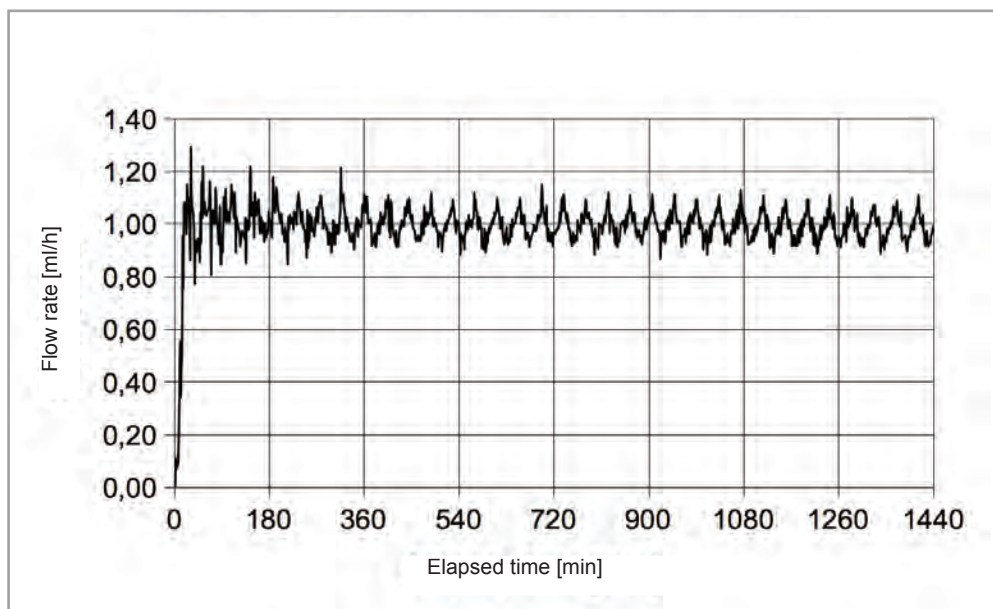
TRUMPET CURVE

1.2 – Flow rate error (trumpet curve)
Flow rate setting: 1 ml/h.
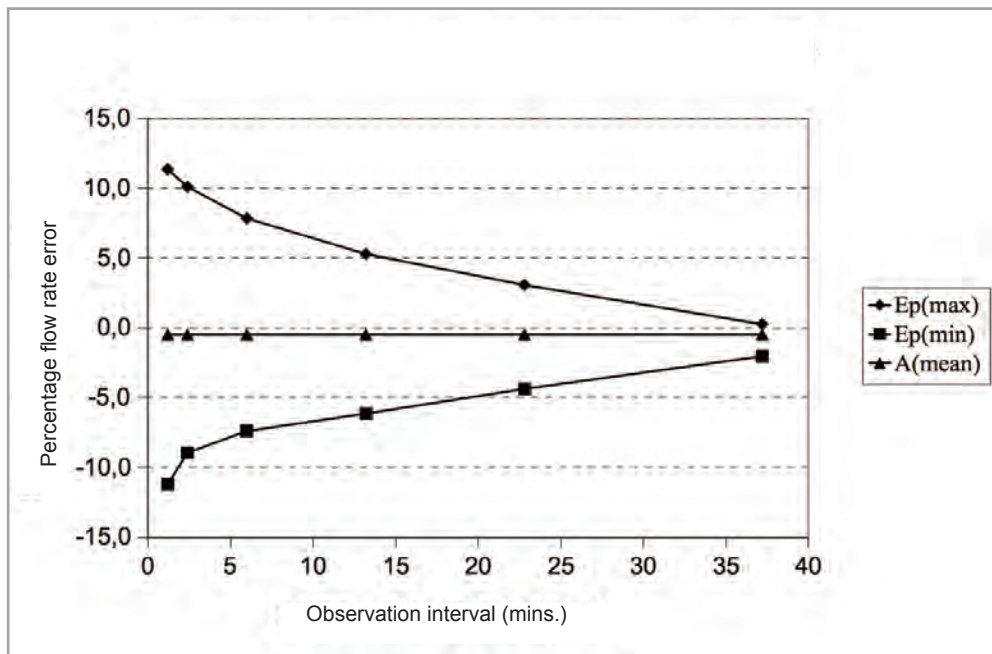
The degree of precision can be different from the information in this manual, according to the type of accessories and extension tubes used in the administration line of the drug.

PRECISION TESTS

2.1 – Start-up flow
Flow rate setting: 25 ml/h.
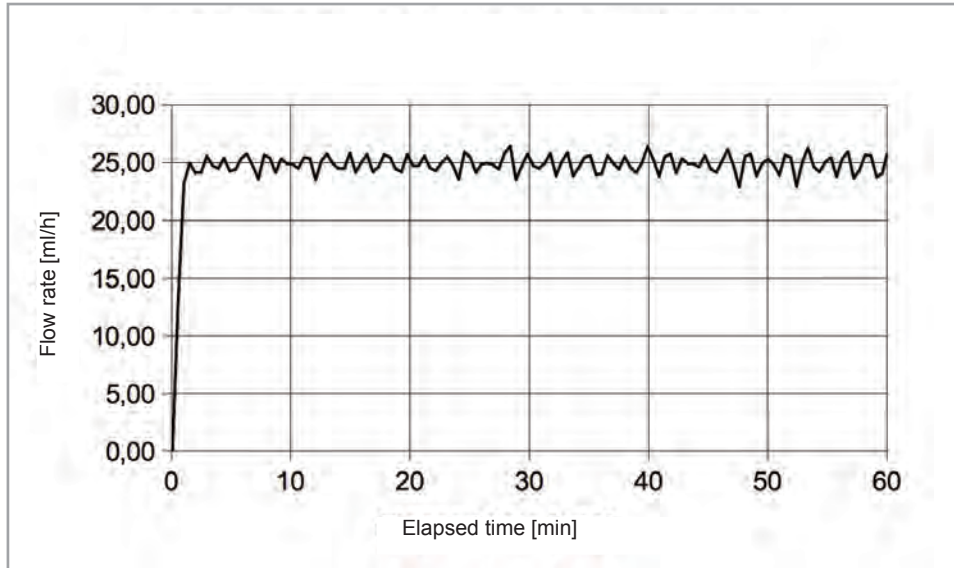
TRUMPET CURVE
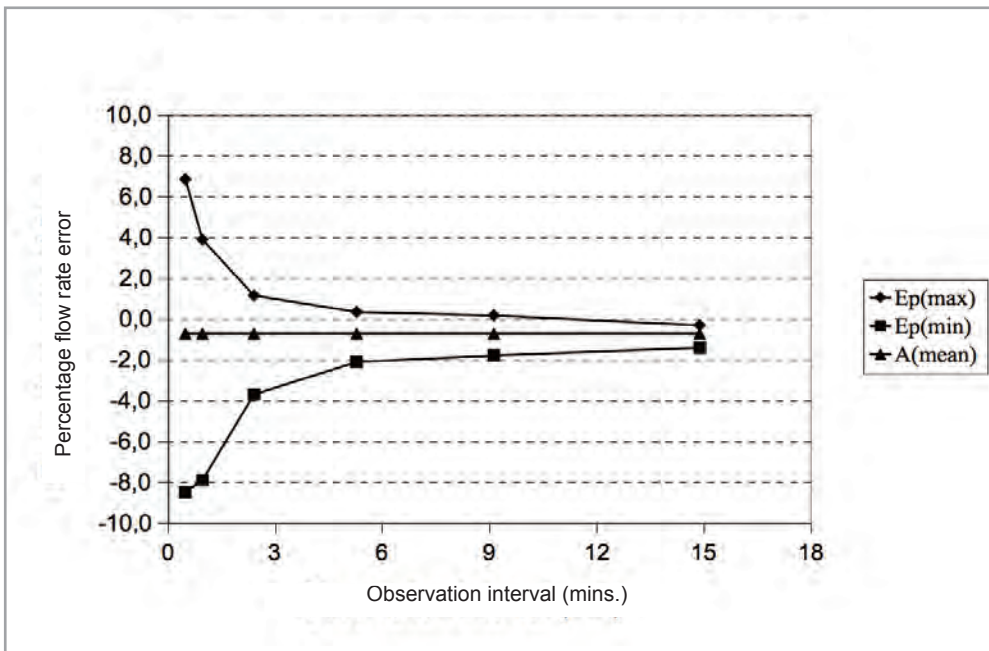
2.2 – Flow rate error (trumpet curve)
Flow rate setting: 25 ml/h.

The degree of precision can be different from the information in this manual, according to the type of accessories and extension tubes used in the administration line of the drug.

PRECISION TESTS

2.1 – Start-up flow
Flow rate setting: 50 ml/h.
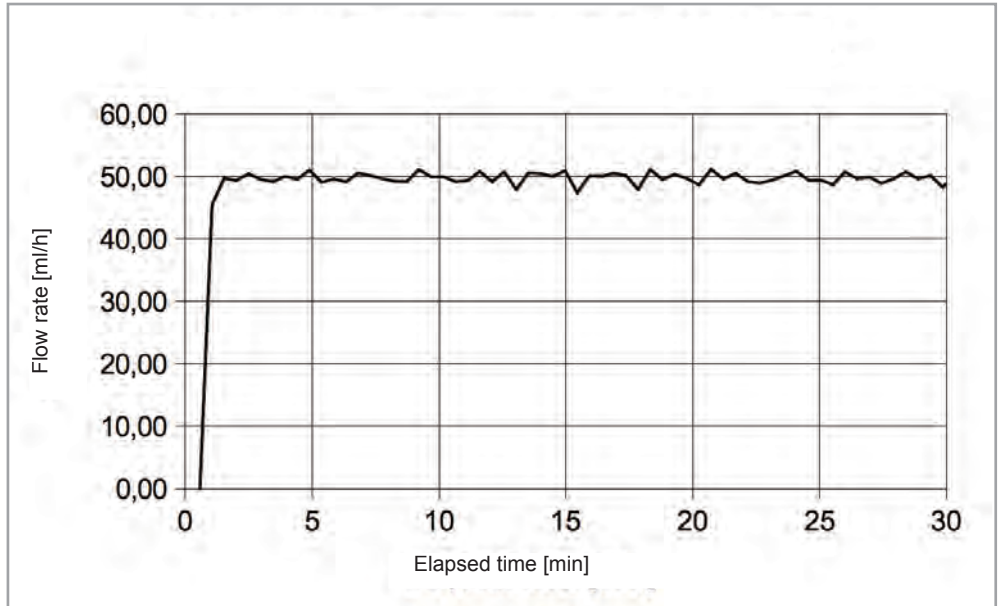
TRUMPET CURVE
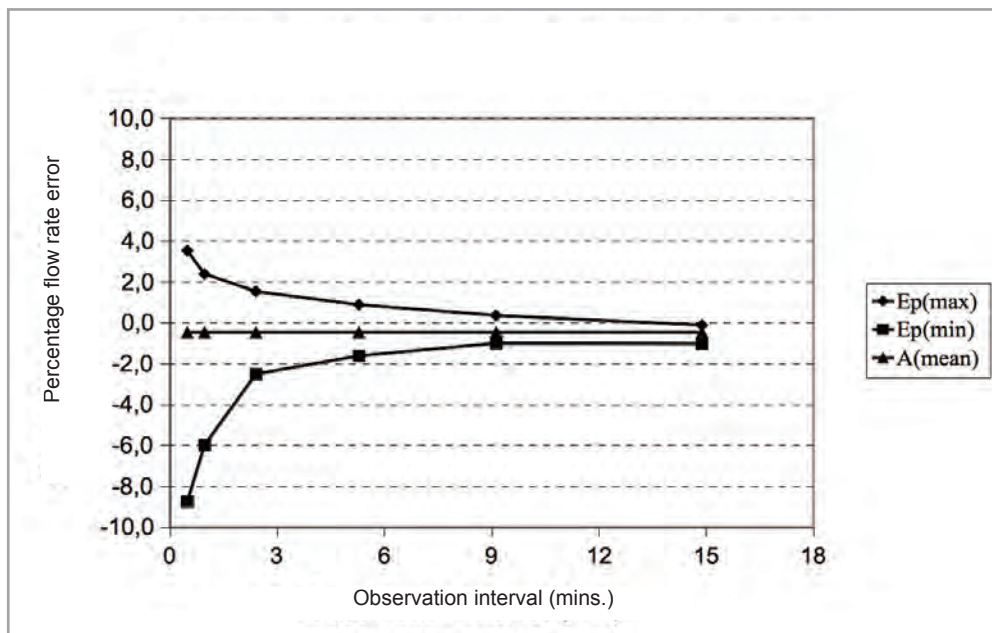
2.2 – Flow rate error (trumpet curve)
Flow rate setting: 50 ml/h.

The degree of precision can be different from the information in this manual, according to the type of accessories and extension tubes used in the administration line of the drug.

TIME NEEDED TO SIGNAL AN OCCLUSION

The time needed to signal an occlusion is the interval between the beginning of the occlusion condition and the recognition of the condition by the pump. This value depends on the flow rate, because the lower the flow rate, the longer the time needed by the pump to recognise the occlusion condition.
The values given here consider the time needed jointly by the pump and the *reservoir* to signal the occlusion.

Flow rate	Time needed to signal an occlusion
1 ml/h	About 2 hours
25 ml/h	About 4 minutes
50 ml/h	About 2 minutes

WARNINGS ⚠️

• The time needed to signal an occlusion is dependent on the flow rate, because the lower the flow rate, the longer the pump will take to activate the occlusion alarm.

• The time needed to signal the occlusion can increase if there is air in the line, if you are using catheters, filters and extension tubes of other dimensions, or in an elastic material, or when the line from the pump is connected to other devices.

• For patients who could suffer severe harm if there is an interruption in the administration of the drug by the pump, arrangements must be made for them to be under the strict supervision of a doctor who can take any immediate corrective action required.

POST-OCCLUSION BOLUS

When the occlusion alarm sounds, the pump has detected an excessive back pressure in the infusion line. This back pressure must be removed in order to avoid releasing a post-occlusion bolus, which might cause serious harm to the patient. The volume of a *CRONO S*-PID 50 post-occlusion bolus, considering only the combined volume of the pump and the *reservoir* is about 1.8 ml.

WARNINGS

• The volume of the bolus dose released post occlusion can increase if there is air in the line, if you are using catheters, filters and extension tubes of other dimensions or of a softer material, or when the line from the pump is connected to other devices.

• After the occlusion alarm is given, take any and all measures appropriate to avoid the administration of a post-occlusion bolus to the patient.

• Patients who might suffer severe harm from the accidental release of a post-bolus occlusion must receive adequate instructions and / or training, from medical or paramedical personnel, on what to do in such a situation.

ELECTRO-MAGNETIC COMPATIBILITY

The electro-magnetic compatibility tests were performed in compliance with the standards:

• IEC 60601-2-24:2012, Medical electrical equipment, Part 2: Particular requirements for the safety of infusion pumps and controllers.

• IEC EN 60601-1-2 Ed. 2, Medical electrical equipment, Part 1: General requirements for basic safety and essential performance – collateral standard: Electro-magnetic compatibility – Requirements and tests.

Guide and declaration by the manufacturer - electro-magnetic emissions		
CRONO S-PID 50 is designed to operate in the electro-magnetic environment specified below. The customer or user of the *CRONO S*-PID 50 must ensure that it is operated in such an environment.		
Emission test	**Conformity**	**Electromagnetic environment - guide**
RF Emissions CISPR11	Group 1	*CRONO S*-PID 50 uses RF energy only for its internal operation. As a consequence, its RF emissions are very low and would thus not be expected to cause any interference to electronic devices in the vicinity.
RF Emissions CISPR11	Class B	*CRONO S*-PID 50 is designed for use in all environments, including domestic environments and those environments directly linked to the low voltage mains supplying residential buildings.
IEC 61000-3-2 harmonic emissions	N/A	
IEC 61000-3-3 emissions in the event of voltage fluctuations or flicker	N/A	

Guide and declaration by the manufacturer - electro-magnetic immunity			
CRONO S-PID 50 is designed to operate in the electro-magnetic environment specified below. The customer or user of the *CRONO S*-PID 50 must ensure that it is operated in such an environment.			
Immunity test	**IEC 60601 test level**	**Level of compliance**	**Electromagnetic environment - guide**
IEC 61000-4-2 electro-static discharge (ESD)	15 kV in air 8 kV on contact	15 kV in air 8 kV on contact	The flooring must be of wood, concrete or ceramic. If the floor is covered in a synthetic material, the relative humidity must be at least 30%.
Magnetic fields	400 A/m 50 and 60 Hz	400 A/m 50 and 60 Hz	

Guide and declaration by the manufacturer - electro-magnetic immunity

CRONO S-PID 50 is designed to operate in the electro-magnetic environment specified below. The customer or user of the *CRONO S*-PID 50 must ensure that it is operated in such an environment.

Immunity test	IEC 60601 test level	Level of compliance	Electromagnetic environment - guide
Radiated immunity	80-2,500 MHz 10V/m AM 80% 1 KHz	10V/m	Interference could occur in the vicinity of devices marked with the following symbol:
	20-80 MHz 10V/m AM 80% 1 KHz	10V/m	

Recommended separation distance between mobile and portable radio communication devices and the *CRONO S*-PID 50.

CRONO S-PID 50 is designed to operate in an electro-magnetic environment in which radiated RF disturbances are under control. The customer or user of the *CRONO S*-PID 50 can help prevent electro-magnetic interference by ensuring a minimum distance between mobile and portable communication devices using RF (transmitters) and the *CRONO S*-PID 50 , as recommended below, relative to the maximum output power of the radio-communication devices.

Maximum specified output power of transmitter (W)	Separation distance at the transmitter frequency (m)	
	150 kHz to 80 MHz	80 MHz to 800 MHz
0.01	1.2	0.12
0.1	3.8	0.38
1	12	1,2
10	38	3.8
100	120	12

REFERENCE DIRECTIVES

- **Council Directive 93/42/EEC:** Medical devices.

- **Legislative Decree no. 46, 24th February 1997:** Implementation of Council Directive 93/42/EEC concerning medical devices.

- **Directive 2007/47/EC of the European Parliament and of the Council:** Amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

- **Legislative Decree No. 37, 25 January 2010**: Implementation of Directive 2007/47/EC.

TECHNICAL STANDARDS

- **IEC EN 60601-1:2007-05.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance.

- **IEC EN 60601-1/EC:2010-05.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance.

- **IEC EN 60601-1-1:2003-06.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Safety requirements for electro-medical systems.

- **IEC EN 60601-1-2/A1:2006-10.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Electro-magnetic compatibility – Requirements and tests.

- **IEC EN 60601-1-2:2010-01.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance - collateral standard: Electro-magnetic compatibility – Requirements and tests.

- **IEC EN 60601-1-4:1997-08.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – 4. Collateral standard: Programmable medical electrical systems.

- **IEC EN 60601-1-4/A1: 2000-06.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Programmable medical electrical systems.

- **IEC EN 60601-1-8:2009-11.** Medical electrical equipment, Part 1: general requirements for basic safety and essential performance – collateral standard: Alarm systems - General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

- **IEC EN 60601-2-24:2012-10.** Medical electrical equipment, Part 2: particular requirements for the safety of infusion pumps and controllers.

- **IEC EN 60529: 1997-06.** Ingress protection ratings provided by enclosures (IP Code).

- **CEI 62-108: 2000-05.** Guide to the maintenance of infusion pumps and control systems.

- **IEC EN 62353:2008-11.** Medical Electrical Equipment - recurrent checks and test after repair of medical electrical equipment.

- **CEI 62-122: 2002-07.** Guide to acceptance testing and periodic maintenance of the safety and / or performance of medical devices powered by a specific power source.

- **CEI 62-143: 2007-05.** Table of correspondence between articles (clauses) in the publication IEC 60601-1:2006 and those of the 1988 edition of the same, and its subsequent modifications.

- **IEC EN 62304:2006-10.** Medical device software – Software life cycle processes.

INFORMATION

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