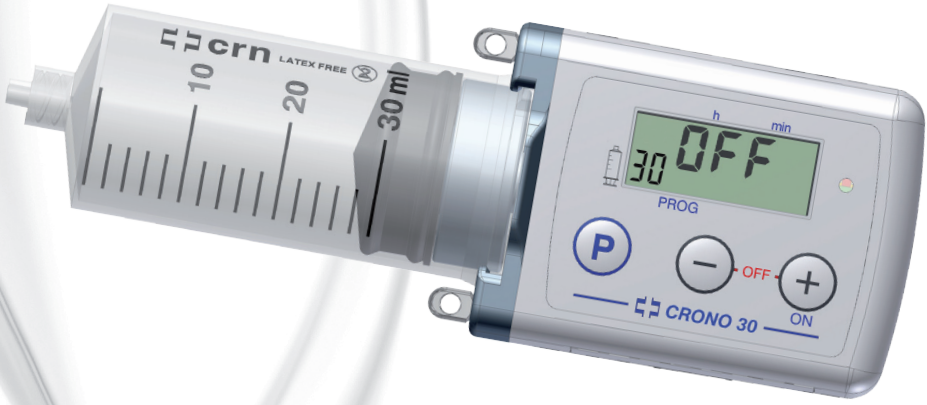
CRONO 30

Ambulatory Infusion Pump



USER GUIDE

CANE
MEDICAL TECHNOLOGY

CANÈ S.p.A. Medical Technology
Via Cuorgnè 42/a 10098 Rivoli (TO) Italy
Tel.+39 011 9574872 - Fax +39 011 9598880
www.canespa.it - mailbox@canespa.it

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CRONO 30

Key-pad lock-out instructions

NOTICE

Confidential Information only to the physician

The pump has a key-pad lock-out function in order to avoid non authorised or accidental variations of the selected parameters; if it is opportune that the patient not be able to change the pump settings it is advised that this information not be divulged to the him/her. The device is supplied with the key-pad lock-out level 0.

KEY-PAD LOCK-OUT

Three different levels may be set: 0,1,2.

The levels are useful to avoid undesired operation, and they actually lock-out the key-pad.

- **Level 0 means no restriction.**
- **Level 1 does not allow you to select:**

- infusion time;
- enable/disable the end of infusion acoustic signal

- **Level 2 does not allow you to select:**

-- infusion time;
- partial volume;
- complete forced retraction of the pusher";
- enable/disable the end of infusion acoustic signal

KEY-PAD LOCK-OUT SETTING

In order to set the level key-pad lock-out you need to follow the procedure below:

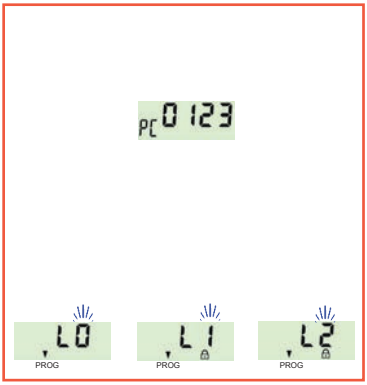
Pump in OFF condition. Display OFF.

Press the button (−) for about 5 seconds; the device will utter the sound ticking of pressed push-button.

The display will read the number of delivered infusions.

Without releasing the (−) button, press the (+) button as well. The display will read the flashing indication of the level previously set.

Acting on (+) and (−) buttons you may increase or decrease the value of the key-pad lock-out level.



The key-pad lock out level is stored even after removing the battery.

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Via Cuorgnè 42/a 10098 Rivoli (TO) Italy Tel.+39 011 9574872 - Fax +39 011 9598880
www.canespa.it - mailbox@canespa.it

WARNING

The pump has a function of key-pad lock-out in order to avoid non authorised or accidental variations of the selected parameters; if it is opportune that the patient not be able to change the pump settings it is advised that this information not be divulged to the him/her. The device is supplied with the key-pad lock-out level 0.

The information concerning the operation of key-pad lock-out and key-pad unlock is provided separately from the current user guide and is only for the physician.

Whenever the key-pad is on lock-out condition, any attempt to modify the protected parameters make the display visualise the padlock indicator () accompanied by an intermittent acoustic signal.

Three different levels may be set: 0,1,2.
The levels are useful to avoid undesired operation, and they actually lock-out the key-pad.

- **Level 0 means no restriction.**
- **Level 1 does not allow you to select:**
  - infusion time;
  - enable/disable the end of infusion acoustic signal
- **Level 2 does not allow you to select:**
  - infusion time;
  - partial volume;
  - complete forced retraction of the pusher";
  - enable/disable the end of infusion acoustic signal

SECTION 8

SECTION 9

SECTION 10

SECTION 11

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 a "**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, describe the functions of the *CRONO 30* 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 65 to 80.

INTRODUCTION

Thank you for having chosen the ambulatory infusion pump, model: ***CRONO 30***.

This manual has been prepared to enable you to make the best use of the ***CRONO 30*** 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 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 30*** 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 28) 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 recommended 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 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 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.

FURTHER INFORMATION

For further information about the ***CRONO 30*** pump, 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
Internet: www.canespa.it E-mail: service@canespa.it

INTENDED USE

The ***CRONO 30*** ambulatory infusion pump is designed for the subcutaneous infusion of drugs for ferrochelation therapy.

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

NOTE

The manufacturer holds itself responsible for the safety of patients 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 functions 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 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 drug.

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

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 precision and the time needed to indicate an occlusion could vary with respect to 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 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 individuals who assist and/or live with the pump user know how the pump works and the information in this user manual.

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

PUMP DESCRIPTION

CRONO 30 is an ambulatory infusion pump for controlled subcutaneous administration of drugs.

CRONO 30 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 30 uses 30 ml dedicated reservoirs.

To improve the absorption of the drugs, ***CRONO 30*** administers 33 µl per shot.

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.

An innovative infusion control system allows the pump to automatically restart and finish an infusion after an occlusion has been removed.

CRONO 30 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 microdoses (shots) of 33 µl at intervals which depend on the configured delivery time.

For example, if the delivery time is 1.00 h, with a 30 ml reservoir, the interval between shots is approx 4 sec, whereas with a delivery time of 10.00 h and a 30 ml reservoir, the interval between shots is approx 40 seconds.

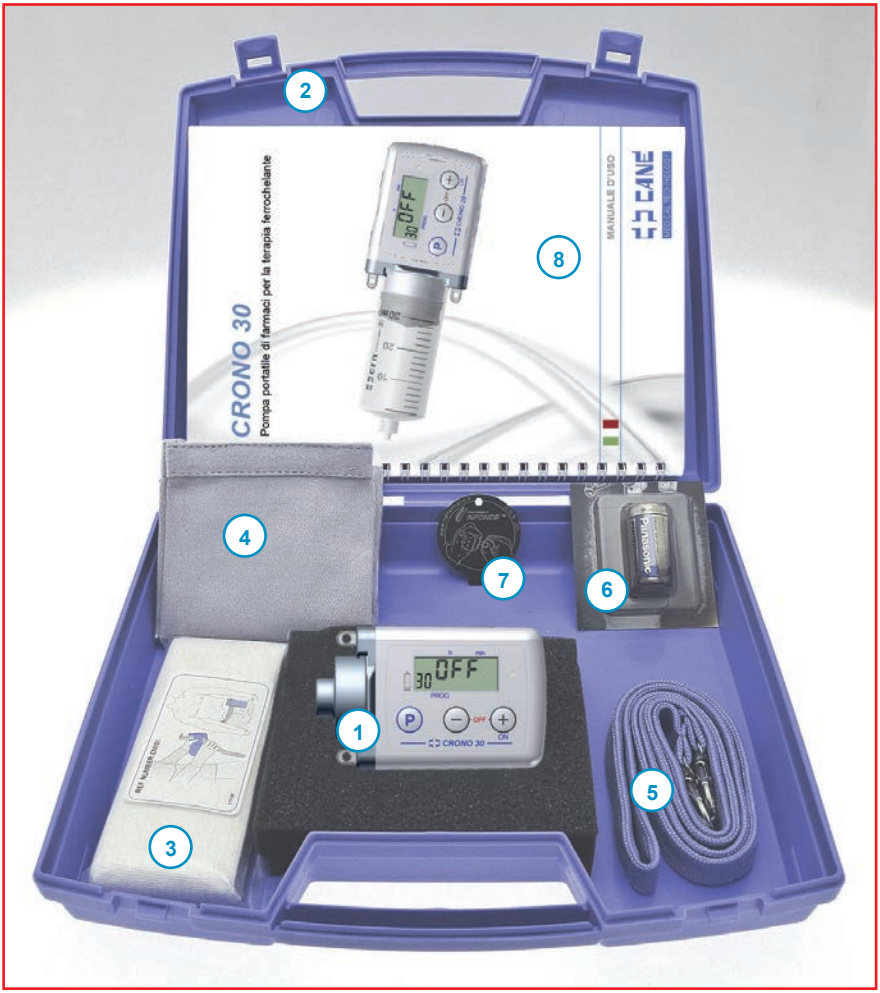
TECHNICAL CHARACTERISTICS

Pump dimensions	80 x 47 x 30 mm (3.14 x 1.85 x 1.18 in).
Weight	125 g (4.40 oz.), including battery.
Battery	Lithium CR 123A 3V (battery life approx 200 infusions).
Single-use *reservoirs*	Dedicated, with a 30 ml capacity and a "*Luer-Lock*" universal safety attachment.
Partial volume	From 1 to 30 ml in steps of 1 ml
Delivery time	Programmable from: 1 h to 99 h in steps of 15 min.
Available *priming* volume	1.5 ml.
Flow rate precision	+/-2%.
Occlusion pressure	4,5 bar +/-2,0
Shot volume	33 microlitres (shot: quantity administered for every rotation of the motor).
Occlusion signalling time	See Appendix 4.
Post-occlusion bolus	Approx 1.2 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) (1.1 x 2.8 cm; 0.43 x 1.0 in).

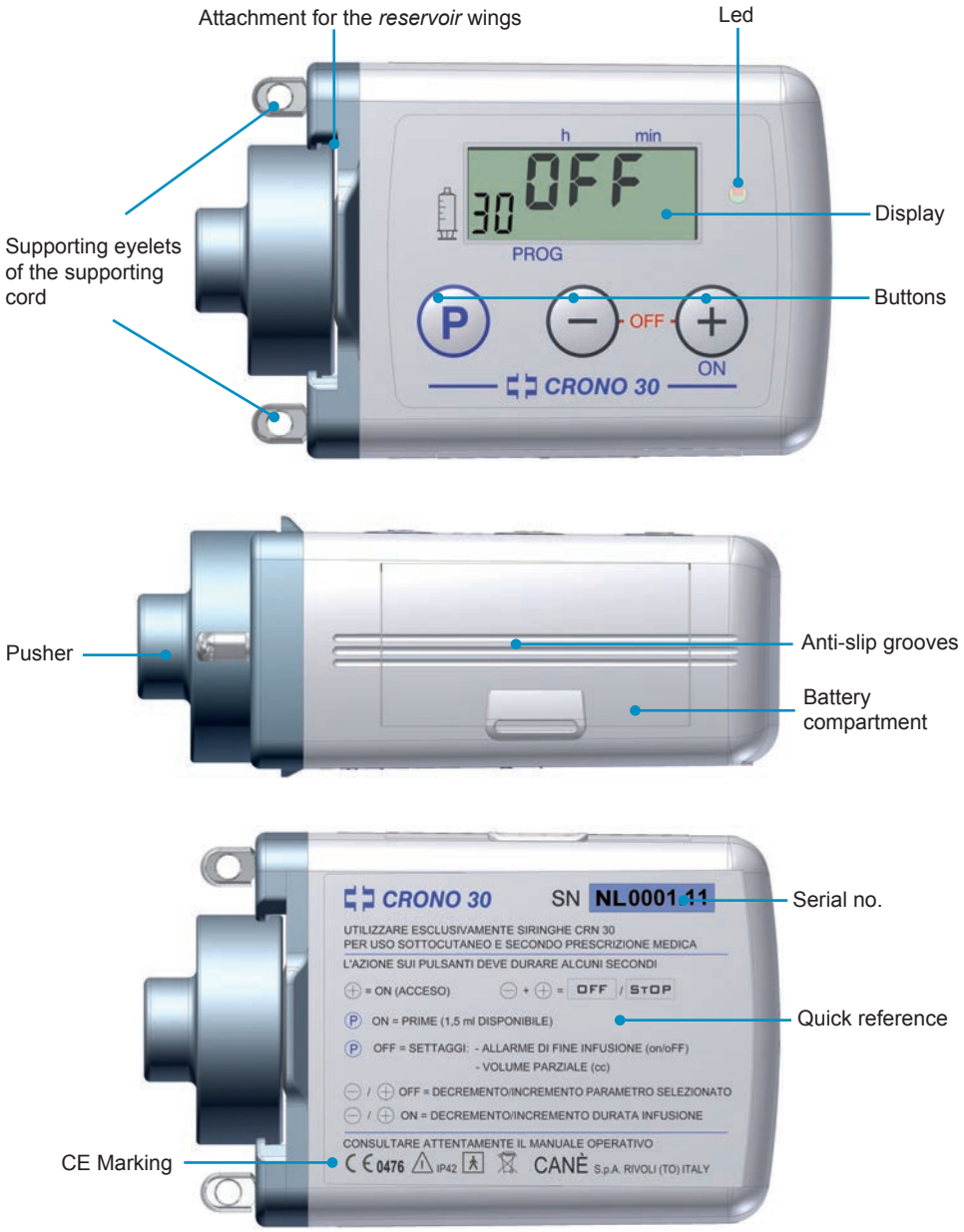
Motor	Coreless DC motor, the rotation of which is controlled by an infrared system.
Settings lock	Two configurable levels.
Electronic circuit with twin microcontrollers	Ensures a more reliable and safer infusion system.
Safety circuits	These check that the device is functioning correctly, intervening 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 30*** ambulatory infusion pump.
2. Infuser carry-case (Code: VAL/01R).
3. Elastic belt (Code: CM/01).
4. Fabric pouch (Code: CM/02).
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.
8. User Manual.



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
h
min
OFF
30
PROG
P
OFF
ON
CRONO 30
CRONO 30
SN NL0001 11
UTILIZZARE ESCLUSIVAMENTE SIRINGHE CRN 30
PER USO SOTTOCUTANEO E SECONDO PRESCRIZIONE MEDICA
L'AZIONE SUI PULSANTI DEVE DURARE ALCUNI SECONDI
= ON (ACCESO)
+ = OFF / STOP
ON = PRIME (1,5 ml DISPONIBILE)
OFF = SETTAGGI: - ALLARME DI FINE INFUSIONE (on/oFF)
- VOLUME PARZIALE (cc)
OFF = DECREMENTO/INCREMENTO PARAMETRO SELEZIONATO
ON = DECREMENTO/INCREMENTO DURATA INFUSIONE
CONSULTARE ATTENTAMENTE IL MANUALE OPERATIVO
CE 0476 IP42
CANÈ S.p.A. RIVOLI (TO) ITALY

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 clicking sound when pressed.

A brief beep 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 34 and 35 and in Section 10.

LED

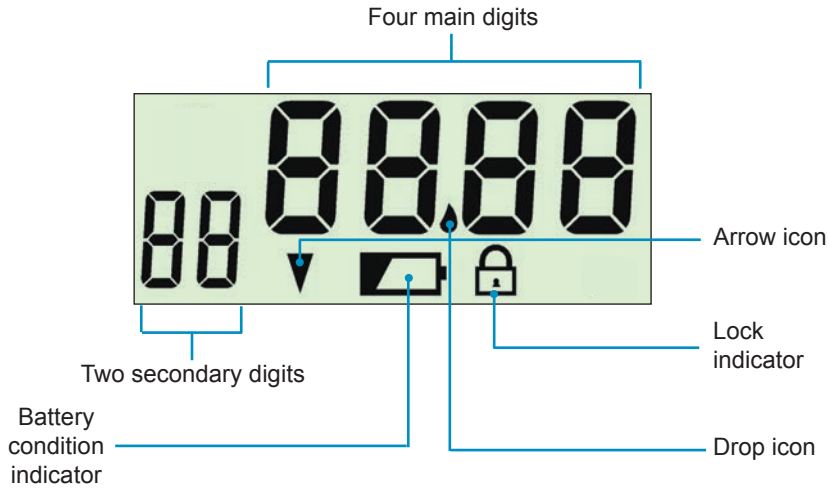
The red LED to the right of the display is switched on in the following circumstances:

1 - When the battery is inserted during the pump verification checks, see Page 36.

2 - When an error has occurred, see Pages 29-30.

LIQUID CRYSTAL DISPLAY (LCD)

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



Four main digits of the display

Display principal information related to the values of the settings, error information, etc.

Two secondary digits of the display

Display alternately:

- The volume remaining 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 low (see related section on Page 25).

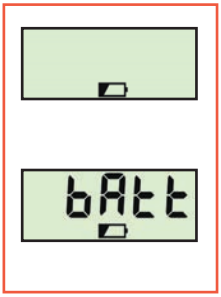
Drop icon
Flashing: the hour and minute separator.

Arrow icon
The arrow indicates that the pump is being programmed.

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 (**L1**); i.e. they can be viewed but cannot be changed.

LOW BATTERY INDICATOR



The appearance of the "**LOW BATTERY**" alert (not flashing) on the display indicates that the battery is low.
If the alert remains displayed for several consecutive infusions, the "**SPENT 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** conditions, 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** condition.

If the battery is removed with the pump in the **ON** condition, the pump is automatically re-initialized, i.e. the pusher is withdrawn and 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 of the battery 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 or more), 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.

BATTERY REPLACEMENT

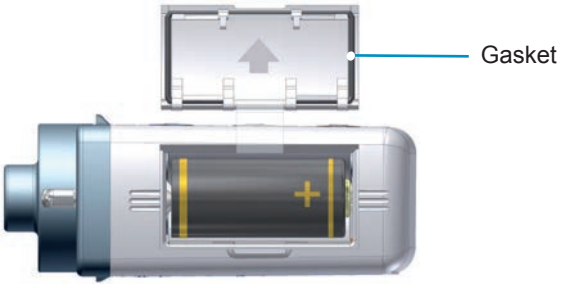
Use a 3 Volt Lithium battery, model 123 A.
To replace the battery, ensure that the pump is switched off (the display showing **OFF** or **StoP**), and then proceed as follows:

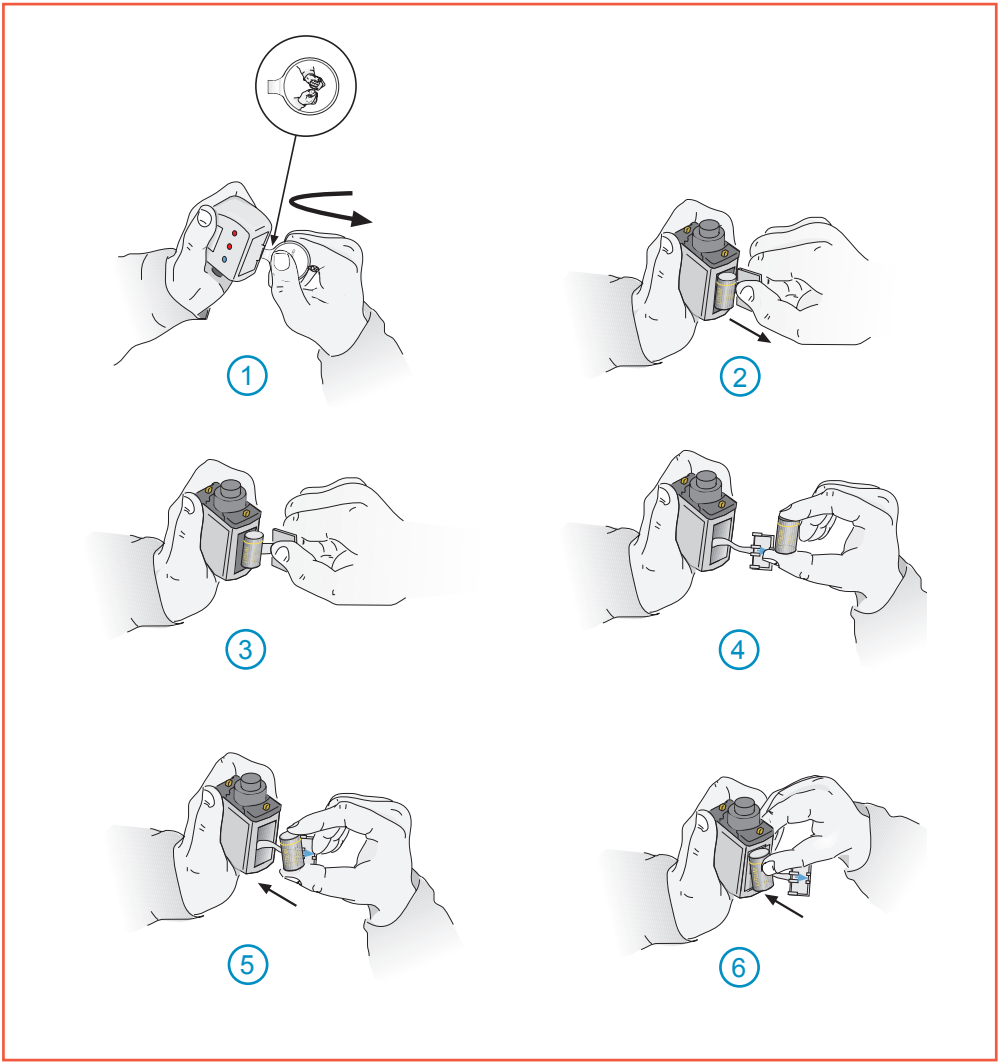
1. Open the battery compartment using the PID battery tool for this purpose.
2. Pull out the cover.
3. Use the small ribbon strap (which lies under the battery) to facilitate the removal of the battery.
4. Remove the discharged battery and discard it properly.
5. Insert the new battery checking that it is in the correct position and that the ribbon strap is under the battery.
6. After having installed the battery, close the 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:

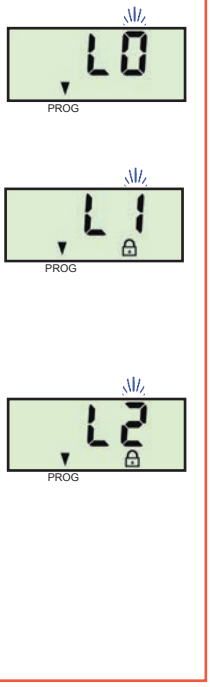
- Hold the pump and the compartment cover firmly in one hand.
- Strike the palm of your other hand with the pump to jolt the battery from the compartment.
- The cover is supplied with a gasket which must remain in position as indicated in the illustration.




1
2
3
4
5
6

SETTING LOCK

The ***CRONO 30*** pump has 3 access configurations:



- **L0 (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.

- **L1 (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 (the delivery time, enabling/disabling the end of infusion acoustic signal); when the pump is set to **L1** the display shows the lock indicator.

- **L2 (locked)**: in this configuration the keyboard allows the control of operating functions (on/off, prime) but not the setting of parameters (delivery time, the partial volume, pusher withdrawal, enabling/disabling the end of infusion acoustic signal). When **L2** is selected the display shows the padlock symbol.

Before attempting to modify any of the settings, ensure that the selected access level of the pump is **L0** (**OFF** symbol).

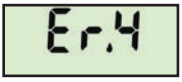
WARNINGS

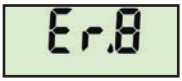
- This access level for the functions remains in the memory even if the battery is removed.

- When the settings access is **L1** (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	AUDIBLE SIGNAL	ERROR DESCRIPTION	CORRECTIVE ACTION
	Brief beep.	Operation not allowed	---
	Continuous tone and flashing LED.	Critical problem in the safety system.	Press the ⊕ button
	Beep repeated every 10 sec approx.	Anomaly in the motor circuit.	Press the ⊕ button
	Beep repeated every 10 sec approx.	Mechanism of the pusher blocked while withdrawing (could be caused by a foreign body preventing its movement).	Eliminate the cause and initialize the pump.
	Beep repeated every 10 sec approx.	Pusher mechanism blocked.	Press the ⊕ button
	Beep repeated every 10 sec approx.	Motor anomaly.	Initialize the pump.
	Beep repeated every 10 sec approx. (possibly accompanied by flashing LED).	Communication error between the two microcontrollers.	Press the ⊕ button

DISPLAY	AUDIBLE SIGNAL	ERROR DESCRIPTION	CORRECTIVE ACTION
	Beep repeated every 10 sec approx.	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.
	Beep repeated every 10 sec approx.	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.
	Beep repeated every 10 sec approx.	Anomaly in the pusher mechanism.	Initialize the pump.
	Beep repeated every 10 sec approx.	Mechanism blocked because of an occlusion in the infusion line.	Eliminate the cause and press the ⊕ button. See Page 32.

WARNINGS

- Following the display of error message **Er,8** and the successive initialisation, the system reverts to the factory settings (see Page 33): 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 a beep and the system stops.

- To initialize the device, remove the battery 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 drug has been interrupted by external means, such as, for example, the kinking of the infusion set tube and consequent occlusion.

An occlusion can be resolved in two ways:

1° - automatically by the pump, which attempts to continue every two minutes;

2° - if the pump's automatic attempts do not work, you must intervene and remove whatever was causing the occlusion. Then re-start the infusion manually by pressing the + button.

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 post occlusion bolus of the ***CRONO 30***, considering the pump-syringe set only, is approximately 1.2 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:

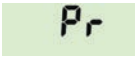
Reservoir	**30 ml**
End of infusion acoustic signal	**AL on** (active)
Lock level set	**L0** (unlocked)
Delivery time	**10 h**
Number of infusions	**0**

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	BATTERY INSERTION	DISPLAY
		• Self-diagnosis test • Automatic positioning of the pusher • Automatic switch-off	

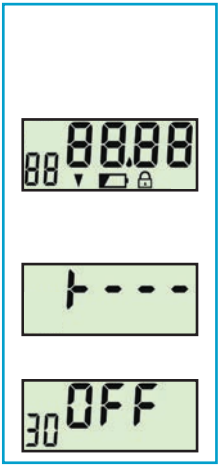
	BUTTONS	PROGRAMMING	DISPLAY
PUMP SET TO OFF		Programming conditions: - Pump switched off - Beginning of a new infusion - Settings lock unlocked.	
	d 1st press	• Selection of end of acoustic signal (this parameter can always be programmed)	
	d 2nd press	• Partial dose volume programming (also availlable in **L1**)	
	− / +	• Decrease/Increase the preceding parameter values	
	NUMBER OF INFUSIONS		
	− press for 4 seconds	Number of infusions (**PC**: Partial Counter)	
	SWITCHING ON		
	+	• Switching on the pump	
		• *Priming* phase	
	+	• Start of infusion	

	BUTTONS	PRIMING	DISPLAY
PUMP SET TO ON	d keep pressed	• *Priming* (max 1.5 ml)	Pr Pr 0.56
	− and + press contemporaneously	• Switching off the pump	Pr 30 OFF
	PROGRAMMING		
		• Delivery time	30 1.00
	−	• Setting of infusion time (keypad unlocked):	t 1.30 PROG
	− / + Decrease/increase time	- from 1 h to 99 h in steps of 15 minutes	
	SWITCHING OFF THE PUMP / EARLY WITHDRAWAL OF THE PUSHER		
	− and + press contemporaneously	• Switching off the pump	30 OFF 26 StoP
	d and − press contemporaneously	• Interruption of an active infusion, withdrawing the pusher to the start position of the infusion	End t--- 30 OFF

	BUTTONS	END OF INFUSION	DISPLAY
END OF INFUSION		• End of the infusion	End
		• Automatic repositioning of the pusher to the starting position	t---
		• Automatic switch-off	30 OFF

PUMP INITIALISATION

When you insert the battery, the pump runs the initialization sequence, during which it:



1. Runs a self-diagnosis test, emitting a series of brief beeps, flashing the red LED and displaying all the indicators and icons on the screen;
2. At the end of the self-diagnosis test the pusher is withdrawn; (if the battery was removed after an error or with the pump in **ON**).
3. When the pusher has been fully withdrawn 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 26.
- 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.

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 SEQUENCE WITH THE PUMP IN OFF or StoP CONDITION

To change the settings the pump must:
- be in the **OFF** or **StoP** condition
- have the settings lock off (i.e. set to **L0**).

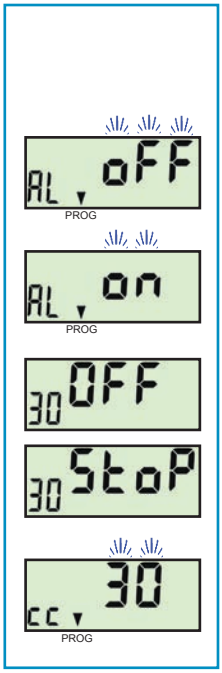
SETTING OF END OF INFUSION ACOUSTIC SIGNAL

1. While the display is showing the type of reservoir selected, press the d button: the pump enters 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 end of infusion sound. Selecting **on** activates the end of infusion acoustic signal, which will sound 5 min and 10 min before the end of the infusion;

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

4. Press the d button before **OFF** is displayed (while the value of the end of infusion sound is still flashing) to pass to the setting of the successive parameter: **SETTING THE PARTIAL VOLUME**.



NOTES

- Setting the reservoir type, the end of infusion sound and the partial dose volume is only possible when the settings are unlocked (**L0**).

- When the settings lock is on (**L1**), if any attempts are made to change the parameter then the display will show the flashing lock symbol and beep several times.

SETTING THE PARTIAL VOLUME

The partial volume function is used when the therapy requires an infusion with less than 30 ml.

The partial volume can be set from 1 cc to 30 cc in 1 cc increments.
Access the setting of this parameter by pressing the d button again, while the parameter value is still flashing. The partial volume can be set only before the start of a new complete or partial infusion.

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.

- The partial volume can only be programmed at the start of a new infusion.

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 dose volume.

SETTING THE DELIVERY TIME

The delivery time can be set from 1 h to 99 h, in increments of 15 minutes.

Procedure:

1. Push the (+) button to switch on the pump.

2. The pump enters the prime function.

3. Push the (+): the infusion begins.

4. Push the (−) button to program the delivery time: the time shown on the display begins to flash.

5. While the time is flashing it is possible to decrease the value with the (−) button, and increase it using the (+) button. Holding either of the buttons down causes the time to change more rapidly.

If no button is pressed for 10 seconds the display stops flashing.

NOTES

• The delivery time is automatically stored by the pump.

• Holding either of the buttons down causes the delivery time to change more rapidly.

• If either of the keypad lock levels (**L1** or **L2**) is active, each time an attempt is made to change the parameter the padlock symbol flashes and the bumps emits a series of acoustic signals.

SWITCHING ON THE PUMP

From the **OFF** condition, 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 42):

  a. Postpone the *priming*.
  b. Cancel the *priming*.
  c. Perform the *priming*.

- Having carried out the *priming,* or if the pump is turned on to resume the infusion from the **StoP** condition, the display will show the delivery time.

THE PUMP IN ON CONDITION

When the pump is in action, the display shows the delivery time counting down at 1 minute intervals to the end of the infusion.

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 set tube with the drugs contained in the reservoir.

The volume available for *priming* is 1.5 ml.

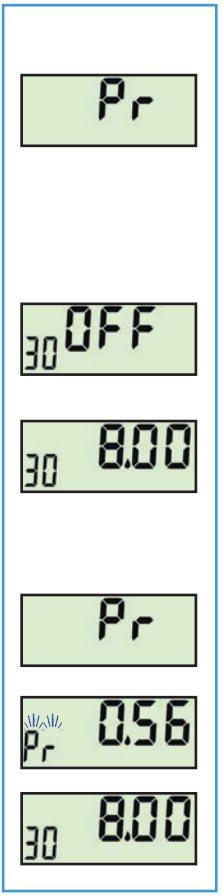
The priming function is enabled when the device is switched on and the pusher is in the infusion start position, regardless of whether the settings lock is on.

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. Skip the *priming*.
c. Perform the *priming*.



a. Postpone the *priming*
Wait 10 seconds, the pump will turn **OFF** automatically.

b. Skip the *priming*
Press the (+) button: the pump begins the infusion and the display shows the time remaining until the end of the infusion.

c. Perform the *priming*
Press and hold down the (d) button: the pump delivers the priming dose until you release the button. The display then shows a flashing letter **Pr** 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 d 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 d button. The display shows **Pr** again, and you again have the choice of postponing, skipping (to start the infusion) or performing the priming function, as described above.

WARNINGS

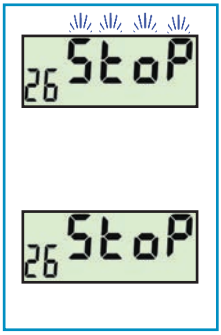
- Do not *prime* the infusion set with the tube connected to the patient.

- 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.

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.

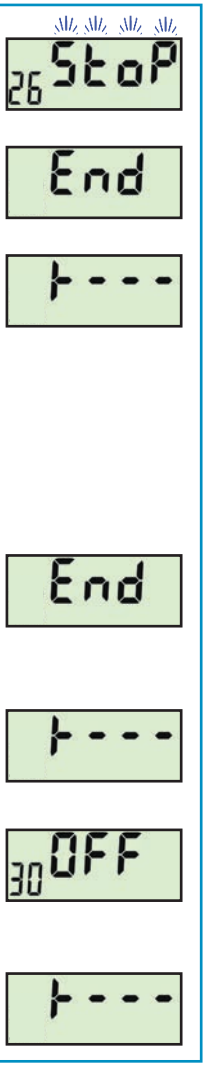
WITHDRAWING THE PUSHER

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 stop an active infusion, do the following:

- Turn off the pump by pressing the ⊕ and ⊖ buttons simultaneously.
- Press the d and ⊖ buttons simultaneously: the display shows **End** for 10 seconds and then begins to withdraw the pusher.
- During the 10 seconds that the display shows **End** the withdrawal request may be cancelled by pressing the ⊕ and ⊖ buttons together.



2. Withdrawal of the pusher at the end of the infusion

If **AL** is active, ten minutes before the end of the infusion the device emits an intermittent acoustic signal for 2 seconds. The same signal is repeated twice 5 minutes before the end of the infusion, and at the end of the infusion a continuous acoustic signal is emitted and the the display shows the "**End**" message.

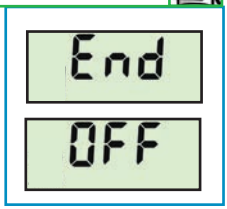
The pusher remains stationary at the end-infusion position for around 10 seconds, after which it begins to withdraw until it reaches the start-infusion position.

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.

NOTES



• 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 pressed again the pump recommences the withdrawal of the pusher.

• The duration of the withdrawal of the pusher is approximately 6 minutes for a volume of 30 cc; the duration is proportionally shorter for smaller volumes.

WARNING

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

DISPLAYING THE SETTINGS

This function displays the programmed pump settings.
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 **L0** (settings lock off) the settings flash and can be modified. If the settings are displayed when the settings lock is set to **L1** or **L2** (settings lock on, with the display showing the “lock” indicator), the settings do not flash and cannot be modified.

Proceed as follows:

1. Press the d button for approx 1 second: the display will show the menu for selecting the end of infusion acoustic signal;

2. Press the d button again and the display will show the **selected partial volume**; (in **L2** only the visualization is possible);

3. Do not press any button for 5 seconds, and the setting phase will end. The display will show **OFF** or **StoP**.

RESETTING THE NUMBER OF INFUSION COUNTER

The device contains two infusion counters: one which is a partial count of infusions and can be reset, and another which shows the total number of infusions effected.

To reset the number of infusion counter, proceed as follows:

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

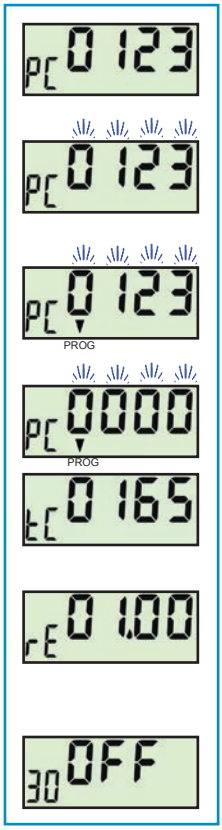
2 - Without releasing the (−) button, press the (d) button: the partial counter of infusions begins to flash;

3 - Press the (d) button once more to invoke the programming mode (the down arrow is displayed);

4 - Press either the (−) or the (+) buttons to set the or partial counter of infusions to zero. Alternatively, press the (d) button to display the total count of infusions effected: **tC** (Total Counter);

5 - Press the (d) button again to display the firmware release: **rE** (Release);

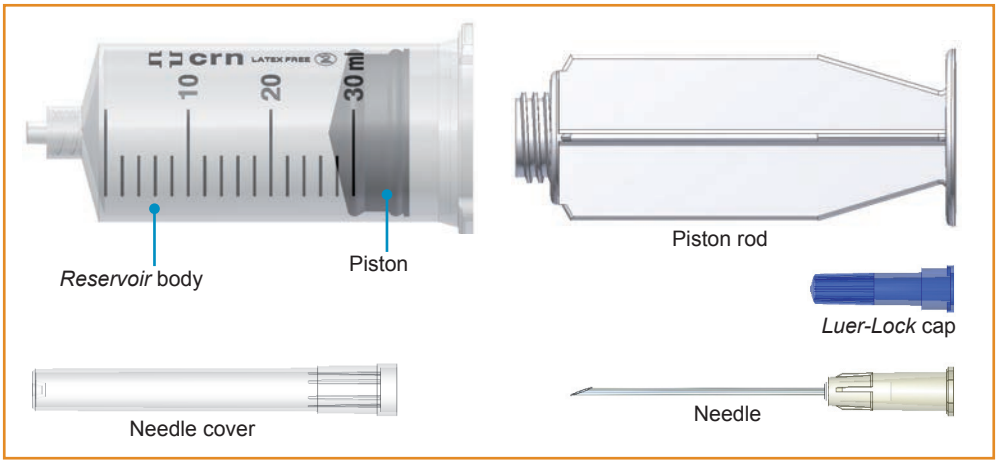
6 - If you do not press anything for approx 10 seconds or press the (d) button again, the display changes to **OFF**.



RESERVOIR PARTS

The ***CRONO 30*** pump uses model CRN® CRONO® Syringe 30 ml dedicated *reservoirs*.

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



WARNINGS

- For safety reasons, you are recommended to use original CRN® Crono® *reservoirs*.
- 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.

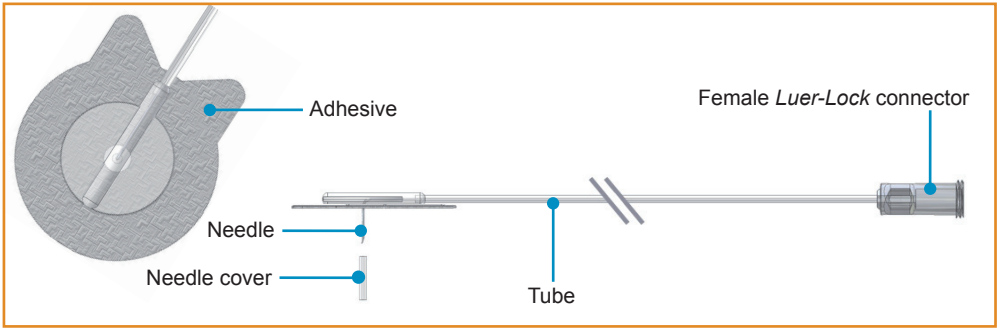
LUER-LOCK CAP FUNCTIONS

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

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 90 cm;
- Anti-kink tubing.

INFUSION SET PARTS



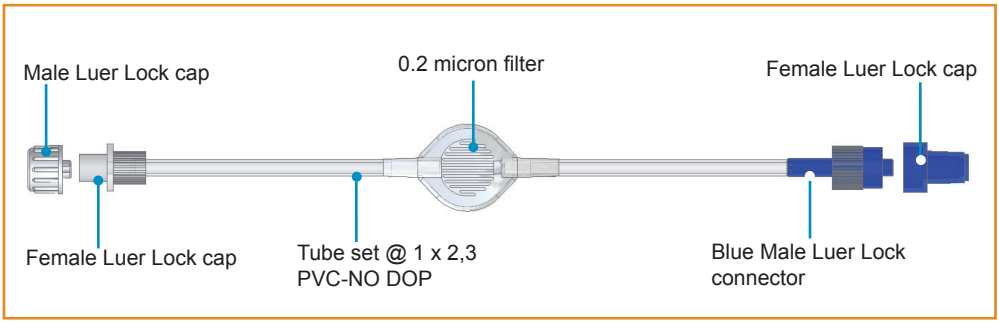
NOTE

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

FILTER

For a safe infusion the use of filters is advised to:
- Prevent possible infections due to bacteria;
- Remove air from inside the syringe and the infusion set;
- Retain micro-particles such as glass and plastic fragments.

IDENTIFYING THE FILTER COMPONENTS

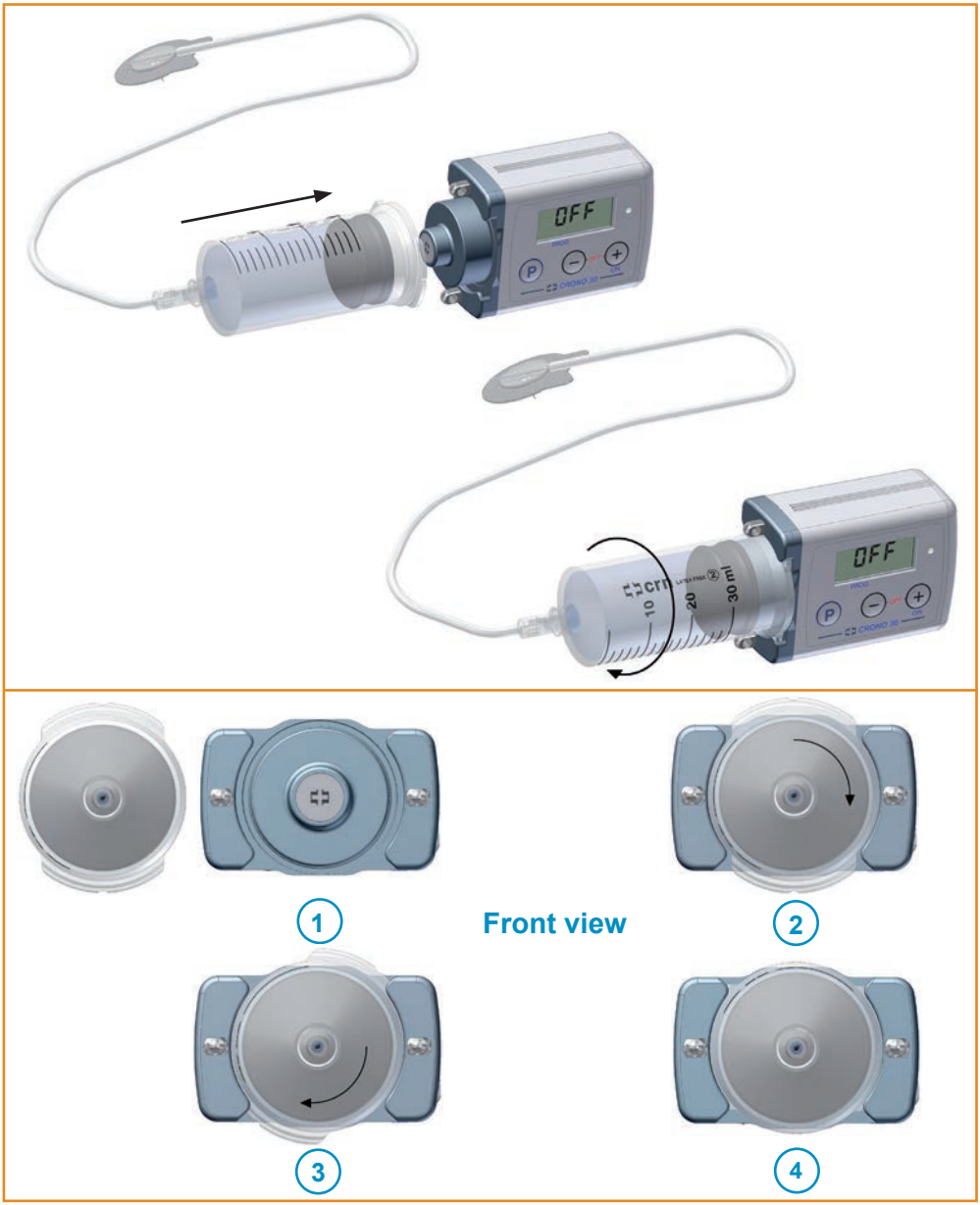


PREPARATION OF THE *RESERVOIR* AND CONNECTION TO THE PUMP

1. Screw the needle onto the réservoir in a clockwise direction and remove the needle cover.
2. Fill the réservoir aspirating the liquid slowly and checking that the quantity of the drug does not exceed its capacity or any partial dose volume you may have set.
3. Remove the needle used to fill the syringe and insert the cone of the infusion set over réservoir.
4. Unscrew the stem, turning it anticlockwise with a reasonably rapid movement.
5. Insert the syringe into the pump. Rotate through 90° and it will click and engage with the pusher.

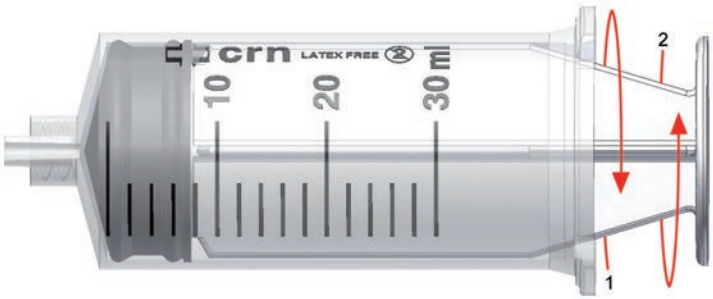
CONNECTION OF THE *RESERVOIR* TO THE PUMP

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



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.

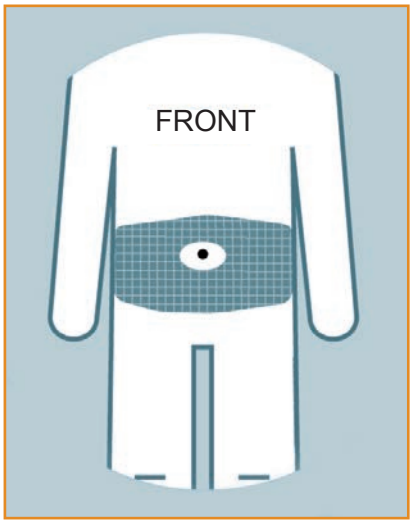
• **Inserting the *reservoir* into the pump**
To avoid any leakage of the drugs while the *reservoir* is being inserted into the pump you can use the infusion set, as an alternative to the *Luer- Lock* cap indicated on Page 50.

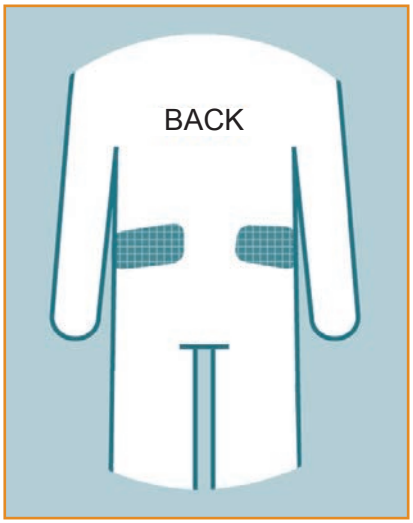
When making the connection, avoid exerting any pressure on the *reservoir* walls, because this could cause liquid to leak past the piston rings.

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 drugs.

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.

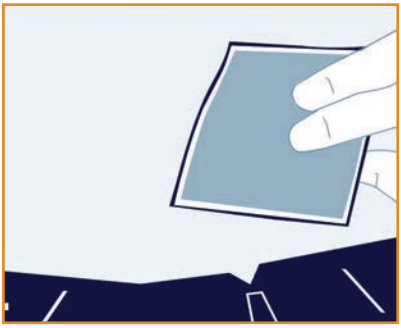
WARNING

Always work in antiseptic conditions, to reduce the risk of infection to the minimum.

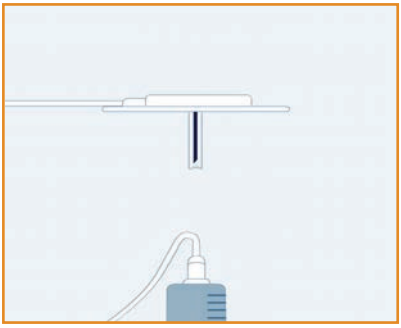
The images refer to the Neria™ infusion set from Unomedical, a Convatec Company.

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*.

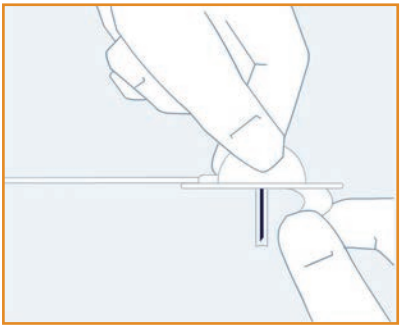


Hold the infusion set by the wings. Prime the infusion line manually or use the priming function of the pump. Ensure there are no air bubbles in the infusion line.

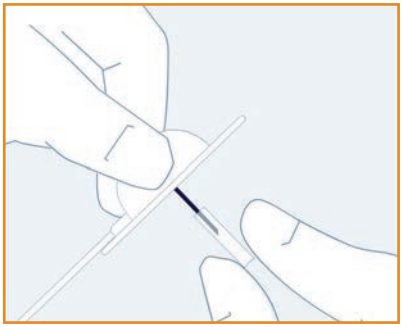
WARNING

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 drugs can come into contact with the protecting adhesive paper.

Remove the protective adhesive paper.

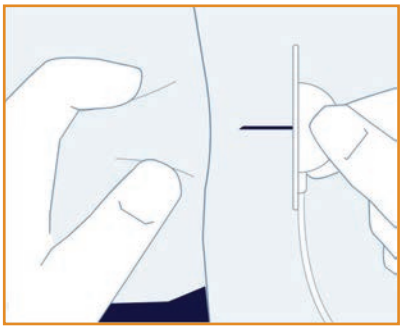


Remove the needle cover, extracting it with care, before inserting the needle.

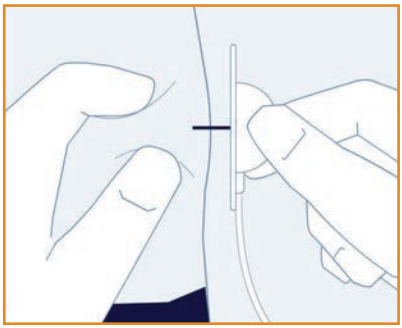


WARNING

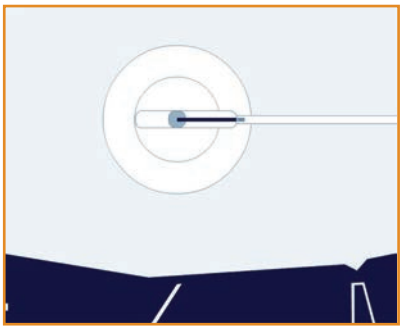
Be careful not to touch the Neria™ needle when you remove the protection.



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.



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.

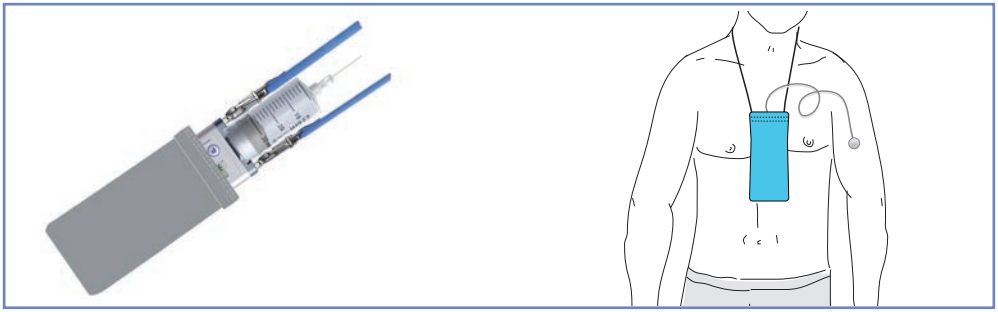


HOW TO USE THE ACCESSORIES SUPPLIED

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

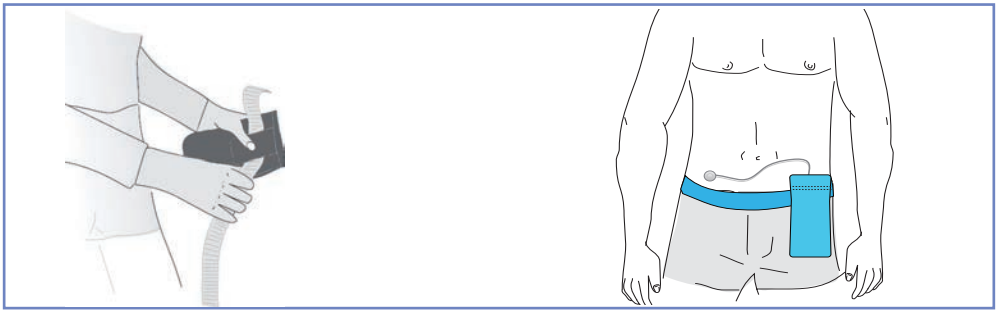
WEARING THE PUMP AROUND THE NECK

The pump worn with the collar strap and a fabric case.



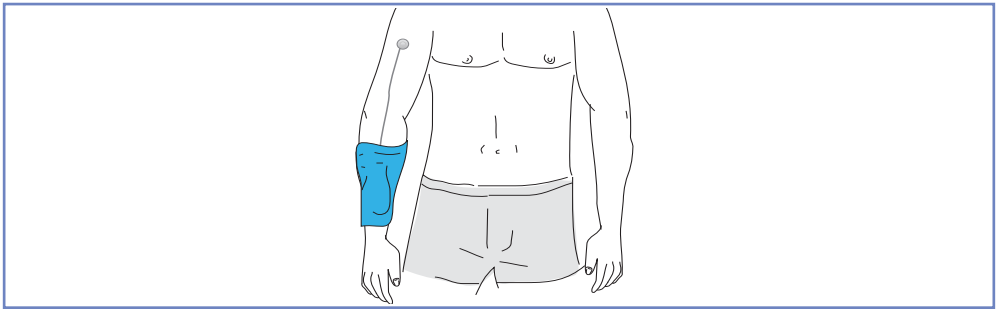
WEARING THE PUMP AT THE WAIST

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



PUMP WORN ON THE ARM

Pump carried using an elastic armband (accessory available upon request)



GENERAL WARNINGS

The device can be damaged by liquids 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 drug, or overnight bedwetting), you must ensure it is checked by the CANÈ S.p.A. Customer Support Service.

The device must be kept away from:
- Sources of heat (radiators, gas rings, stoves, etc.)
- The direct rays of the sun
- Strong electro-magnetic fields (magnets, loudspeakers, mobile devices), details are supplied in Appendix 6
- Ionizing 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.

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 any period 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

With this warranty CANÈ S.p.A. guarantees the product from any faults in materials or manufacturing faults for the duration of 2 (two) years starting from the original purchase date.

Should faults in materials or manufacturing faults be found during this warranty period, CANÈ S.p.A. shall repair or replace the faulty components under the terms and conditions stated below, without any charge for the costs of manpower or spare parts; the cost of sending the device to the CANÈ S.p.A. Customer Support shall remain on the Customer's account.

CANÈ S.p.A. reserves the right to vary the characteristics or the model of its devices, with no obligation to make changes to already manufactured and sold devices.

Conditions:

1. The warranty shall only apply if the fault is claimed within the terms of the warranty.

2. This warranty does not cover the costs and/or any faults due to modifications or adaptations made to the product, without prior written authorization issued by CANÈ S.p.A.
CANÈ S.p.A. declines any responsibility towards purchasers or third parties, which may concern people or objects due to improper use of the device, not intended use and due to non-compliance with the regulations reported in the instruction manual. The buyer undertakes to exempt CANÈ S.p.A. from any claim made by third parties concerning the above.

3. This warranty is void if the model indication or the serial number indicated on the product have been modified, deleted, removed or in any case made illegible.

4. The following is excluded from the warranty:
• Periodic maintenance interventions;
• Damage due to improper use, including but not limited to:
- incorrect electrical power supply;
- use of the product for purposes other those it is intended for;
- repair interventions performed by unauthorized personnel or by the Customer;

- Unforeseeable and accidental events, such as falls and infiltration of liquids;
- Natural events and malicious or culpable actions;
- The accessories provided with the pump.

5. CANÈ S.p.A. undertakes, for a period not exceeding 4 (four) years from the purchase date, to perform repairs to the device.
After this period CANÈ S.p.A. is exempt from the obligation to repair.
CANÈ S.p.A. declines any responsibility towards purchasers or third parties, for damages which may occur during the use of the device after 4 (four) years from the purchase date.

6. After the warranty expires, assistance shall be provided by CANÈ S.p.A. which charges for the replaced components, manpower and transportation in force at the time.

7. The company declines all responsibility towards the patient and/or third parties for any health problems and/or difficulties arising during any period in which the device is returned to CANÈ for technical assistance.

8. The company declines all responsibility towards the patient and/or third parties for any difficulties or delays regarding the shipment of the device.

DECLARATION OF CONFORMITY

CE

0476

The Company CANÈ S.p.A., with headquarters in Via Cuorgnè, 42/a 10098 Rivoli (Turin) - Italy, manufacturer of the medical device ***CRONO 30*** ambulatory infusion pump with “réservoir” for drug administration

Serial no.

declares that the device complies with all the fundamental requirements specified in Appendix I of Directive 93/42/EC, amended by Directive 2007/47/EC, as per 9813 medical certificate issued by Notified Body No. 0476 according to Appendix II of the Directive itself. This device is put on the market in accordance with the laws applied by the individual European states.

Rivoli, 03/08/2012

The Chairman

APPENDICES

ICONS USED ON THE PUMP

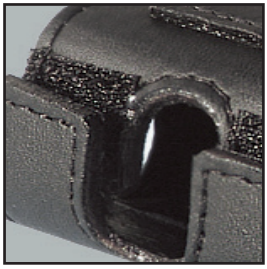
SN	**Serial no. of the pump**
IP 42	**IP protection rating** 1st digit (4) = protection from solid objects larger than 1 mm. 2nd digit (2) = protection from water droplets sprayed at an angle (up to 15º degrees from the vertical).
CE 0476	**CE marking**
	**Electro-medical device** Electrical classification: Class I, Type BF.
	**Warning: read instructions before use**
	**Separated waste collection of electrical and electronic equipment** **In accordance with article 13 of Legislative Decree 151 of 25 July 2005, no. 151 "Implementation of 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
	Non-pyrogenic
	Keep dry
	Keep away from sunlight
	Expiry date
STERILE EO	Sterilized 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 opening system with aperture for infusion set

Detail of belt clip

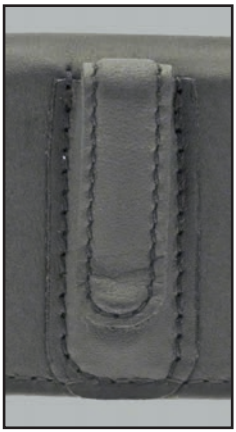
Item code: CM/15

Colour: black

Dimensions (CM/15): approx 16 x 5.5 x 4 cm

Weight (CM/15): approx 60 g

2. Horizontal leatherette case, similar to a spectacle case.



Detail of belt clip

Item code: CM/22

Colour: black

Dimensions (CM/22): 16 x 5.5 x 4 cm

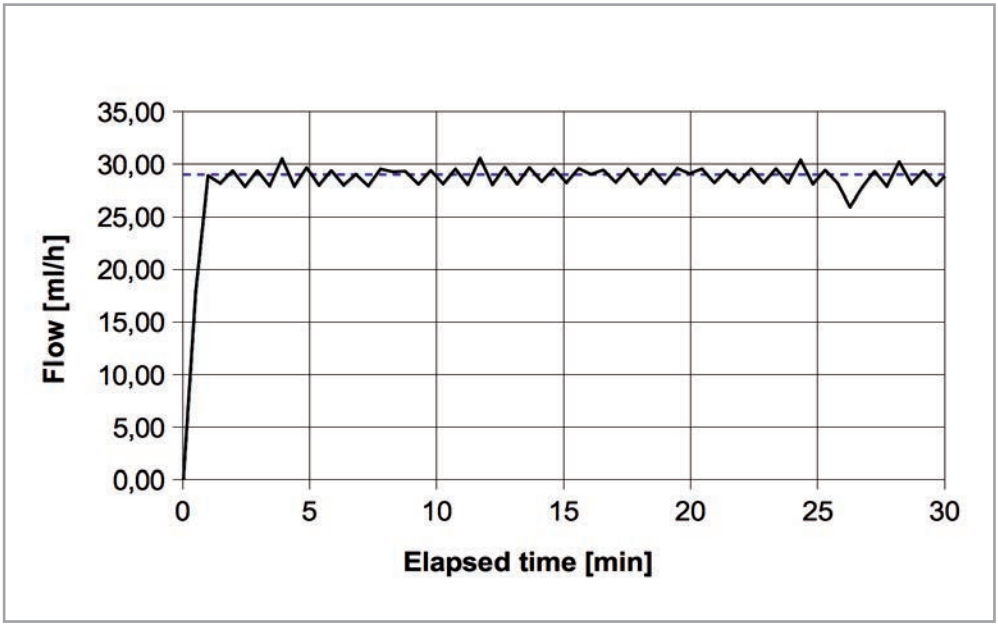
Weight (CM/22): Approx 50 g

PRECISION TEST

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 drugs.

1.1 – Start-up flow

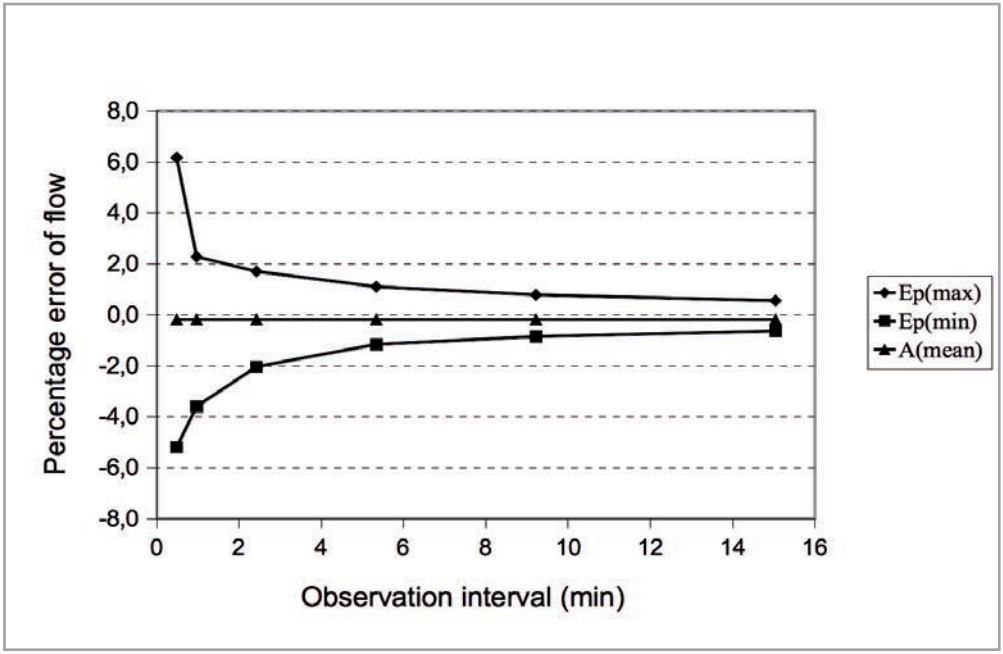
- Programmed delivery time: 1 h
- Volume administered 29cc (corresponding to a flow of 29 ml/h).



TRUMPET CURVE

1.2 – Flow rate error (trumpet curve)

- Programmed delivery time: 1 h
- Volume administered 29cc (corresponding to a flow of 29 ml/h).

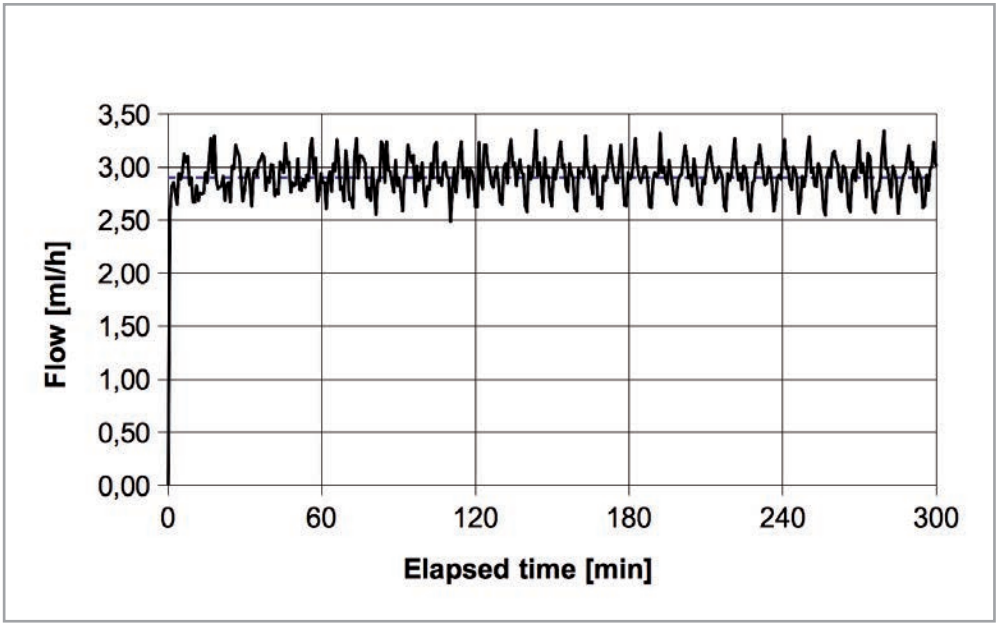


The actual degree of precision may differ from that indicated in this manual, depending on the type of accessories and extension tubes used in the administration line of the drugs.

PRECISION TEST

2.1 – Start-up flow

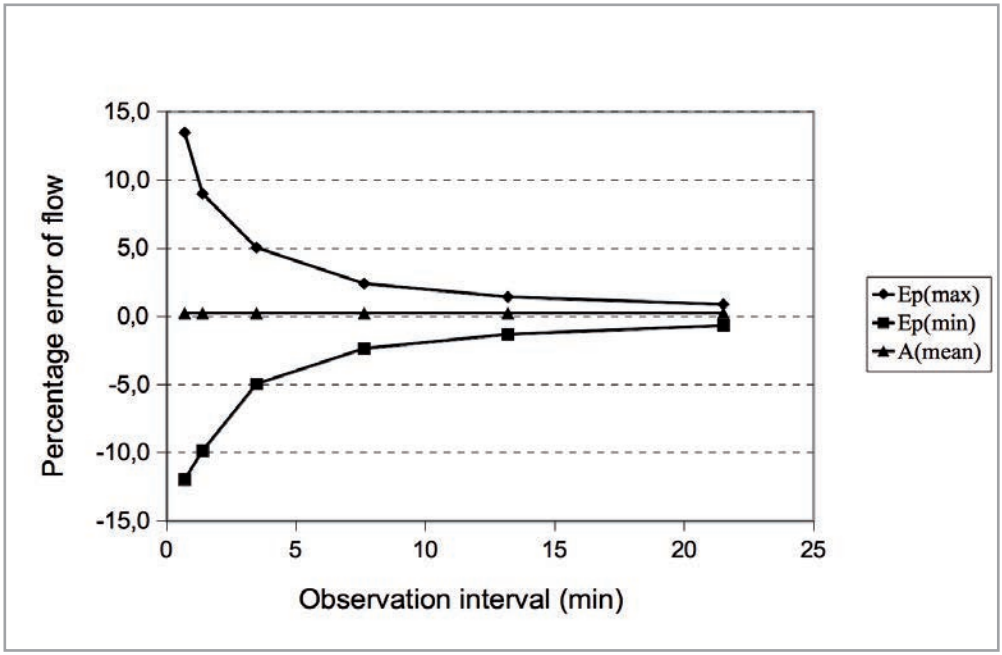
- Programmed delivery time: 10 h.
- Volume administered 29cc (corresponding to a flow of 2,9 ml/h).



TRUMPET CURVE

2.2 – Flow rate error (trumpet curve)

- Programmed delivery time: 10 h
- Volume administered 29cc (corresponding to a flow of 2.9ml/h).



The actual degree of precision may differ from that indicated in this manual, depending on the type of accessories and extension tubes used in the administration line of the drugs.

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.

Delivery time	Time needed to signal an occlusion
1 h	Approx 5 minutes
10 h	Approx 30 minutes
50 h	Approx 2 hours and 30 minutes

WARNINGS

- The time needed to signal an occlusion is dependant on the flow rate, because the lower the flow rate, the longer the time needed by the pump 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 30*** post-occlusion bolus, considering only the combined volume of the pump and a single *reservoir*, is approx 1.2 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 sounds, 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-occlusion bolus must receive adequate instructions and/or training from medical or paramedical personnel on how to proceed 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 30 is designed to operate in the electro-magnetic environment specified below. The customer or user of the ***CRONO 30*** must ensure that it is operated in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guide**
CISPR 11 RF emissions	Group 1	***CRONO 30*** 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.
CISPR 11 RF emissions	Class B	***CRONO 30*** 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 30 is designed to operate in the electro-magnetic environment specified below. The customer or user of the ***CRONO 30*** 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 30 is designed to operate in the electro-magnetic environment specified below. The customer or user of the ***CRONO 30*** must ensure that it is operated in such an environment.			
Immunity test	**IEC 60601 test level**	**Level of compliance**	**Electromagnetic environment - guide**
Radiated immunity	80-2500 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 radiocommunication devices and the *CRONO 30*		
CRONO 30 is designed to operate in an electro-magnetic environment in which radiated RF disturbances are under control. The customer or user of the ***CRONO 30*** can help prevent electro-magnetic interference by ensuring a minimum distance between mobile and portable communication devices using RF (transmitters) and the ***CRONO 30*** 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 60601-2-24:1999-07.** Medical electrical equipment, Part 2: particular requirements for the safety of infusion pumps and controllers.

- **IEC EN 60529: 1997-06.** Degrees of protection 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.

FURTHER INFORMATION

For further information about the ***CRONO 30*** pump, contact:

Servizio Assistenza Clienti (Customer Support Service)
CANÈ S.p.A. Medical Technology
Via Cuorgnè, 42/a
10098 Rivoli (Torino) - Italy
Tel. +39 011 957 4872
Fax +39 011 959 8880
Internet: www.canespa.it E-mail: service@canespa.it

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