CRONO Super PID

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USER'S GUIDE

Ambulatory infusion pump

CANE
MEDICAL TECHNOLOGY

CRONO Super PID

USER'S GUIDE

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Manual code: MAN 01/USA/10 Super PID 11/18

TABLE OF CONTENTS

FOREWORD

CAUTION: US Federal law restricts this device for sale by or on order of a physician.

This manual is written for users of the *CRONO Super* PID pump. The instructions and information in this manual are fundamental for the correct and safe use of this device.

Please take the time to read all the information before using the pump and keep this guide together with the pump for future reference.

NOTE

The manufacturer only considers itself responsible for the safety and reliable working of this pump, provided that it is used in accordance with the current instructions for use.

The manufacturer declines all responsibility towards the purchaser and any other person for any damage to the pump caused by tampering, improper use, modifications and/or repairs by unauthorised persons.

INTENDED USE

The ambulatory infusion pump *CRONO Super* PID is designed exclusively for subcutaneous drug infusions. The pump is not suitable for intravenous infusions.

CANÈ S.p.A. declines all responsibility for the administration of drugs and solutions and/or methods of drug infusion which are not described in this user manual.

USER ASSISTANCE INFORMATION

For further information on the *CRONO Super* PID, please contact:

Customer Service Assistance
Intra Pump Infusion Systems
401 Southwestern Blvd., Suite 160
Coppell, TX 75019 USA
Tel: 1-866-211-7867
www.intrapump.com

DESCRIPTION OF THE PUMP

CRONO Super PID is an ambulatory syringe infusion pump intended for the controlled, subcutaneous administration of liquids. *CRONO Super* PID combines high technology with innovative design. The small size and other features makes the pump ideal for ambulatory use, which means that the patient can be completely mobile during the infusion and does not have to interrupt daily life or leisure activities.

Specially designed PID syringes have to be used for either 10 ml or 20 ml infusions.

CRONO Super PID has a particular mechanism, which pushes directly on the rubber syringe plunger, which makes it possible to reach a significant thrust force and high accuracy of administration.

CRONO Super PID administers 22 µl per impulse (using a 10/20 ml syringe).

In case of infusion set occlusion, an innovative infusion control system makes it possible to proceed with the infusion automatically and, after the occlusion is eliminated, to complete the infusion.

CRONO Super PID is fitted with a liquid crystal display which shows the time it takes to complete the delivery, the syringe size and the battery charge status.

FACTORY SETTINGS

The *CRONO Super* PID pumps are pre-programmed at the factory as outlined below but can be reprogrammed by the user to fit other drug protocols (see section 7-9).

Syringe size	20 ml
Acoustic signal for end infusion	AL.1 (Active)
Lock level	L 0 (unlocked)
Delivery time	1 h

TECHNICAL DATA

Pump size	77 x 48 x 29 mm (3 x 1.9 x 1.1 inch).
Weight	116 g (battery included).
Battery	CR 123A 3V Lithium battery.
Syringes	10 and 20 ml dedicated syringes with universal “luer-lock ” steps.
Delivery time	Programmable from: -1 h to 99 h with 15 min steps; -15 min to 1 h with 5 min steps (10 ml syringe); -30 min to 1 h with 5 min steps (20 ml syringe).
Accuracy	+/-2%.
Occlusion pressure	6,0 +/-2 bar.
Data storage	Programmable data are automatically stored in the pump’s memory. The data is not lost even if the battery is removed.
Lock level	Locked /unlocked.
Safety circuits	Designed to control the regular working of the pump, alarming in the event of an anomaly and displaying alarm messages.
Buzzer sound pressure level	52.3 dBA, 54.5 dBA continuous.
Operating conditions	+5°C to +40°C 15% to 93% RH 700 hPa to 1060 hPa.
Storage conditions	-25°C to +70°C Max 93% RH 500 hPa to 1060 hPa.
Warm up time in 20° environment (-25°C to 5°C)	15 minutes
Cool down time in 20° environment (70°C to 40°C)	18 minutes

STANDARD EQUIPMENT SUPPLIED

1. *CRONO Super* PID ambulatory infusion pump.
2. Pump case.
3. Elastic belt.
4. Collar strap.
5. Fabric holder.
6. 2 batteries - one already inserted in the pump.
7. User's guide.
8. Battery tool.

Fig.1

OPTIONAL ACCESSORIES

Optional accessories are available upon request:

1. Heightwise leatherette case similar to a cellular phone holder (Code: CM/15).

Fig. 2

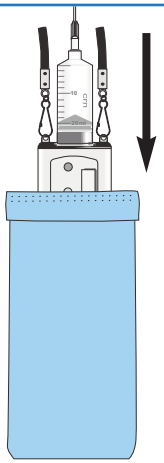
2. Lengthwise leatherette case similar to a glasses case with a belt loop (Code: CM/14).

Fig. 3

HOW TO USE THE STANDARD EQUIPMENT SUPPLIED

The following pictures show how the pump and its accessories should be used.

Fig.4



How to attach the collar strap to the pump and insert the pump into the fabric holder

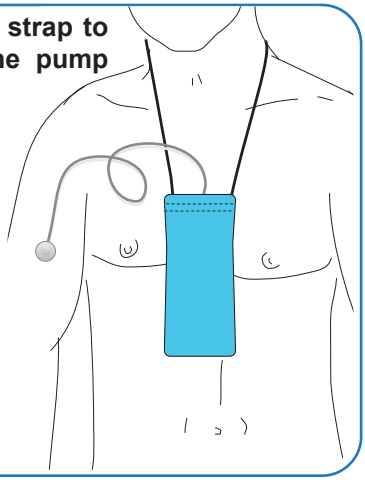
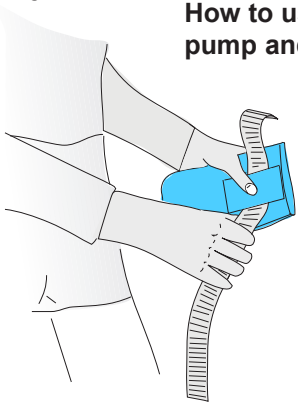
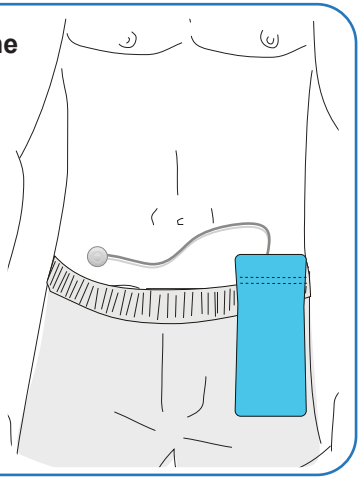


Fig.5

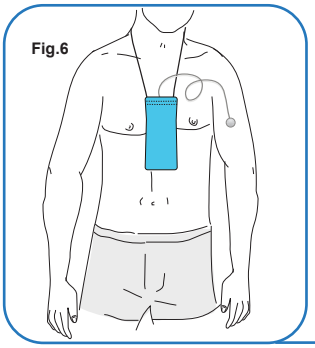
How to use elastic belt with the pump and the fabric holder





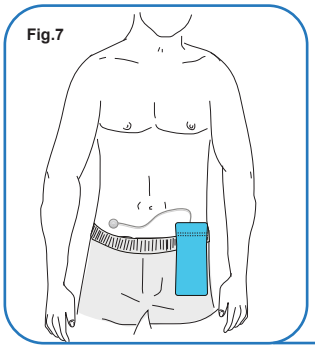
HOW TO WEAR THE PUMP

The following pictures show the various ways the pump can be worn.



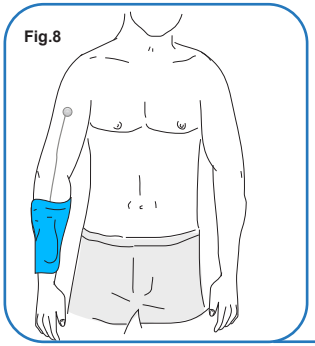
WEARING THE PUMP AROUND THE NECK

Wearing the pump around the neck with a collar strap and a fabric holder (imitation leather holder similar to spectacle case is optional).



WEARING THE PUMP AT THE WAIST

Wearing the pump at the waist with an elastic belt and a fabric holder (imitation leather holder similar to a mobile telephone holder is optional).

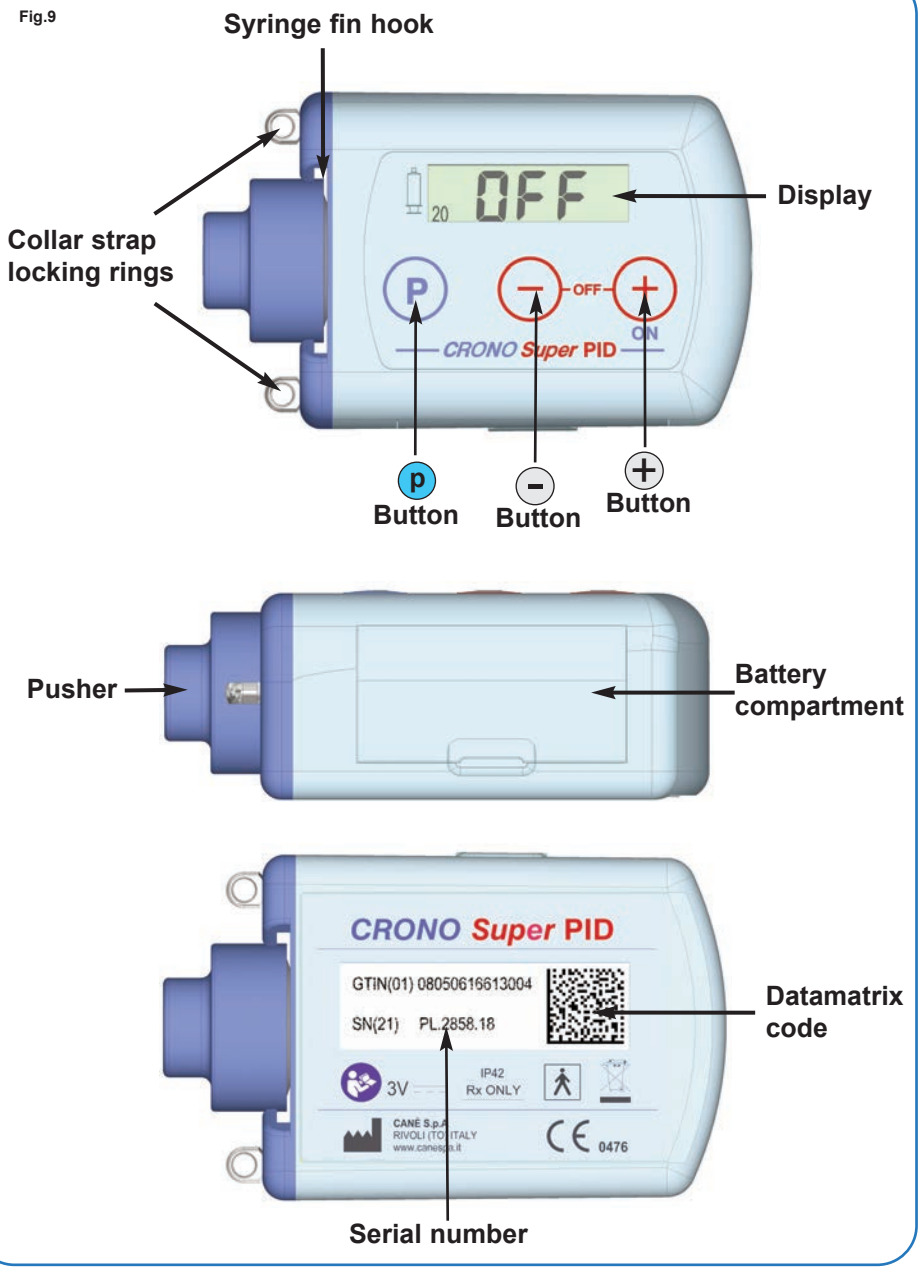


WEARING THE PUMP ON THE ARM

Wearing the pump on the arm with an elastic belt (optional).

PUMP OVERVIEW

Fig.9



LIQUID CRYSTAL DISPLAY (LCD)

This is a screen on the front of the pump where symbols are displayed informing about operations in progress as well as giving warnings and alarm messages.

"Low battery" symbol: appears when the battery charge is low (see page 32).

10 **"10 ml"** symbol: indicates that the pump has been programmed to be used with a 10 ml syringe.

20 **"20 ml"** symbol: indicates that the pump has been programmed to be used with a 20 ml syringe.

"Drip" symbol: flashes when the device is on; it alternates with indication of hours and minutes.

MAIN SCREEN INDICATIONS

	PROGRAMMED DELIVERY TIME AND REMAINING DELIVERY TIME
	PUMP OFF
	SELECTED SYRINGE SIZE (10 OR 20 ML)
	END INFUSION ACOUSTIC SIGNAL (ON)
	END INFUSION ACOUSTIC SIGNAL (OFF)
	ERROR MESSAGE
	FORWARDS/BACKWARDS MOVEMENTS OF THE PUSHER
	END INFUSION
	LOW BATTERY
	BATTERY DISCHARGED
	NUMBER OF INFUSIONS
	BEGINNING OF PARTIAL VOLUME PHASE
	PARTIAL VOLUME POSITIONING INDICATION (EXAMPLE)
	PUMP UNLOCKED INDICATION
	PUMP LOCKED INDICATION

SYRINGE PARTS

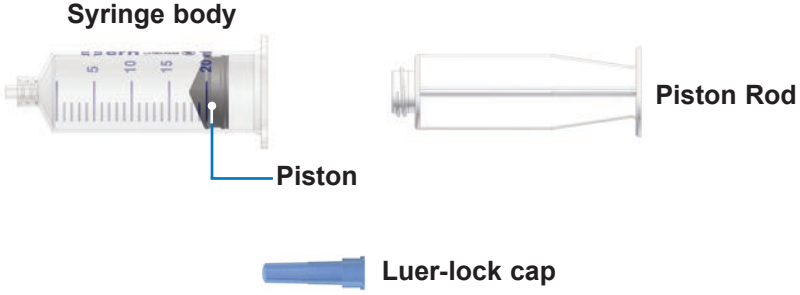
The *CRONO Super* PID pump uses especially designed PID syringes, which are available in two sizes:

- CRN® 10 ml CRONO® Syringe
- CRN® 20 ml CRONO® Syringe

The syringes are:

- sterile
- single use only
- to be used only if packaging is not damaged
- pyrogen-free

Fig. 10



WARNINGS

- For safety purposes must be used only original CRN® Crono® Syringes.
- The use of syringes of other types may damage the pump and harm its user.
- CANÈ S.p.A. assumes no responsibility if the device is used with non-original syringes different from those recommended.
- **Refer to the Medication's Instructions for Use when selecting the appropriate device for transferring of the medication from the vial into the Crono Syringe.**

USE OF LUER LOCK CAP

- Replace the luer-lock cap on the syringe after the syringe has been filled.
- This simplifies the removal of the rod and keeps the solution intact before the infusion starts.

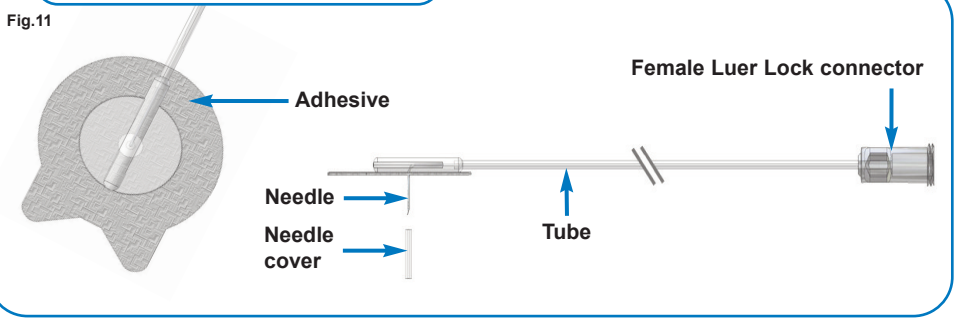
INFUSION SET

The most appropriate infusion sets have the following specifications:

- Length of the catheter not exceeding 90 cm;
- Catheter with dead space less than 0.5 ml;
- Anti-kink catheter.

INFUSION SET PARTS

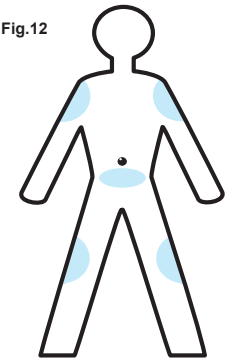
Fig.11



INFUSION SITES

Infusion sites can be any of the following:
- Anterior area of upper arm.
- Anterior abdominal wall.
- Anterior area of thighs.

Fig.12



If the total volume to be administered subcutaneously is too much to administer in one infusion site without causing skin problems, put the pump in "**OFF**" by pushing the ⊖ and ⊕ buttons simultaneously for a few seconds, change infusion site, and restart the pump by pushing the ⊕ button for a few seconds.

PREPARATION FOR INFUSION

Before preparing the pump for the infusion, it is advisable to follow these precautions:

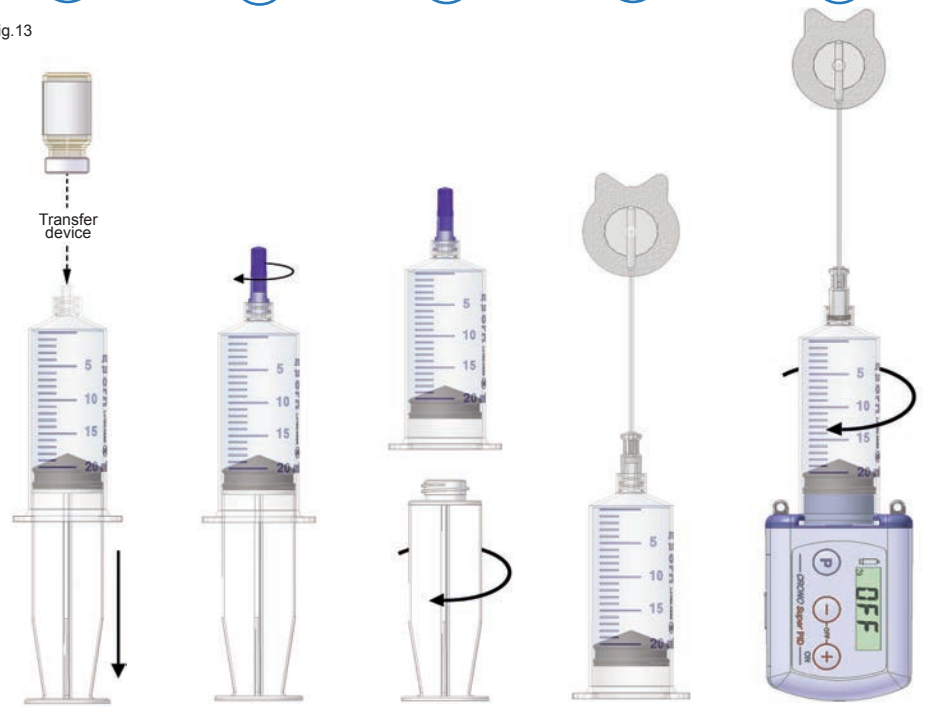
1. Wash your hands.
2. Prepare a clean working area.
3. Check that all necessary material for the infusion is at hand.

PREPARATION OF THE SYRINGE

1. **Refer to the Medication's Instructions for Use when selecting the appropriate device for transferring of the medication from the vial into the Crono Syringe.**
2. Attach the luer-lock cap.
3. Unscrew the rod of the syringe with a counter-clockwise rotation with a fairly swift movement.
4. Attach the infusion set to the syringe.
5. Attach the syringe to the pump by turning it 90°. You will hear a click when the syringe is securely in place.

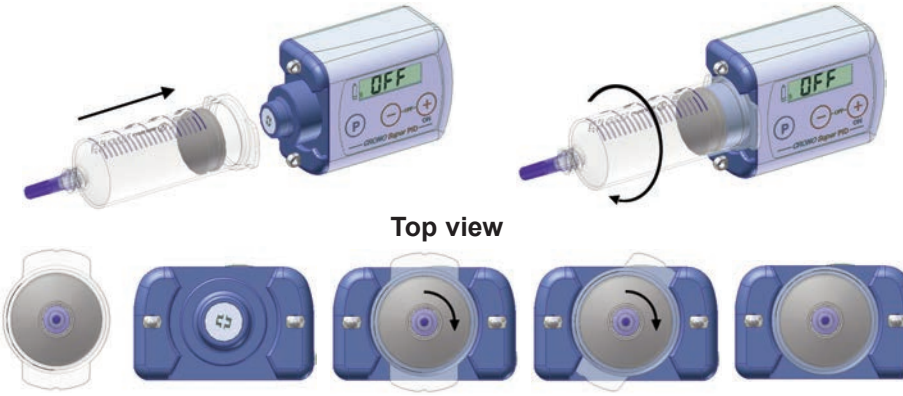
PREPARATION OF THE SYRINGE

Fig.13



CONNECTION OF THE SYRINGE TO THE PUMP

Fig.14



WORKING INSTRUCTIONS

- Press the buttons with your finger-tips only, do not use sharp or pointed objects.

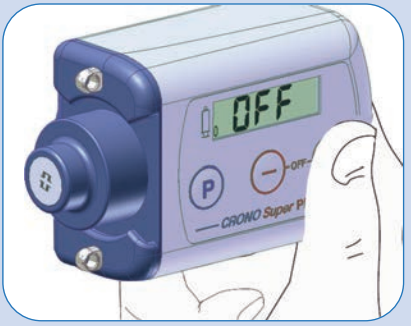
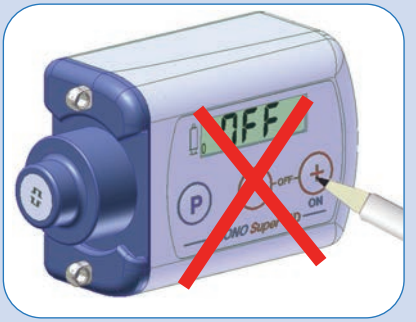


Fig.15



- **The buttons are time-controlled:** keep buttons pressed for a few seconds to activate commands.
- Buttons activation is confirmed by a ticking sound, except when inserting the battery.
- Command execution is confirmed by a brief acoustic signal.
- Before starting the infusion, check that the 10 ml or 20 ml syringe setting has been selected correctly.
- The pump is supplied with a battery already inserted.

LOCK FUNCTIONS

The Crono Super PID pump has 2 lock levels:

• **L 0 (unlocked):** permits complete access to all settings and operating functions.
• **L 1 (locked):** permits restricted control of operating functions.
This table lists the operations that are accessible in each lock level while the pump is in OFF or ON:

Operation and setting	Lock levels	
	L 0	L 1
Start/Stop the pump	YES	YES
Syringe size setting	YES	NO
End of infusion acoustic signal setting	YES	NO
Partial volume setting	YES	NO
Delivery time setting	YES	NO
Prime	YES	YES*
Pusher reversing	YES	YES
Number of infusions delivered	YES	YES

*LIMITATIONS: a maximum of 10 boluses can be administered up to 2 minutes after the infusion started. Any priming outside these two limits will result in error message Er.d.

In lock level L 1 you can re-priming the infusion line each time that you switch ON the pump.

NOTE

• The lock level is stored even after removing the battery.
• When the pump is in lock level L 1, the syringe symbol blinks.

ATTENTION

The information concerning lock level setting is provided separately from the current user guide and is only for the physician.

DEVICE ACTIVATION

1. Insert the battery.

2. The display will show all symbols.

3. At the same time the pump will carry out a self-test, during which acoustic signals are emitted.

4. When the self-test is completed, the pump's mechanical pusher positions itself in the correct starting position and the display will read OFF.

PROGRAMMING

1. Syringe size.
2. End of infusion acoustic signal: OFF/ON.
3. Partial volume.
4. Delivery time.

NOTE 1

Function 1-3 can only be reprogrammed when:
- Pump in OFF.
- Start of a new infusion.
- Pump unlocked.

NOTE 2

Function 4 can only be reprogrammed when:
- Pump in ON.
- Pump unlocked (L 0).

1. Syringe size setting.

- Press the P button for a few seconds: the pump will enter into the setting phase of the syringe size.

- While the syringe size symbol is flashing (the numbers “10” or “20”), the selection of syringe size can be changed from “10” to “20” or from “20” to “10”.

Use the − or + buttons to make your selection.

If the number “10” is flashing, press the + button and keep it pressed for a few seconds until the number “20” appears.

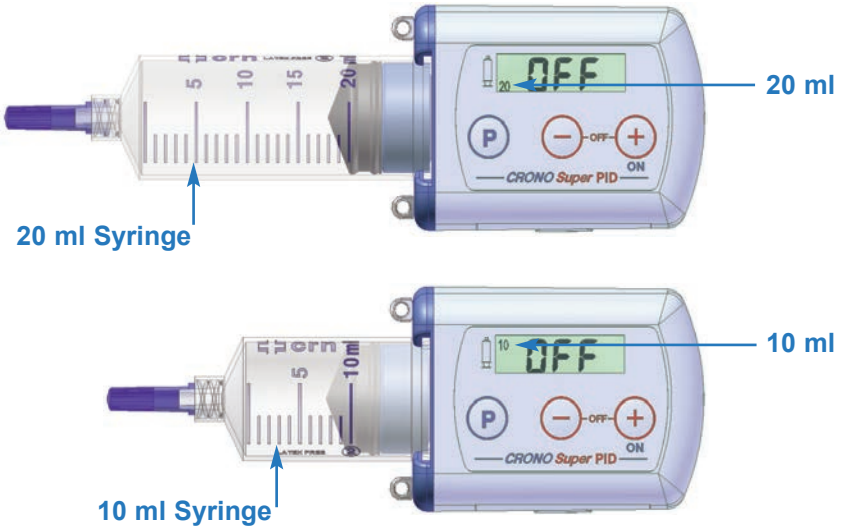
If the number “20” is flashing, press the − button and keep it pressed for a few seconds until the number “10” appears.

10 ml syringe

20 ml syringe

The information regarding the programmed syringe size will always be shown on the display.

Fig.16



The data is not lost when the battery is removed.

2. End of infusion acoustic signal setting.

- After having programmed the syringe size, press the P button while the syringe size is flashing.
- The pump will then enter the setting phase for programming end of infusion acoustic signal.
- While the AL,0 or AL,1 indication is flashing the − and + buttons can be used to change the selection between ON and OFF.

Acoustic signal OFF

Acoustic signal ON

3. Partial volume setting.

- After having programmed the end of infusion acoustic signal, press the P button while the AL,0 or AL,1 is flashing.
- The pump will then enter the setting phase for programming partial volume.
- While the current volume setting is flashing, the − and + buttons can be used to change the partial volume.
- When the buttons are not pushed for a five second period, the changed partial volume is set, the display stops flashing and shows the programmed partial pusher position.
- The pusher moves now automatically to the programmed partial volume position and the display will show the decrease/increase of partial volume as the pusher is moving to its programmed position.
- The display will show OFF when the pusher has reached its programmed position.

NOTE

After installing the battery, the default values for partial volume are:
10 cc for 10 ml syringe.
20 cc for 20 ml syringe.
Partial volume information will be lost when replacing battery.

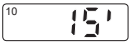
If you have started an infusion and you need to reprogram one or all functions, you will have to switch off the pump and do a total reverse of the pusher (see page 30 for further details).

4. Delivery time setting.

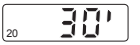
Delivery time can be programmed in the following time intervals:

- Both syringe sizes: from 1 h to 99 h with 15 min steps.

- 10 ml syringe: from 15 min to 1 h,in 5 min steps.



- 20 ml syringe: from 30 min to 1 h,in 5 min steps.



The delivery time can be programmed as follows:

- Push the ⊕ button briefly to start the pump (ON).
- Push either the ⊖ or ⊕ button and the current delivery time starts flashing for 5 seconds.
- When flashing, use the ⊖ button to decrease the delivery time and the ⊕ button to increase the delivery time.
- The new delivery time is set when the display stops flashing.

Continuous button pressure causes a rapid change of the delivery time. When the buttons are not pushed for a five second period, the time is set and the display stops flashing.

NOTE

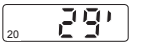
All data will be automatically stored in the memory.

ATTENTION

In case of use of a partial volume the pump can allow the execution of an infusion in less time than the minimum expected (15' for the 10 ml syringe and 30' for the 20ml syringe); this condition is only valid for the infusion in progress, from the next infusion the delivery time automatically returns to the value previously set.

SWITCHING ON THE PUMP

When the ⊕ button is pushed, there is a short acoustic signal and the programmed delivery time will be displayed. During the infusion, the display will show the remaining delivery time as follows:



- Infusion time 15 to 60 minutes: in steps of 1 minute.
- Infusion time 1 to 99 hours: in steps of 15 minutes.

PRIMING THE INFUSION SET

1 - Start the pump by pressing the ⊕ button a few seconds.

2 - If the pusher is not in contact with the rubber plunger, the pusher must be moved forward by pressing the P button. Each push of the P button moves the pusher forward by 0.45 mm corresponding to 0.2 ml.

3 - Repeat this procedure until the priming of the infusion set is completed.

NOTES

A maximum of 10 boluses can be administered in lock level L 1, up to 2 minutes after the infusion started or the last push of the P button. Any priming outside of these two limitations will result in error message Er.d.

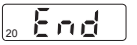
• During priming the flow rate is approximately 122 ml/h.

WARNING

Make sure the infusion set is not connected to the patient during priming!

END OF INFUSION

When the infusion is completed the pump will emit a short acoustic signal (provided that the AL.1 is switched on) and the display will show End.



After a few seconds the pusher will begin returning to the start position. When the pusher has returned to the start position, the display will show OFF and the pump is ready for the next infusion.

SWITCHING OFF THE PUMP

To switch off the pump during the infusion, press the ⊖ and ⊕ buttons simultaneously. The display will show OFF.

PUSHER REVERSING POSSIBILITIES

1. Reverse to starting point.

It is possible to interrupt an infusion already in progress and to reverse the pusher to its starting position:

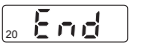
- Switch off the pump by pressing the ⊖ and ⊕ buttons simultaneously.

- Press the Ⓟ and ⊖ buttons simultaneously. The display will show End.

- The pusher will reverse to the starting position.

2. Reverse at END infusion.

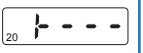
At the end of the infusion the display will show End.



The pusher will automatically return to the starting position. The display will show OFF.

PUSHER MOVEMENTS

When the pusher either moves forwards or backwards, the display will show the symbol indicated in the picture to the right.



END INFUSION ACOUSTIC SIGNAL

At the End of the infusion, the pump will emit an acoustic signal (lasting about 5 seconds).

INFUSION SET OCCLUSION

In the event of an occlusion the pump will emit an acoustic signal, stop and the display will show the symbol indicated in the picture to the right.
Every two minutes the pump will try to start again and provided that the occlusion is eliminated, the pump will continue the delivery but the display will alternatingly flash OCCL and the remaining delivery time until the infusion is finished.

STORING DATA

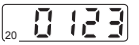
Information regarding the syringe size, acoustic signal of end infusion delivery time and the number of infusion already administered, are automatically stored in the memory.

Stored data is not lost even if the battery is removed.

Partial volume information will be lost when replacing battery.

READING THE NUMBER OF INFUSIONS

Press the ⊖ button for 8 seconds and the display will show the number of infusions already administered as indicated in the picture to the right.



LOW BATTERY ALERT

The LOW BATTERY symbol will appear on the display to indicate that the battery level is low and the battery should therefore be changed as soon as possible.

If the battery is not replaced shortly after the display warning, the infusion could be interrupted.

If the battery fails completely, the display will show the symbol for “BATTERY DISCHARGED”, the pump will stop and the battery has to be replaced in order to be able to continue the infusion.

BATTERY REPLACEMENT

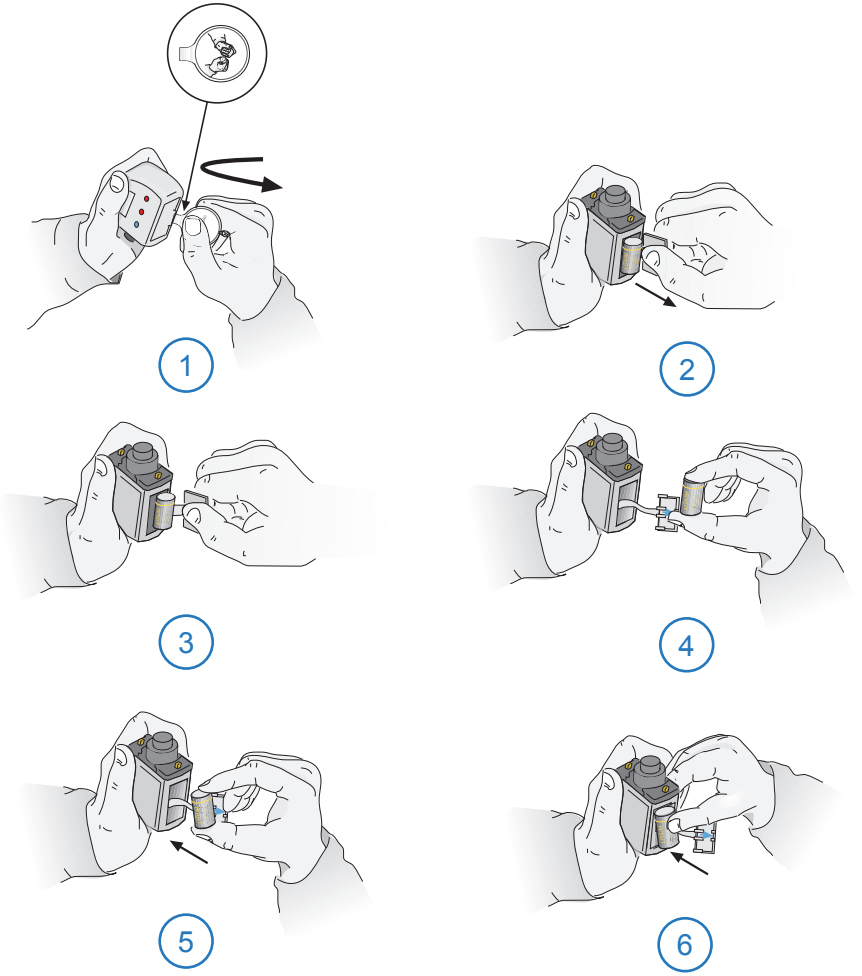
1. Open the battery compartment using the PID battery tool for this purpose.
2. Pull out the cover.
3. Use the small ribbon strap (which lies under the battery) to facilitate the removal of the battery.
4. Remove the discharged battery and discard it properly.
5. Insert the new battery checking that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

If you do not manage to remove the battery using the ribbon strap, do not try to lift the battery with any other object, but do the following:

- Hold the pump firmly in your right hand.
- Tap your right hand on the palm of your left hand until the battery falls out.

BATTERY REPLACEMENT

Fig.17



CAUTIONS

- Use only a lithium 3 Volt CR 123 A battery.
- Batteries other than this type may cause the pump to malfunction.
- Batteries of the above-mentioned type are available in most retail shops.
- During average operating conditions, each battery should last about 150 infusions. Keep a spare battery in a convenient place.
- If the pump is not used for a longer time period, it is best to remove the battery from the pump.
- Remove the pump before taking a bath or shower; the pump may be damaged upon contact with water. If the pump should accidentally come into contact with any liquid (drug solution, sweat, bed wetting) the pump must be checked by the manufacturer or a qualified person authorised by the manufacturer.
- If you suspect that liquid has penetrated into the pump (a leakage or spill), the pump must be checked by the manufacturer or a qualified person authorised by the manufacturer.
- The pump must be kept away from:
  - heating devices (radiators, ovens, stoves);
  - high electromagnetic fields (magnets, loud-speakers, portable radio devices);
  - direct sunlight.
- Keep the pump, and the infusion set when the device is in use, out of the reach of pets or small children. If the settings lock is not active, pay special attention that the settings are not changed unknowingly.
- The pump does not need to be sterilized.
- Syringes, infusion set, and all material used during the infusion process must be discarded properly.

MAINTENANCE AND REPAIR

The CANÈ S.p.A. Medical Technology Company, manufacturer of the Crono model ambulatory infusion pumps, declares that the devices do not need programmed service maintenance if used in conformity with the user guide.

If the pump malfunctions or is damaged the pump has to be returned to the distributor of PID pumps in the country in which it is purchased for forwarding to the manufacturer. The local distributor will provide a loaner pump free of charge until the original pump is repaired and returned.

During the warranty period all repair costs are free of charge.

CLEANING AND DISINFECTION

The infusion pump is a reusable medical device that should be kept clean. The pump must be regularly cleaned in the following way:

Suggested equipment:

- disposable gauzes
- mild neutral detergent
- 70% isopropyl alcohol (IPA) disinfectant
- water at room temperature.

Procedure:

1) Dampen a gauze with water mixed with the detergent, and wipe the outer pump surfaces.
2) Moisten a gauze with water and wipe to remove any detergent residue, then dry with a new gauze.
3) Moisten a gauze with the disinfectant and wipe the outer pump surfaces.
4) After evaporation of the disinfectant, wipe with a moist gauze to remove any residue of disinfectant from the outer pump surface, then dry with a new gauze.

Attention:

- The infusion pump must not be immersed in fluids.
- Should the device get wet, dry it immediately with paper towels to avoid the penetration of liquids into the infusion pump.
- Disinfect the pump before changing the user.
- Do not clean the pump with acetone, solvents or abrasive detergents.
- Do not sterilize the pump.

STORAGE

If the pump is not going to be used for a longer time period (more than 1 or 2 months), it is advisable to remove the battery, put it inside the device case and store it in a dry place.

PUMP LIFE

The accuracy and safe functioning of the pump are guaranteed for 4 years.

SECTION 12

USER ASSISTANCE INFORMATION

Customer Service Assistance
Intra Pump Infusion Systems
401 Southwestern Blvd., Suite 160
Coppell, TX 75019 USA
Tel: 1-866-211-7867
www.intrapump.com

MANUFACTURER'S GUARANTEE

CANÈ S.p.A. guarantees that this product is free from defects in materials and workmanship for a period of 2 (TWO) YEARS beginning from the date of purchase.
If during this warranty period the product proves defective due to improper materials or workmanship, CANÈ S.p.A. will, without charge for labour or parts, repair or replace the defective parts upon the terms and conditions set out below.
CANÈ S.p.A. reserves the right to modify the characteristics or the model of the pump and accessories without obligation to make similar modifications to pumps and accessories previously manufactured or sold.

Conditions:

1. The warranty is only valid if the defect is brought to the attention of CANÈ S.p.A.
2. The warranty does neither reimburse nor cover costs for pumps and accessories which have been damaged as a result of modifications or adjustments made without prior written consent from CANÈ S.p.A. This conforms to the national or local technical or safety standards in force in any country.
3. This guarantee will not apply if the type or serial number on the product has been altered, deleted, removed or made illegible.
4. This warranty does not cover any of the following:
   - Periodic maintenance
   - Damage resulting from misuse, including but not limited to:
     - Failure to use the product for its normal purpose or in accordance with this user's guide.
     - Repair done by non-authorized institutions or persons.
     - Accidental events like falling down, liquid infiltration.
5. CANÈ S.p.A. will aim to carry out repairs to the *CRONO Super* PID pumps over a period not in excess of 4 YEARS, as from the date of purchase. After 4 years, CANÈ S.p.A. will no longer be obliged to make any repairs.
   CANÈ S.p.A. is not responsible towards the purchaser or third parties for any damage deriving from the use of the pump after 4 YEARS as from the date of purchase.

ALARM MESSAGES

ALARM MESSAGES	DESCRIPTION	ACTION
	UNFEASABLE OPERATION	----------
	INCORRECT RESET	RESTART DEVICE*
	CRITICAL CONDITION OF THE SECURITY SYROD	PRESS BUTTON 
	IRREGULARITY OF THE MOTOR CIRCUIT	PRESS BUTTON 
	MECHANICAL BLOCK DURING "END" PHASE CAUSED BY FOREIGN MATTER OBSTRUCTING THE PUSHER'S REVERSAL	1. REMOVE THE CAUSE 2. RESTART DEVICE*
	IRREGULARITY OF THE PUSHER ADVANCEMENT	PRESS BUTTON 
	OCCLUSION	PRESS BUTTON 
	READING MEMORY ERROR (EEPROM)	RESTART DEVICE*
	ERROR WITHIN THE MOTOR PILOTING CIRCUIT	RESTART DEVICE*
	UNFEASIBLE OPERATION Ⓟ BUTTON LOCKED	REFER TO USER GUIDE
	UNFEASIBLE OPERATION PUMP LOCKED	----------

Alarm messages are accompanied by audible signals.

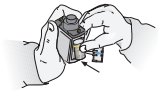
*To restart the device following an alarm message, remove the battery and wait at least 15 seconds before replacing the battery.
*Please note: if your pump shows Err8, and you subsequently re-start it, the programmed settings will revert to the factory settings (see page 8). Therefore, whenever this condition takes place, you must re-program the settings assigned by your doctor or PD nurse.
No intentional delays have been introduced into the alarms, which are raised as soon as the safety system detects them.

If the device will not re-start, contact your authorized distributor.

SUMMARY OF FUNCTIONS AND BUTTONS

Keep buttons depressed for a few seconds to activate commands.

BATTERY COMPARTMENT



BATTERY INSERTION PHASE	SCREEN
• Pump safety test	88.88
• Pusher self-adjust	- - -
• Pump switches OFF	OFF

PUMP OFF

BUTTONS	PROGRAMMING	SCREEN
	Conditions for programming: - Pump in OFF; - Start of a new infusion; - Pump unlocked;	
p 1st depressing	• Syringe size setting (10 / 20 ml)	
p 2nd depressing	• End of infusion acoustic signal setting: OFF / ON	ALO / AL.1
p 3rd depressing	• Partial volume setting: 1-20 ml in steps of 1 ml	Pcc
− / +	• Decrease/Increase above parameters	
	PUSHER REVERSING / NUMBER OF INFUSIONS DELIVERED	
p and − depress simultaneously	• Pusher reversing to the infusion starting position	End - - - OFF
− depressed for 8 seconds	• Number of infusions delivered	0015
	PUMP ON	
+	• Pump switches ON	30'

PUMP ON

BUTTONS	PRIME	SCREEN
p	• Pump unlocked: 0.2 ml each depressing • Pump locked: maximum 10 boluses or 2 minutes for priming	- - -
	PROGRAMMING	
− / +	• Delivery time setting (pump unlocked): - from 1 h to 99 h with 15 min steps - from 15 min to 1 h with 5 min steps (10 ml syringe) - from 30 min to 1 h with 5 min steps (20 ml syringe)	10.15 30'
	PUMP OFF	
− and + depress simultaneously	• Pump switches OFF	OFF

END OF INFUSION

	SCREEN
• End of infusion	End
• Pusher automatic reversing	- - -
• Automatic switch OFF	OFF

PUMP ICON TABLE

SN	**Pump serial number**
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.
Rx ONLY	**For use with doctor's prescription only**
CE 0476	**CE Marking**
	**Medical electrical equipment** Type BF
	**Warning: read instructions befor use**
	**Manufacturing date**
	**Manufacturer**

Separated waste collection of electrical and electronic equipment

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

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 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 follow the system devised to allow for the separate disposal of devices at the end of their life. A proper waste sorting system for the devices destined for recycling, treatment and environmentally compatible disposal helps reduce the potentially negative impact on the environment and health, and facilitates the re-use or recycling of the materials the device is made of. The illegal disposal of a product is punished by administrative penalties as provided in the applicable regulations.

SYRINGE BLISTER ICON TABLE

	Read the instructions
CE 0123	CE mark
	Recycle
	Do not reuse this device
	Pyrogen free
	Protection against moisture
	Do not expose to direct sunlight
	Expiration date
STERILE EO	Sterilized with Ethylene oxide
PP	Polypropylene
LOT	Lot number
REF	Ref number
Rx ONLY	For use with doctor's prescription only
	Latex Free
	Do not use if package is damaged
	Manufacturer

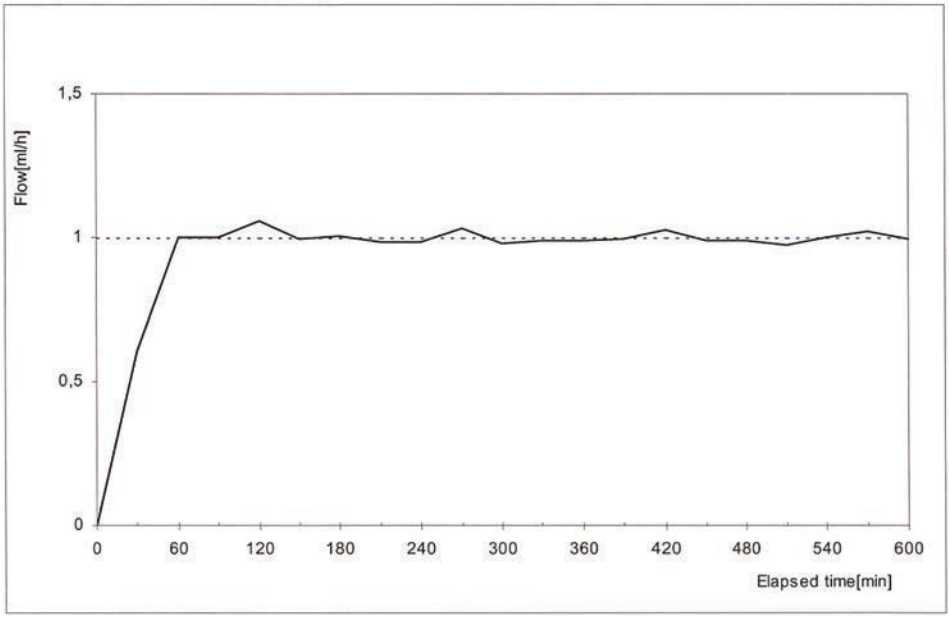
INDEX OF ILLUSTRATIONS

PRECISION TEST

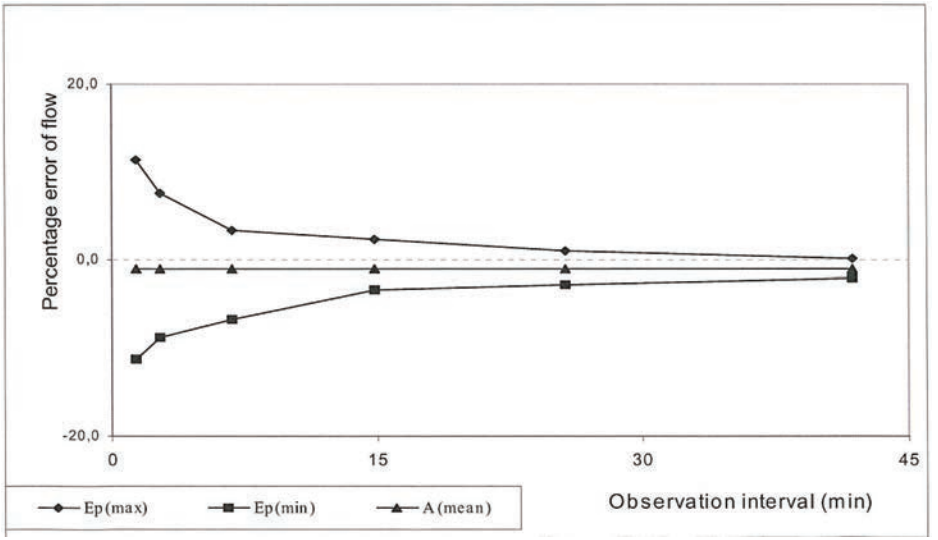
Tests have been conducted according to IEC 60601-2-24 standard, Medical electrical equipment, Part 2: Particular requirements for the safety of infusion pumps and controllers. The following graphs show the precision of the pump in the drug administration.

1.1 – Start-up flow rate

• Delivery time setting: 20 h (equivalent to a flow rate of 1 ml/h for a 20 ml syringe).



1.2 - Flow rate error (trumpet curve)
Delivery time setting: 20 h (equivalent to a flow rate of 1 ml/h for a 20 ml syringe).



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

Legend:
Ep(max.) = maximal percentage variations.
Ep(min.) = minimal percentage variations.
A(mean.) = mean percentage variations.

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. The lower the flow rate, the longer will be 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 syringe to signal the occlusion.

Flow rate	Time needed to signal an occlusion
1 ml/h	About 1h and 15 minutes

ATTENTION

• 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 the CRONO Super PID, post-occlusion bolus, considering only the combined volume of the pump and syringe, is approximately 0.9 ml.

ATTENTION

• 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.

ELECTROMAGNETIC COMPATIBILITY

The electromagnetic 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 60601-1-2:2014, Medical electrical equipment, Part 1: General requirements for basic safety – collateral standard: Electromagnetic compatibility – Requirements and tests.

Guide and declaration by the manufacturer - electromagnetic emissions		
CRONO Super PID is designed to operate in the electromagnetic environment specified below. The client or user of CRONO Super PID must ensure that it is operated in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guide**
Emissions in RF CISPR 11	Group 1	CRONO Super PID 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.
Emissions in RF CISPR 11	Class B	CRONO Super PID is designed for use in all environments, including domestic environments and those environments directly linked to the low voltage mains supplying residential buildings.
Harmonic emissions IEC 61000-3-2	N/A	
IEC 61000-3-3 emissions in the event of voltage fluctuations or flicker	N/A	

Guide and declaration by the manufacturer - electromagnetic immunity			
CRONO Super PID is designed to operate in the electromagnetic environment specified below. The client or user of CRONO Super PID 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 electrostatic discharge (ESD)	15 kV in air 8 kV by contact	15 kV in air 8 kV by contact	The flooring material must be wood, concrete or ceramic. If the floor is covered in a synthetic material, the relative humidity must be at least 30%.
Electromagnetic fields	400 A/m 50 and 60 Hz	400 A/m 50 and 60 Hz	

Guide and declaration by the manufacturer - electromagnetic immunity			
CRONO Super PID is designed to operate in the electromagnetic environment specified below. The client or user of CRONO Super PID 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 10 V/m AM 80% 1 KHz	10 V/m	Interference could occur in the vicinity of devices marked with the following symbol: 

Recommended separation distance between mobile and portable radio communication devices and the CRONO Super PID		
CRONO Super PID is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The client or user of CRONO Super PID can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable communication devices using RF (transmitters) and the CRONO Super PID 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)**	
	80 MHz to 800 MHz	**800 MHz to 2500 MHz**
0,01	0,12	0,23
0,1	0,38	0,73
1	1,2	2,3
10	3,8	7,3
100	12	23

REFERENCE DIRECTIVES

• Council Directive 93/42/EEC: 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.

TECHNICAL STANDARDS

IEC 60601-1:2005/AMD1:2012 Medical electrical equipment, Part 1: general requirements for basic safety and essential efficacy.

IEC 60601-1-2:2014 Medical electrical equipment Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-1-11: 2015 General requirements for basic safety and essential performance - Collateral Standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

IEC 60601-2-24:2012 Particular requirements for the basic safety and essential performance of infusion pumps and controllers.

IEC 60529:1989/AMD2:2013 Degrees of protection provided by enclosures.