

CRONO-Super PID

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ONO Super PID

USER'S GUIDE

Ambulatory infusion pump



CRONO Super PID

USER'S GUIDE



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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 reparations 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 Assistance Service

Intra Pump Infusion Systems 920 Minters Chapel Rd, Suite 200 Grapevine, TX 76051 Tel: 866-211-7867 Fax: (630) 845-2768 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 automati- cally stored in the pump's memory. The data is not lost even if the bat- tery 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.
Operating conditions	+10 °C /+45 °C 30%/75%RH 700 hPa /1060 hPa.
Storage conditions	-10 °C /+60 °C 10%/100%RH 500 hPa /1060 hPa.

STANDARD EQUIPMENT SUPPLIED

- 1. Ambulatory infusion pump (Code: CRONO Super PID English).
- 2. Pump case (Code:VAL/01).
- **3.** Elastic belt (Code:CM/01).
- 4. Collar strap (Code:CM/03).
- 5. Fabric holder (Code:CM/02).
- 6. 2 batteries one already inserted in the pump -(Code:CR/123A).
- 7. User's guide.
- 8. Battery tool (Code:CA/02).



OPTIONAL ACCESSORIES

Optional accessories are available upon request:

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

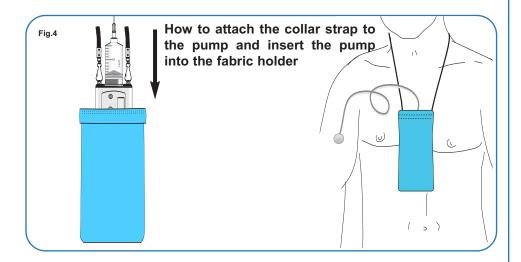


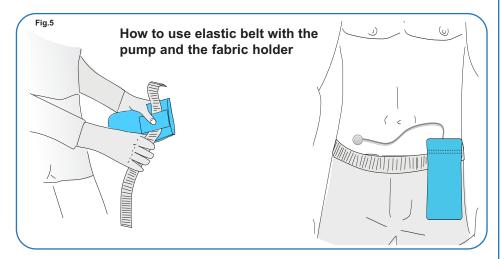
2. Lengthwise leatherette case similar to a glasses case with a belt loop (Code: CM/14).



HOW TO USE THE STANDARD EQUIPMENT SUPPLIED

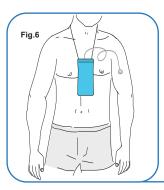
The following pictures show how the pump and its accessories should be used.





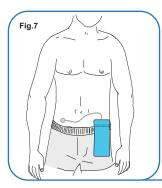
HOW TO WEAR THE PUMP

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



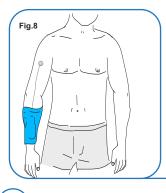
WEARING THE PUMP AROUND THE NECK

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



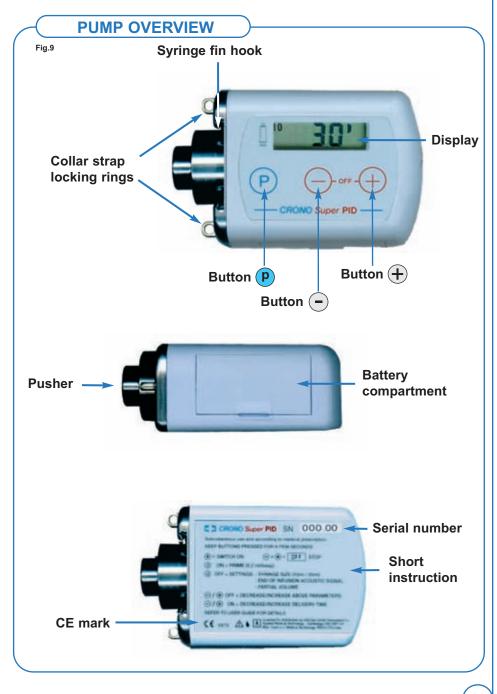
WEARING THE PUMP AT THE WAIST

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).



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

20 30'	PROGRAMMED DELIVERY TIME AND REMAINING DELIVERY TIME
20 DF F	PUMP OFF
20	SELECTED SYRINGE SIZE (10 OR 20 ML)
20 AL. 1	END INFUSION ACOUSTIC SIGNAL (ON)
	END INFUSION ACOUSTIC SIGNAL (OFF)
	ERROR MESSAGE
20	FORWARDS/BACKWARDS MOVEMENTS OF THE PUSHER
20 End	END INFUSION
20	LOW BATTERY
	BATTERY DISCHARGED
20 123	NUMBER OF INFUSIONS
	BEGINING OF PARTIAL VOLUME PHASE
20 18 cc	PARTIAL VOLUME POSITIONING INDICATION (EXAMPLE)
20	PUMP UNLOCKED INDICATION
20	PUMP LOCKED INDICATION

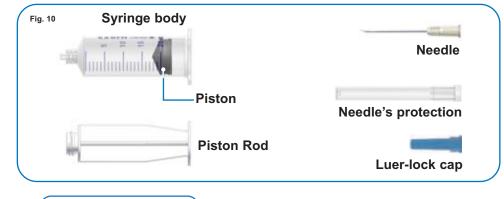
SYRINGE PARTS

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

- CRN[®] 10 ml CRONO[®] PID Syringe
- CRN[®] 20 ml CRONO[®] PID Syringe

The syringes are:

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



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 nonoriginal syringes different from those recommended.

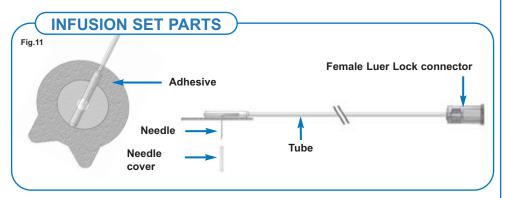
USE OF LUER LOCK CAP

- Replace the luer-lock cap on the syringe after the syringe has been filled and the filling needle removed.
- 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 SITES

Infusion sites can be any of the following:

- Anterior area of upper arm.
- Anterior abdominal wall.
- Anterior area of thighs.

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

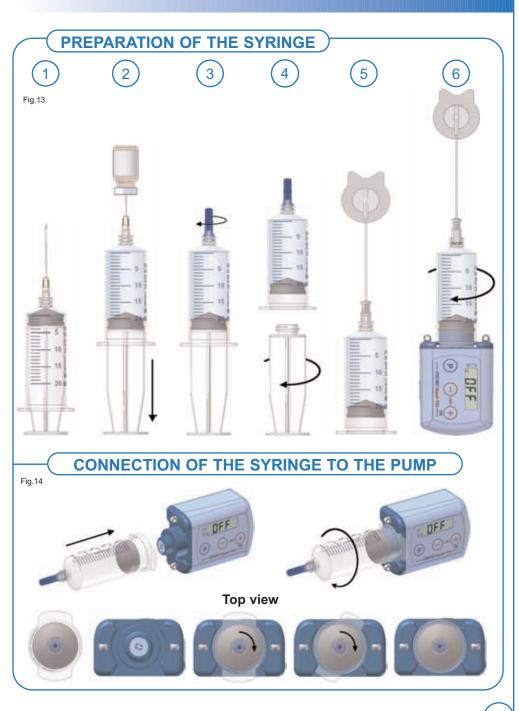


Before preparing the pump for the infusion, it is advisable to follow these precautions:

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

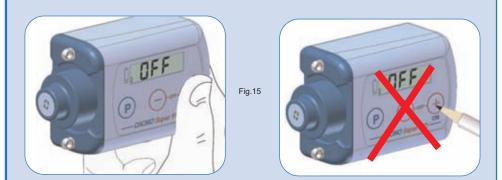
PREPARATION OF THE SYRINGE

- 1. Attach the supplied needle to the syringe with a clockwise rotation.
- 2. Draw up the infusion solution slowly. Do not overfill the 10 ml or 20 ml syringes.
- 3. Attach the luer-lock cap.
- **4.** Unscrew the rod of the syringe with a counter-clockwise rotation with a fairly swift movement.
- 5. Attach the infusion set to the syringe.
- 6. Attach the syringe to the pump by turning it 90°. You will hear a click when the syringe is securely in place.



WORKING INSTRUCTIONS

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



- 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
Partilal volume setting	YES	NO
Delivery time setting	YES	NO
Prime	YES	YES*
Pusher reversing	YES	YES
Number of infusion 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 informations concerning lock level setting are provided separately from the current user guide and are 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 position 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".

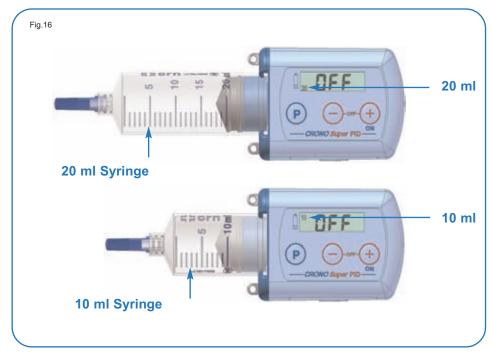
Use the e or to buttons to make your selection.

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

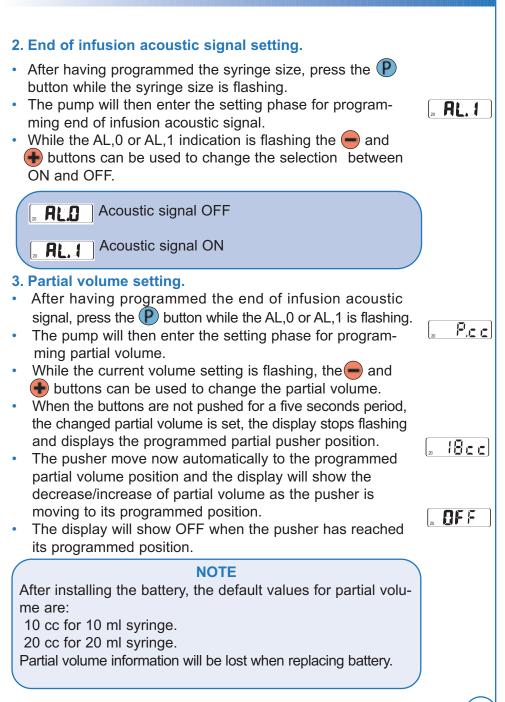
If the number "20" is flashing, press the button and keep it pressed for a few seconds until the number "10" appears.

10 ml syringe	20 ml syringe

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



The data are not lost when the battery is removed.



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 to 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 dislay stops flashing.

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

NOTE

All date 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 301 and the programmed delivery time will be displayed. During the infusion, the display will show the remaning delivery time as follow: יובייבן Infusion time 15 to 60 minutes: in steps of 1 minute. Infusion time 1 to 99 hours: in steps of 15 minute. 9,15 **PRIMING THE INFUSION SET** 1- Start the pump by pressing the 🛖 button a few seconds. 10.15 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. NOTE 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 d button. Any priming outside of these two limitations will result in error message Er.d. 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 displaywill 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
 and
 simultaneously.
- Press the P and buttons simultaneously. The display will show END.
- The pusher will reverse to the starting position.

2. Reverse at END infusion.

29

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.



l. Fod

AF E

RF F

End





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. **HEEL** Every two minutes the pump will try to start again and provided ¹ 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 e button for 8 seconds and the display will show . I leave 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.

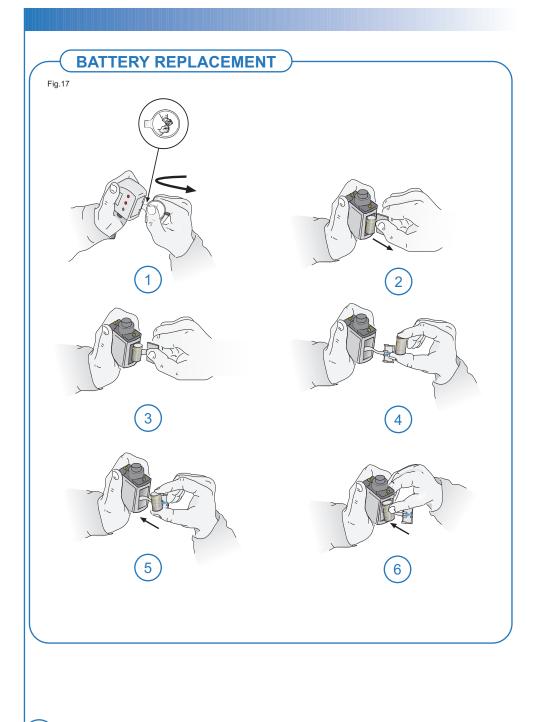


BATTERY REPLACEMENT

- 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.



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.
- The pump does not need to be sterilized.
- Syringes, infusion set, needles 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 ambulatory infusion pumps Crono model, declare 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

The exterior shell of the pump can be cleaned with a damp, soft cloth. Do not use alcohol or other solutions and make sure that no liquid penetrates 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.

USER ASSISTANCE INFORMATION

Customer Assistance Service

Intra Pump Infusion Systems 920 Minters Chapel Rd, Suite 200 Grapevine, TX 76051 Tel: 866-211-7867 Fax: (630) 845-2768 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.

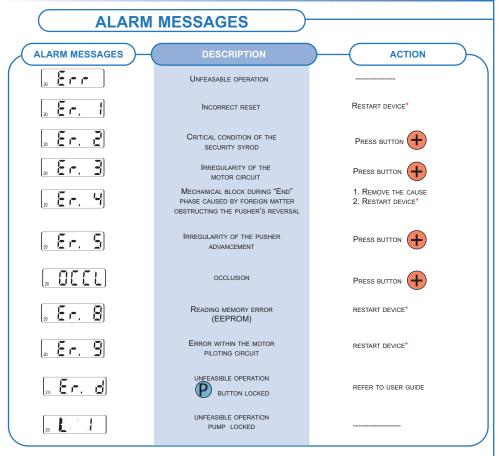
CANÈ S.p.A. reserves the right to modify the characteristics or the model of the pump and accessories without obligation to make similar modifications to pumps and accessories previously manufactured or sold.

Conditions:

- 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.
- 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.

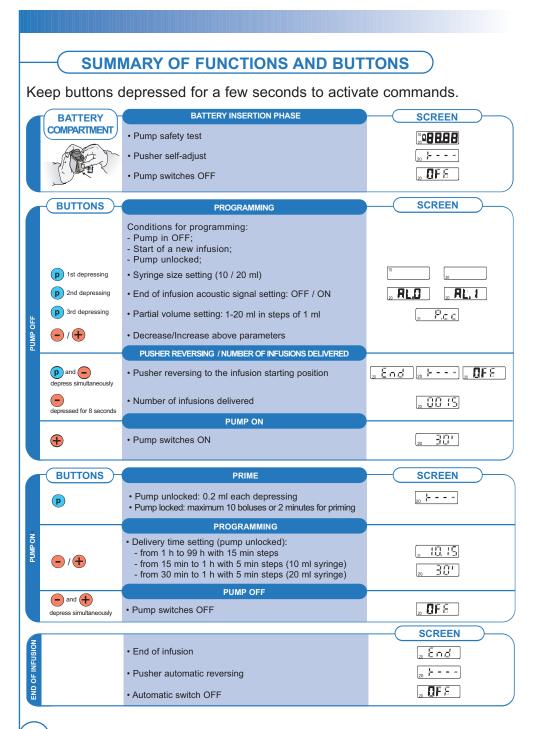


Alarm messages are accompanied by audible signals.

*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.

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



X	Dispose of used electric and electronic devi- ces in an environmentally safe manner, using the appropriate containers and according to any regulations that may apply.
	Warning: see instructions for use
*	Electro medical equipment BF type
CE 0476	CE Mark
	Drip-proof instrument It can withstand occasional liquid dripping. It must not be immersed in liquid.
SN	Pump serial number
	PUMP ICON TABLE

SYRIN	
	Read the instructions
CE 012	CE mark
Õ	Recycle
2	Do not reuse this device
PYNGGEN	Pyrogen free
Ť	Protection against moisture
淡	Do not expose to direct sunlight
	Expiration date
STERILE EO	Sterilized with Ethylene oxide
PP	Polypropylene
LOT	Lot number
REF	Ref number
NEEDLE	Needle dimensions

STATEMENT OF CONFORMITY

CE 0476

CANÈ S.p.A. is a registered office with its headquarters in Rivoli (TO) Italy, Via Cuorgnè 42/a. CANÈ S.p.A. is the manufacturer of portable, electrically-operated ambulatory infusion pump *CRONO Super* PID.



Serial number Manufacturing date

CANÈ S.p.A. declares that this product conforms to the safety provisions as set out in Annex II, risk class IIb, following the directive 93/42/EEC dated 14 June 1993 as certification N. MED-9813 issued by Notified Body 0476.

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