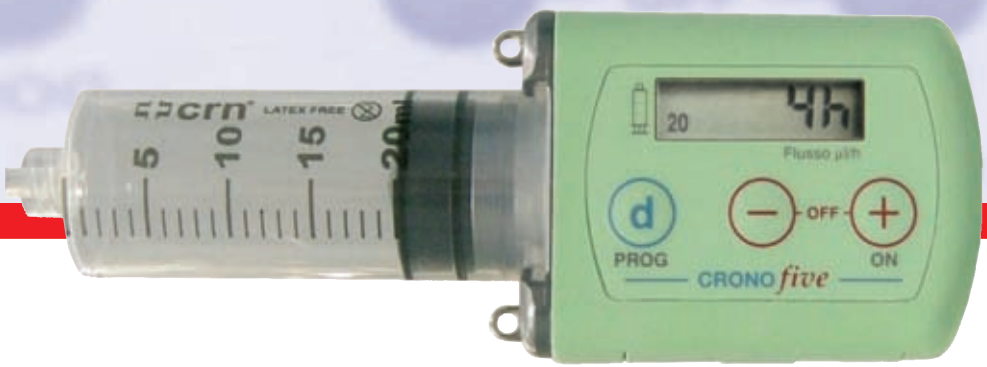
PATIENT USER GUIDE



CRONO *five*

CANE

MEDICAL TECHNOLOGY

CRONO five

PATIENT USER GUIDE

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SECTION 1

INTRODUCTION

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

The instructions included in this manual are intended only for the ambulatory drug infusion pump CRONO Five and are addressed to the pump user.

The pump is provided with key-pad lock-out in order to avoid accidental or non authorised variations of the selected parameters.

The information as to lock or unlock the key-pad are exclusively addressed to the physician.

When the key-pad is locked any attempt to modify the protected parameters will cause the indication Lo,1 to appear on the screen.

WARNINGS

Do not use the Crono Five without first reading and understanding the complete pump user guide. Improper programming and/or incomplete understanding of the operating functions and of the warnings could result in death or serious injury to the patient.

Keep the user guide together with the pump for references.

Before using the pump for a specific infusion therapy check the suitability of the device for the use and for the patient considering carefully the following aspects:

- the technical specifications of the pump;
- the infusion set that will be used;
- the eventual use of infusion set with various lines and clamps along the infusion line;
- the kind of therapy for which the patient has to undergo;
- the psycho-physical and cognitive condition of the patient.

The above list given is only an illustration, not exhaustive, concerning the procedural clinical aspect whose responsibility is on the part of the doctor or the medical assistant.

The pump must be used:
- under strict medical control,
- using proper procedure and suitable measure to the patient that could suffer serious consequences (injury or death) following involuntary misuse and/or device failure with consequently interruption of the drug administration.

Do not prime any kind of tubing when connected to a patient, as this could result in over-delivery of medication and air embolism.

Eliminate all air bubbles in all lines before starting an infusion to avoid air embolism.

Inspect the whole fluid path for kinks or closed clamps or any other obstruction before the infusion is started.

Accuracy, time to an occlusion alarm signal and post-occlusion bolus size may deviate from the information in this user guide depending on which type of extension set, tubing and access devices are used for the administration of a medication (details are supplied on ANNEX 1, 2 and 3).

The improper connection between the syringe piston and the pump pus her can cause a free flow of medication, in other words, medication administered by gravity and not controlled by the pump, (for example when the pump is positioned much higher than the infusion site). Such situation can cause serious injury or death of the patient. Please refer to Section 5 of this User Guide for detailed instructions of Safety System to Avoid Free-Flow.

For patients that are likely to be adversely af fected by interrupted medica - tion or fluid delivery from Crono Five, close supervision for immediate cor - rective action should be provided.
If you know or suspect that the pump has been damaged in any way for example through water or impact, please contact your local Customer

Service representative to verify if the pump is operational. Do not use a pump that is damaged.

Liquid on the outside of the pump should be wiped off immediately with a soft cloth. Please observe that any liquid penetrating the pump can cause serious damage to the pumps' electronic circuits.

Epidural drug infusions delivering drugs dif ferent from the ones specifically indicated for those kinds of administrations can cause serious lesions or death.

CANÈ S.p.A. recommends an annual check up on all Crono Five pumps with the aim of evaluating the correct function and accuracy . Such check ups must be carried out only by CAN È S.p.A. or an authorized distributors.

NOTE

The manufacturer only takes the responsibility for the safety and reliability of this pump, provided that it is used in accordance with the current instructions for use and only in case any repairs and changes to the device are made exclusively by the manufacturer.

INTENDED USE

The ambulatory infusion pump of drug Crono Five has been designed to be used in the pain treatment for subcutaneous, intravenous and epidural infusions.

The pump is not designed for life sustaining treatments.

INFORMATION – TECHNICAL ASSISTANCE

For further information, technical assistance or if you have questions concerning the operation of the pump, please contact:

UNITED STATES:
INTRA PUMP INFUSION SYSTEMS
920 Minters Chapel Road, Suite 200
Grapevine, Texas 76051
Tel: 866-211-7867
Fax: 630-845-2768
Email: info@intrapump.com

MANUFACTURER:
CANÈ S.p.A. MEDICAL TECHNOLOGY
Via Cuorgnè, 42/a 10098 Rivoli (TORINO) Italy
Tel: 0039-011-9574872
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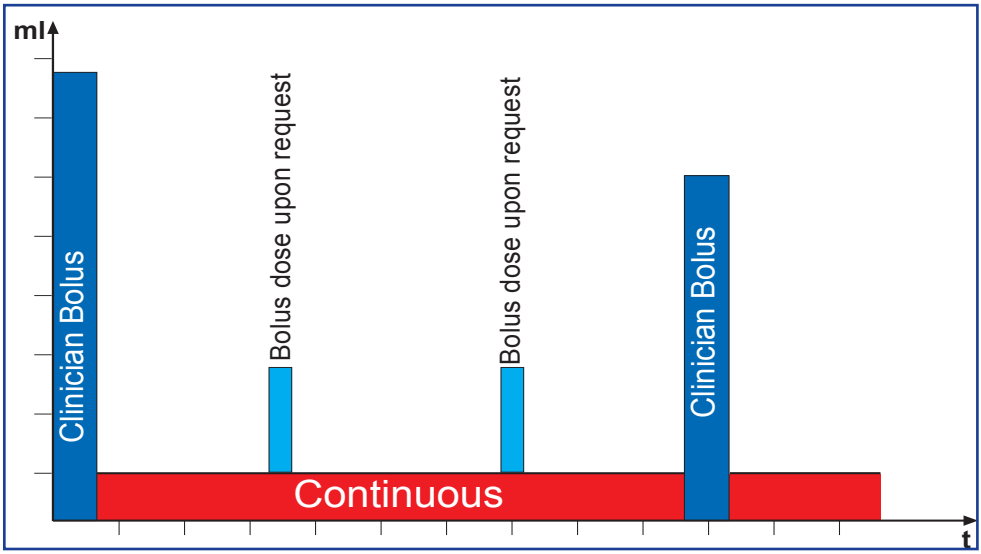
DESCRIPTION OF THE PUMP

CRONO Five is a new , innovative PCA pump that is very appreciated by health care professionals and patients due to its small size and technical features.
CRONO Five is an ambulatory infusion pump especially suited for control - led drug administration on patients in hospital or undergoing a therapy at home.
The pump is suitable for subcutaneous, intravenous and epidural infusions allowing 4 different administration modalities:

1. Continuous
2. Bolus dose upon request (PCA)
3. Clinician bolus (managed by clinician)
4. Combined (continuous + bolus upon request + clinician bolus)

The chart below explains the different combined methods of administration.



The pump is provided with key-pad lock-out functions in order to avoid un-authorized reprogramming of the drug administration protocol.
The liquid crystal display (LCD) shows the information which are helpful both for the clinician and the patient like programming, reading of administered drug volumes and control functions of the pump.

INFUSION SYSTEM

The pump administers shots of 5 microliters (µl or mcl) for any given flow rate. The time interval between shots decrease proportionally to increases in programmed flow rates.

TECHNICAL FEATURES

Pump size	77 x 47 x 29 mm.
Weight	115 g (battery included).
Battery	CR 123A 3V Lithium battery (battery life: about 6 months).
Syringe	Dedicated 10 and 20 ml capacity with luer-lock connector.
Administration volumes	From 1 ml to 20 ml with increments of 1 ml.
Priming	Available only at the beginning of an infusion or partial infusion. The maximum deliverable volume is 1.5 ml with 0.5 ml increments.
Flow rate	Programmable from 5 to 5000 mcl/h with the following increments: - from 5 to 1000 mcl/h with 5 mcl/h increments; - from 1000 to 5000 mcl/h with 10 mcl/h increments; The flow rate can be programmed to 0 ml.
Bolus dose	Programmable from 0.01 to 2.00 ml with 0.01 ml increments: The bolus dose can be programmed to 0 ml.
Clinician bolus	Programmable from 0.01 to 2.00 ml with 0.01 ml increments: This function is always locked.
Minimum time between bolus doses	Programmable from 5' to 24 h as follows: - from 5' to 1h with increments of 5'; - from 1 h to 24 h with increments of 15'; - this function can be deactivated by programming 0.

Number of boluses doses per hour	- from 1 to 12 boluses. - this function can be deactivated by programming 0.
Flow accuracy	+/-2% (observation period 40 minutes).
Max. occlusion pressure	2.2 bar +/-0.8.
Time to an occlusion alarm	Please, see ANNEX 2.
Post-occlusion bolus	About 0.4 ml (details are supplied on ANNEX 3).
Electric circuit	Electric circuit managed by a micro controller equipped with a dedicated software.
Data storage	The selected data are automatically stored in the pump memory and they are not lost when the battery is removed.
Display	LCD.
Motor	Direct current coreless motor.The microcontroller manages the rotation through infrared encoder.
Safety circuits	To monitor the correct working of the device intervening in case of anomalies with acoustic warnings and error messages.
Anti free-flow system	To avoid a non controlled flow inside the delivery set due to the force of gravity.
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

FACTORY SETTINGS

The following factory settings are programmed at the delivery of the pump:

Key-pad lock-out level	L 0
Syringe	20 ml
Flow rate	1000 mcl/h
Bolus dose	0.2 ml
Interval between bolus doses	1 h
Number of bolus doses in 1 hour	1
Clinician Bolus	0.00 ml
Number of infusions	0

STANDARD EQUIPMENT SUPPLIED

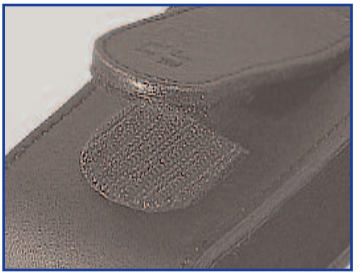
1. Ambulatory infusion pump.
2. Pump case.
3. Elastic belt.
4. Collar strap.
5. Fabric holder.
6. 2 batteries (one already inserted in the pump).
7. Battery tool.
8. User guide.

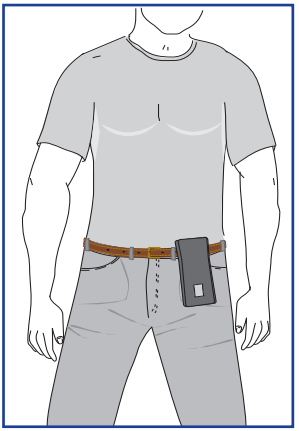
OPTIONAL ACCESSORIES

Heightwise leatherette case similar to a cellular phone holder.

Detail
belt clip

Detail
opening





Color: black

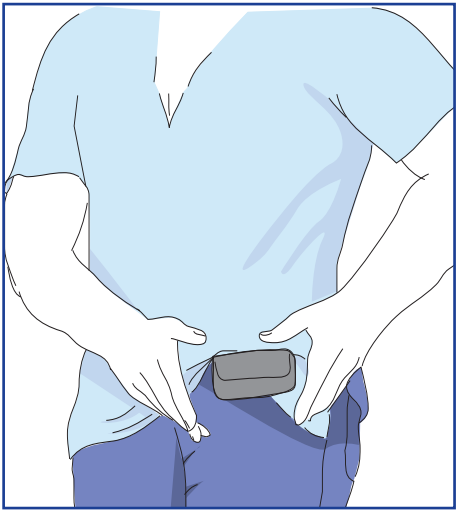
Size: 14 x 5,5 x 4 cm

Weight: about 36 g

Article code: CM/15

Lengthwise leatherette case similar to a glasses case.

Detail of belt loop



Color: black

Size: 13 x 5,5 x 4 cm

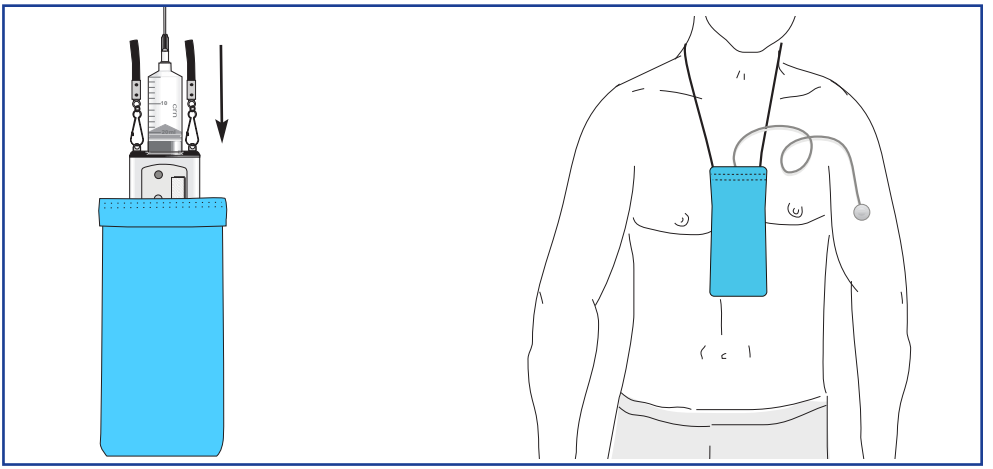
Weight:: About 50 g.

Article code: CM/14

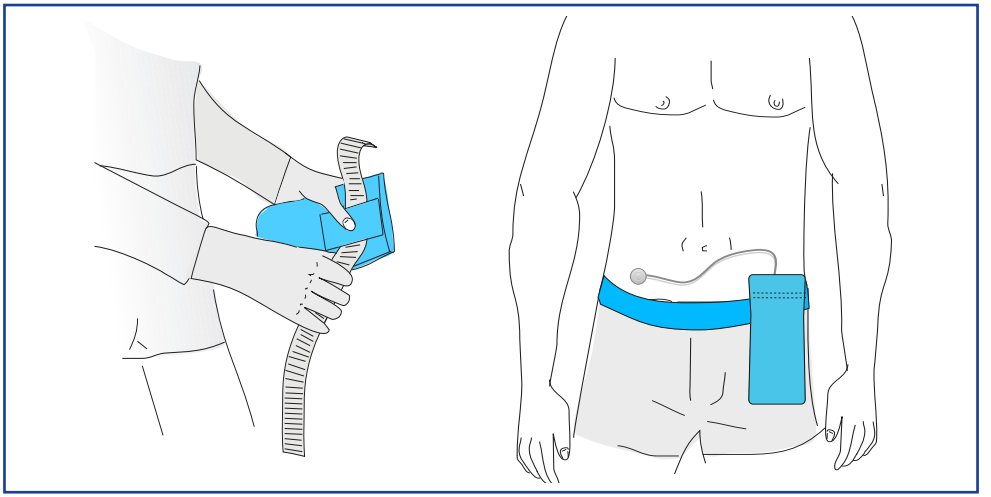
HOW TO USE THE STANDARD EQUIPMENT SUPPLIED

The following illustrations show how the pump and its accessories can be set up.

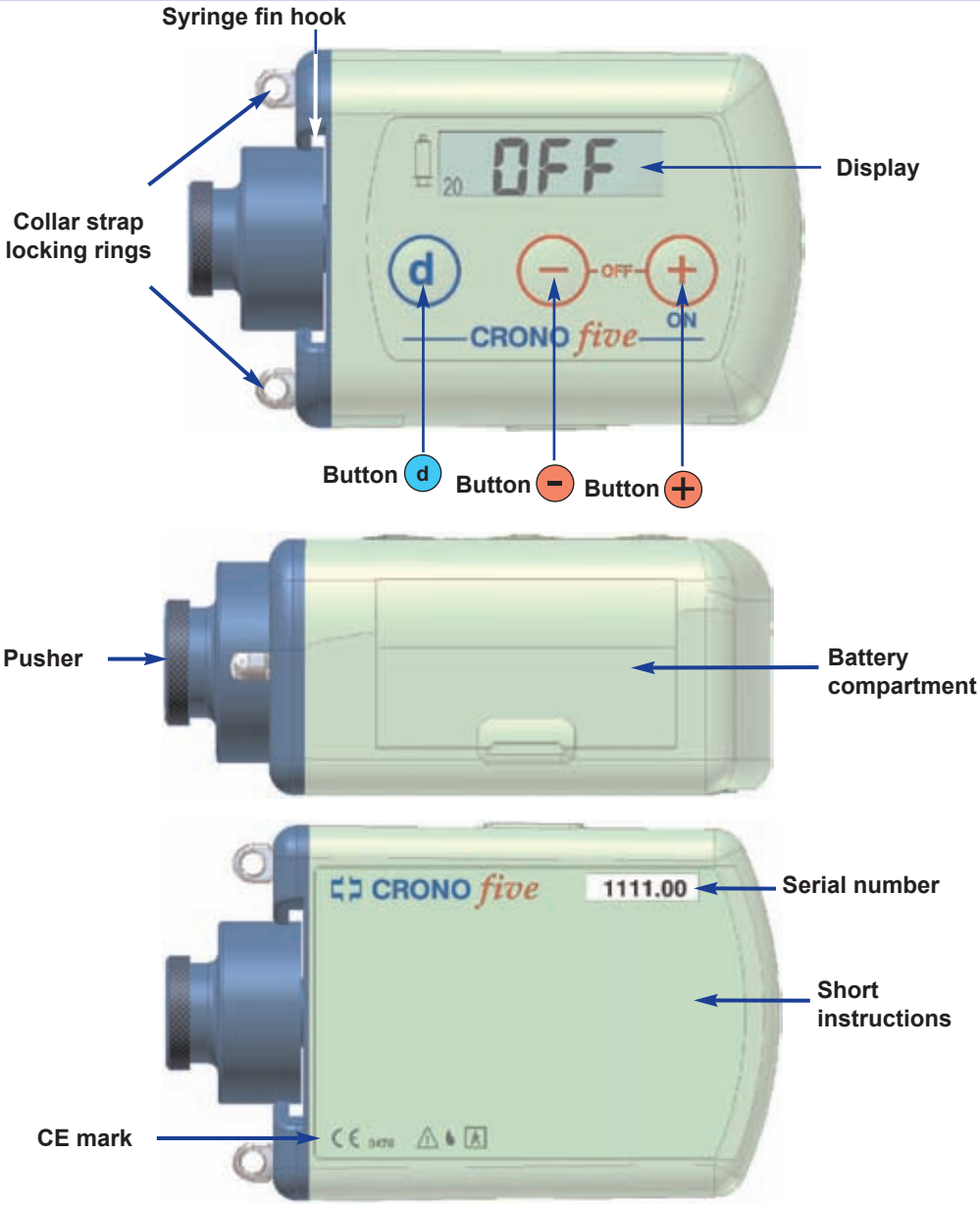
How to attach collar strap to the pump and the fabric holder .



How to use elastic belt with pump and fabric holder .



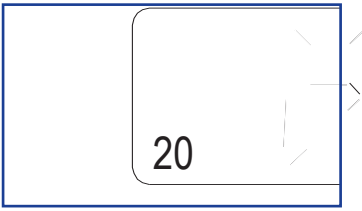
PUMP OVERVIEW



LIQUID CRYSTAL DISPLAY (LCD)

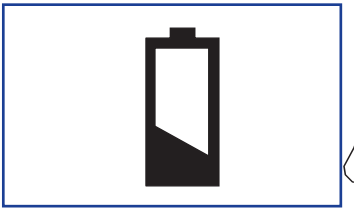
This is a screen on the front of the pump where symbols and messages are displayed informing the user about operations in pro - gress as well as giving warnings and alarm messages.

Symbol "10 ml" : indicates the device has been set to use 10 ml (CRN 10) syringe set- ting.

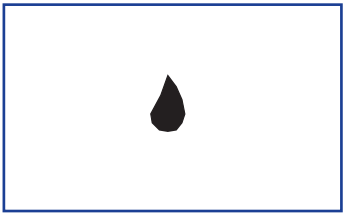


Symbol "20 ml" : indicates the device has been set to use 20 ml (CRN 10) syringe set ting.

“Low battery” symbol:
appears when the battery charge is low (see page 65).



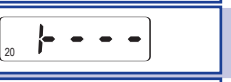
“Drip” symbol:
separates whole numbers from decimals.



“apostrophe” symbol:
used when the duration of infusion is given in minutes.

MAIN SCREEN INDICATIONS

Pump OFF	
Prime function	
Prime execution	
Flow rate	
Time left to end of infusion (hours)	
Time left to end of infusion (mins.)	
Bolus dose	
Minimum time interval between boluses	
No time interval between boluses	
Number of bolus doses in 1 hour	
No restriction of bolus doses per hour	
Partial volume	
Operation not performed	
Pump unlocked	
Pump locked	
Number of delivered infusions	
Error message (see page 73)	

Occlusion	
Feed/reversal motion of the pump pusher	
End of infusion	
Low battery	
Battery discharged	
Volume delivered (ml) as basal flow rate	
Volume delivered (ml) as bolus doses	
Number of bolus doses already delivered	
Volume delivered (ml) as clinician bolus	
Total volume delivered (ml) (basal flow rate + bolus doses + clinician bolus)	
10 ml syringe selected	
20 ml syringe selected	

The above screens are given as example of what can be displayed.

KEY-PAD

The key-pad has 3 buttons for pro - gramming and for the operation of the pump.

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 inser- ting the battery.

- Command execution is confirmed by a brief acoustic signal.

During the selection of the parame - ters the ⊖ button is used to decrease the value displayed on the screen, the ⊕ button to increase the value.

CAUTION

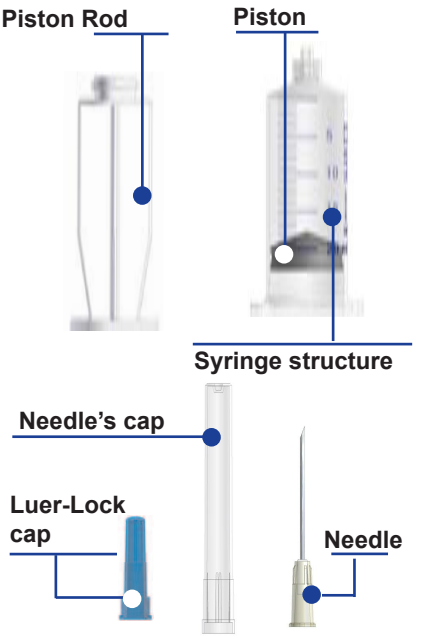
Press the buttons with your finger- tips only, do not use sharp or poin - ted objects.

SYRINGES

The ambulatory infusion pump CRONO Five uses dedicated 10-20 ml syringes.

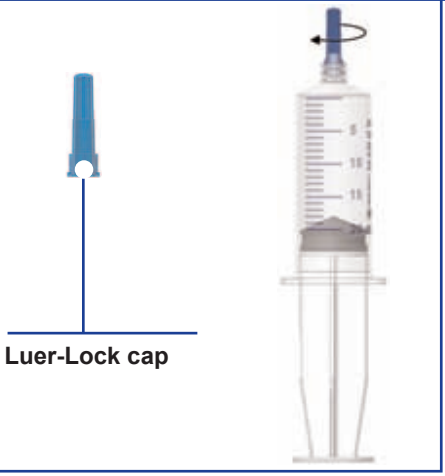
The 10-20 ml syringes are:

- Sterile.
- Single use only.
- Pyrogen-free.
- To be used only if packaging is not damaged.



LUER LOCK CAP

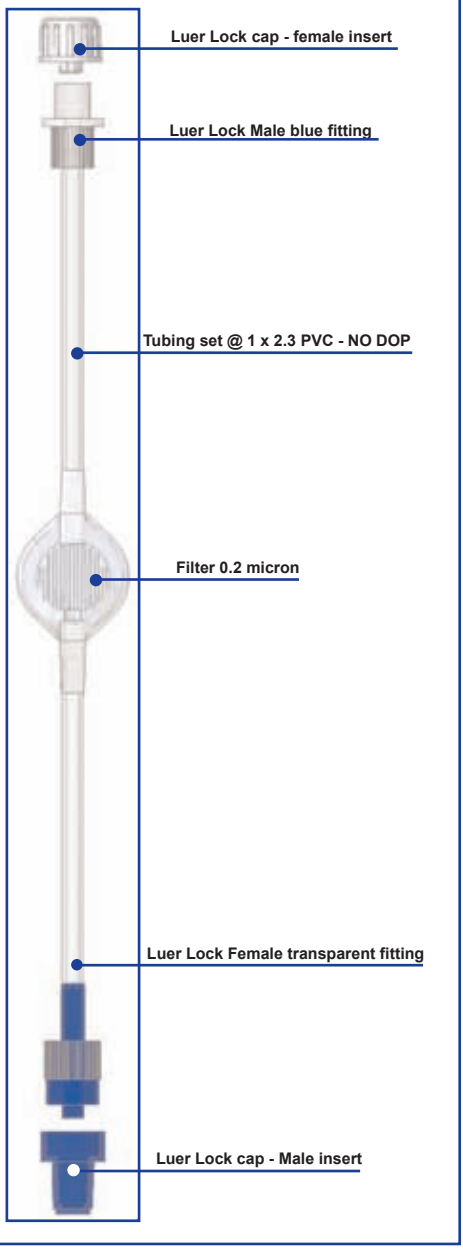
The luer lock cap should be used to protect a filled syringe from contamination if the syringe isn't used immediately after filling.



FILTRAJET

Filter can be used to:

- Prevent bacterial infections.
- Eliminate air in the syringe and in the infusion set.
- Trap any fragments of glass or plastic to secure a safe and proper drug administration.



INFUSION SET

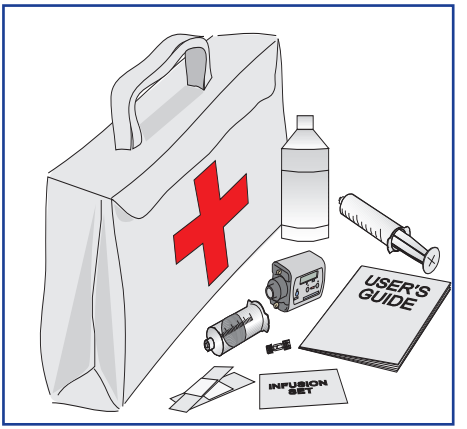
- For information about infusion sets, please see the instruction supplied with the products.

- Epidural drug infusions must be delivered using infusion sets specifically suitable for such purpose.

PREPARATION FOR INFUSION

Before the pump and other disposa - bles are prepared to be used, make sure that you take the following pre - cautions to avoid any contamination:

1. Wash your hands;
2. Prepare a clean working area.



SYRINGE PREPARATION

1. Attach the supplied needle to the syringe with a clockwise rotation;

2. Draw up the liquid slowly to avoid disconnection between the rubber piston and the piston rod and make sure the volume corresponds exactly to the prescription;

3. Attach luer-lock cap then unscrew the piston rod of the syringe counter-clock wise with a fairly swift movement;

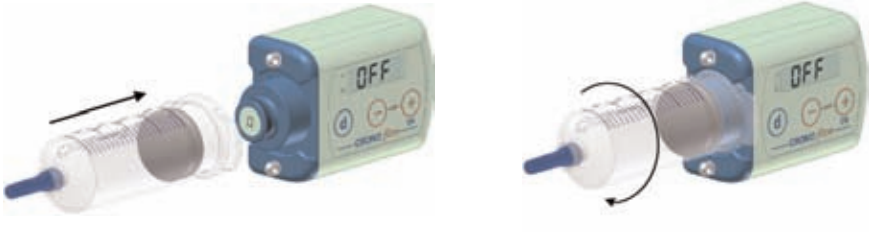
1

2

3

CONNECTING THE SYRINGE TO THE PUMP

Connect the dedicated syringe, CRN 10-20, to the pump with a 90° rotation: a click is confirming that the syringe is correctly attached to the pump.



Top view

WARNING

It is important to draw up the intended quantity as accurate as possible, independently if it is a full syringe of 10 ml or 20 ml or a partial volume 1-9 ml or 1-19 ml.

1. By excess volumes, it will be very dif ficult to attach the syringe to the pump without aspirating the excess volume.

2. By incomplete volumes, the infusion will not start before the pusher reaches the piston and the free flow function will not be activated.

SAFETY SYSTEM TO AVOID FREE-FLOW

"Free flow" means an uncontrolled release of the infusion solution from the syringe caused by gra - vity. In order to prevent this from happening, the tip of the pump pusher has been knurled, which part must be inserted inside the rubber piston of the Crono 10-20 ml syringe, allowing a secure con- nection to be made with the syrin - ge piston.

CAUTIONS

Before the drug administration is started the rubber piston has to be connected to the pump pusher ,if this is not the case the following unwanted effects may occur:

- The infusion starts late and is not performed with accuracy.
- The anti free flow function is not operational.

WARNING

The improper connection between the syringe piston and the pump pusher can cause a free flow of medication, in other words, medi - cation administered by gravity and not controlled by the pump, (for example when the pump is posi - tioned much higher than the infu - sion site). Such situation can cause serious injury or death of the patient.

WARNING

This safety system will only work if the connection between the syringe rub - ber piston and the pump pusher is made correctly, as shown in the dra - wing below.

4. Attach the syringe to the pump with a 90° rotation and continue the movement until the syringe clicks into its correct position.

5. Attach the butterfly needle cone onto the syringe

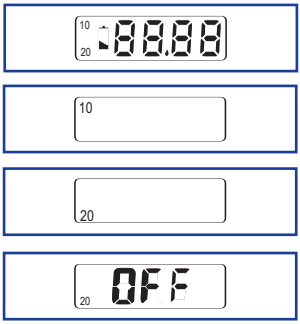
4

5

DEVICE ACTIVATION

When you insert the battery the pump starts a sequence of activation during which:

1. The pump will carry out a self-test with brief acoustic signals and all symbols will appear on the screen.
2. Select the syringe size options.
3. The pump's mechanical pusher will place itself in the correct starting position and at the end of this self-adjusting, **OFF** will appear on the screen.



NOTE

- The pump is supplied with a battery already inserted.
- Refer to the relevant paragraph for instructions how to insert a new battery (see page 66).
- Take out the battery of the pump if it is not going to be used for a long period of time (1-2 months).

SELECTING THE SYRINGE SIZE

While syringe size symbol is flashing (the number "10" or "20"), the selection of syringe size may be made.

Use the ⊖ or ⊕ buttons to make your selection.

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

WARNING

Selecting the syringe size option can only be carried out during the device activation phase, immediatly after the insertion of the battery.

KEY PAD LOCK OUT

The pump is provided with a key-pad lock-out in order to avoid non authorised or accidental variations of the selected parameters.

The CRONO Five pump has 2 lock levels:

- **L 0**: permits complete access to all settings and operating functions.
- **L 1**: permits restricted control of operating functions.

Before proceeding to the pump settings make sure that the lock level selected is **L 0.**

The information relating to the operations of key-pad lock/unlock are exclusively to be used by the physician.

CAUTIONS

- The key pad lock-out is retained even when the battery is removed.
- When the key-pad is locked any attempt to access protected operations is signalled by the device through an acoustic message and **L 1** will appear on the screen.

TABLE OF KEY-PAD FUNCTIONS

The following table lists the accessible functions at any key-pad lock-out level (**L 0** or **L 1**) both when the pump is in **OFF** and **ON** condition.

FUNCTIONS AND SELECTIONS	OFF		ON	
	L0	L1	L0	L1
Switching ON the pump	YES	YES	NO	NO
Switching OFF the pump	NO	NO	YES	YES
Prime	NO	NO	YES*	YES*
Bolus dose	NO	NO	YES	YES
Displaying delivery time	NO	NO	YES	YES
Displaying volume delivered as flow rate	NO	NO	YES	YES
Displaying volume delivered as bolus dose	NO	NO	YES	YES
Displaying number of bolus dose delivered	NO	NO	YES	YES
Clearing the number of bolus doses delivered	YES	NO	NO	NO
Displaying volume delivered as clinician bolus	NO	NO	YES	YES
Displaying total volume delivered	NO	NO	YES	YES
Displaying programmed parameters	NO	NO	YES	YES
Flow rate setting	YES	NO	NO	NO
Bolus dose setting	YES	NO	NO	NO
Interval between bolus doses setting	YES	NO	NO	NO
Number of bolus dose in one hour setting	YES	NO	NO	NO
Partial volume setting	YES	NO	NO	NO
Displaying the number of complete infusions	YES	YES	NO	NO
Clearing the number of complete infusions	YES	NO	NO	NO
Lock/Unlock the keyboard	YES	YES	NO	NO
Clinician bolus	YES	YES	NO	NO

* Available only at the beginning of a new infusion or a new partial infusion.

PROGRAMMING

For programming, the pump must be:

- In **OFF** condition.
- With key-pad lock-out in **L0**.

Depress the d button for about 1 second to access the pump programming sequence. The first programming option displayed on the screen is **flow rate**. The flow rate can be changed with the − button or the + button as long as the presently programmed flow rate is flashing.

The second depressing of the d button will display the second programming option **bolus dose volume**. The bolus dose volume can be changed with the − button or the + button as long as the presently programmed bolus dose volume is flashing.

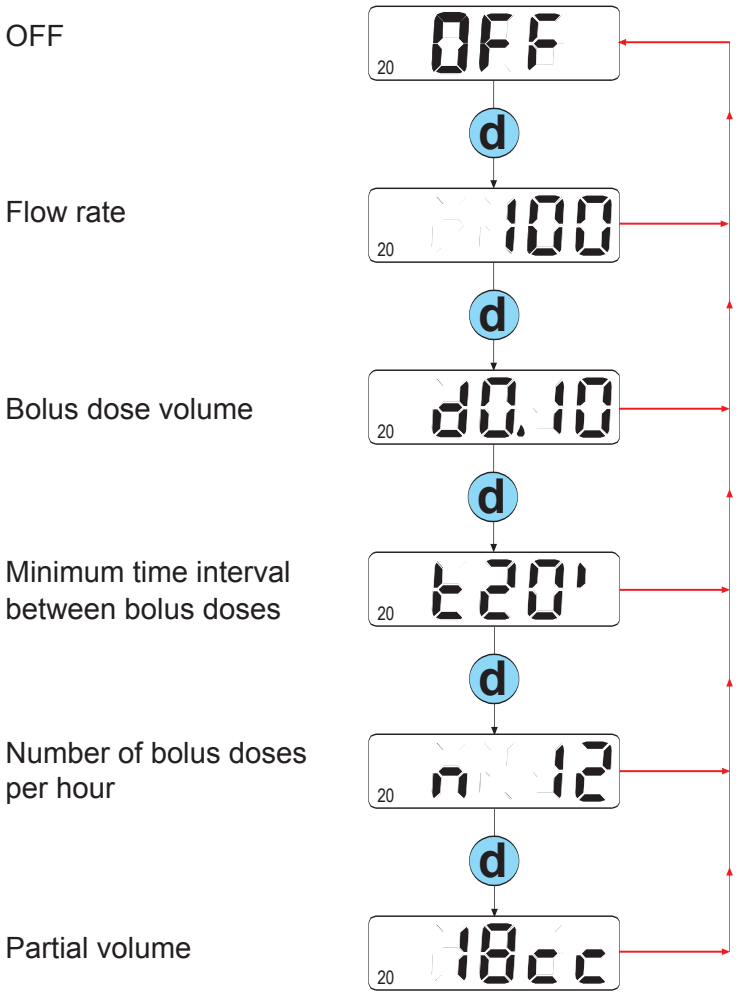
The third depressing of the d button will display the third programming option **minimum time interval between bolus doses**. The minimum time interval between bolus doses can be changed with the − button or the + button as long as the presently programmed interval time is flashing.

The fourth depressing of the d button will display the fourth programming option **number of bolus doses per hour** . The number of bolus doses per hour can be changed with the − button or the + button as long as the presently programmed number of bolus doses per hour is flashing.

The fifth depressing of the d button will display the fifth programming option **partial volume**. The partial volume can be changed with the − button or the + button as long as the presently programmed partial volume is flashing. The partial volume can only be programmed when the pusher is in the start position.

NOTE

If the key pad lock-out is programmed to **L1**, depressing the d button will display **L1** (key pad lock-out: programming is not allowed).



The following screen displays are examples of programmed values as they appear on the screen.

PROGRAMMING OF FLOW RATE

The flow rate can be programmed from 5 mcl/h to 5000 mcl/h as follows:

- From 5 mcl/h to 1000 mcl/h with increments of 5 mcl/h.
- From 1000 mcl/h to 5000 mcl/h with increments of 10 mcl/h.

Programming procedure:

1. When the d button is depressed for about 1 second with the pump in OFF condition, the presently programmed flow rate will be displayed and flashing
2. By depressing the + button the value will increase; by depressing the − button the value will decrease. Any change in value is followed by an acoustic signal.
3. If no button is depressed within 8 seconds in the programming phase, the value stops flashing and **OFF** appears on the screen.
4. Depressing the d button before the **OFF** message appears (the flow rate value is still flashing) moves the programming sequence to the next option: **bolus dose.**

NOTE

- You can accelerate (scrolling) the display of new values by depressing the − or the + button continuously (in increments of 20 or 40 mcl/h depending on the range).
- Programmed flow rates are automatically stored.
- By programming 0 the flow rate is eliminated.

PROGRAMMING OF BOLUS DOSE

The bolus dose can be programmed from 0.01 ml to 2.00 ml with increments of 0.01 ml.

The bolus dose is accessed by the second depressing of the d button in the pump programming sequence (see page 37).

Programming procedure:

1. When the d button is depressed for a second time, a "**d**" is displayed and the presently programmed bolus dose is flashing.
2. By depressing the + button the value will increase; by depressing the − button the value will decrease. Any change in value is followed by an acoustic signal.
3. If no button is depressed within 8 seconds in the programming phase, the value stops flashing and **OFF** appears on the screen.
4. Depressing the d button before the **OFF** message appears (the bolus dose is still flashing) moves the programming sequence to the next option: **minimum time interval between bolus doses.**

NOTE

- You can accelerate (scrolling) the display of new values by depressing the − or the + button continuously (in increments of 0,04 ml).
- Programmed bolus doses are automatically stored.
- By programming **d 0,00**, the bolus dose is eliminated.

MINIMUM TIME INTERVAL BETWEEN BOLUS DOSES

The minimum time interval between bolus doses can be programmed from 5 minutes to 24 hours as follows:

- From 5 minutes to 1 hour with increments of 5 minutes.
- From 1 hour to 24 hours with increments of 15 minutes.

This function limits the patient to access the programmed bolus dose before a certain time has elapsed from the latest administered bolus dose.

The minimum time interval between bolus doses is accessed by the third depressing of the d button in the pump programming sequence (see page 37).

Programming procedure:

1. When the d button is depressed for a third time, a "**t**" is displayed and the presently programmed interval time is flashing.
2. By depressing the + button the value will increase; by depressing the − button the value will decrease. Any change in value is followed by an acoustic signal.
3. If no button is depressed within 8 seconds in the programming phase, the value stops flashing and **OFF** appears on the screen.
4. Depressing the d button before the **OFF** message appears (the interval time is still flashing) moves the programming sequence to the next option: **bolus doses per hour**.

NOTE

- "**t**" appears only before the programmed interval time when the interval time is less than 10 hours.

- You can accelerate (scrolling) the display of new values by depressing the ⊖ or the ⊕ button continuously (in increments of 10 or 30 minutes depending on the range).

- Programmed interval time is automatically stored.

- By programming "**no,Lt**", the minimum time between bolus doses is eliminated.

PROGRAMMING OF BOLUS DOSES PER HOUR

The number of bolus doses per hour can be programmed between 1 and 12 boluses per hour.
This function limits the patient to access more boluses per hour than programmed.
The number of bolus doses per hour is accessed by the fourth depressing of the d button in the pump programming sequence (see page 37).

Programming procedure:

1. When the d button is depressed for a fourth time, an "**n**" is displayed and the presently programmed number of bolus doses per hour is flashing.
2. By depressing the + button the value will increase; by depressing the − button the value will decrease. Any change in value is followed by an acoustic signal.
3. If no button is depressed within 8 seconds in the programming phase, the number of bolus doses per hour stops flashing and **OFF** appears on the screen.
4. Depressing the d button before the **OFF** message appears (the number of bolus doses per hour is still flashing) moves the programming sequence to the next option: **partial volume**.

NOTE

- Programmed bolus doses per hour is automatically stored.
- By depressing the − button when the dis-

play is showing "**n 1**", will eliminate the bolus dose per hour function and the display will show "**n 0**", which means that no boluses can be administered.

- By depressing the ⊕ button when the display is showing **n 12**, will eliminate the bolus number per hour restriction and the display will show **no,Ln**, which means that there is no longer any restriction how many boluses that can be administered by the patient.

PROGRAMMING OF PARTIAL VOLUME

Partial volume is used when less than 20 ml is drawn up in the syringe for a specific treatment or for a specific patient, for example children who needs less than the adult dose.
Partial volume can be programmed between 1 ml and 20 ml with increments of 1 ml.
Partial volume is accessed by the fifth depressing of the d button in the pump programming sequence (see page 37).
Please observe that partial volume is only available at the beginning of a new or new partial infusion.

Programming procedure:

1. When the d button is depressed for a fifth time, the presently programmed volume in ml is flashing:
2. By depressing the + button the value will increase; by depressing the − button the value will decrease. Any change in value is followed by an acoustic signal.
3. If no button is depressed within 8 seconds in the programming phase, the selected volume in ml stops flashing and **P,cc** appears on the screen.
4. The pusher will automatically position itself for the programmed partial volume. During the movement of the pusher , there will be an acoustic signal and the delivery time corresponding to the selected partial volume will be displayed on the screen.
5. When the pusher reaches its programmed position, the display will show **OFF.**

NOTE

- Partial volume is automatically stored for the next delivery, unless reprogrammed.
- At the end of a partial infusion the pusher moves automatically back to the programmed partial volume position.
- By depressing the ⊖ button and ⊕ button simultaneously, the movement of the pusher is interrupted and **OFF** is displayed on the screen. This position of the pusher is not stored but the programmed partial volume remains active.

WARNINGS

- Do not perform this operation with an infusion set attached to the syringe.
- It is not possible to reprogram the partial volume during an ongoing infusion.
- The partial volume is automatically stored until you remove or replace the battery at which time the programmed volume will revert to the standard volume of 10 or 20 ml.

STARTING THE PUMP

Depress the ⊕ button when the pump is in **OFF** and there will be a short acoustic signal and the display will show either:

- Pr (priming function) provided that the pusher is in the start position for a new, full or partial volume, infusion

or

- remaining infusion time in hours and (minutes) when the pump is restarted during an ongoing infusion

NOTE

The remaining time to the end of the infusion is displayed in days until less than one day remains, in hours until less than one hour remains, then in minutes.

WARNINGS

Before starting an infu - sion:

- in order to avoid the free flow make sure that the connection between the syringe rubber piston and the pump pusher is made correctly;
- inspect the flow line in order to check that there aren't any kinks, closed clamps and other occlu sions before proceeding;
- eliminate eventual air bubbles.

PRIMING

The priming function is used for filling the infusion set with drug from the syringe. A total of 1.5 ml, in steps of 0.5 ml, can be primed using the priming function.

Priming can only take place when the pusher is in the starting position for a new, full or partial volume infusion. If another priming is necessary during an ongoing infusion, the clinician bolus can be used.

The prime function is available at all the two lock levels.

WARNINGS

- Do not prime the infusion set when attached to the patient.
- The infusion set should be attached to the syringe before priming starts
- The infusion set must be completely filled before it is attached to the patient.
- Check that all air is eliminated from the infusion set before administration starts.

Priming procedure:

1. Depress the ⊕ button when the pump is in **OFF**.
2. The display shows **Pr**. There are three different alternatives to choose from:

a. To postpone priming
b. To skip priming
c. To start priming

a. To postpone priming

Depress the ⊖ button and the ⊕ button simultaneously; the pump will switch to **OFF**; or wait 10 seconds and the pump will automatically switch to **OFF**.

b. To skip priming

Depress the ⊕ button; the pump will start the infusion and the display will show the remai - ning infusion time.

c. To start priming

Depress the d button: the pump will deliver 0,5 ml and the display will show a **P** followed by the volume in ml that has been primed.
After the first priming of 0.5 ml, the display will show **Pr** again and the procedure can be repeated two more times up to 1,5 ml has been primed.
There is no time limit to finish the priming procedure.

NOTE

- If no button is depressed for 10 seconds in **Pr**, the pump will switch to **OFF**.

- The priming volume is not included in the administration volume.
- The priming can be interrupted at any time by depressing the ⊖ button and the ⊕ button simultaneously. The display will show **Pr** and alternative a, b or c can be selected again.

PUMP IN ON (RUNNING)

The remaining infusion time is displayed in days hours and minutes when the pump is in ON (running).

The letter d flashes when the remaining infu - sion time is displayed in days.

The letter h flashes when the remaining infu - sion time is displayed in hours.

The “apostrophe” symbol flashes when the remaining infusion time is displayed in minu - tes.

When the flow rate is programmed to 0, only patient and clinician boluses will be delivered and the display will show **F0,00** with the letter **F** flashing.

BOLUS DOSE

The bolus dose is used by the patient to administer an additional dose of medication as needed.
If the bolus dose is programmed to 0 ml, no bolus dose can be administered.

Delivering a bolus dose

Bolus doses can only be delivered when the pump is in ON (running).

1. Depress the d button and the pump will emit an acoustic signal, which indicates that the pump starts to deliver the programmed bolus dose. The display will show a flashing d followed by the current volume in ml being delivered. For every 0.125 ml being delivered, the pump emits an acoustic signal, makes a pause of 2 seconds and continues to deliver the next 0.125 ml of the programmed bolus dose.
2. When the delivery of the bolus dose is completed, the pump will emit an acoustic signal and the remaining infusion time will be displayed. If the flow rate is programmed to 0.00 ml, **F0,00** will be displayed instead of remaining infusion time.

NOTE

- By depressing the, ⊖ and the ⊕ buttons simultaneously, the bolus dose delivery can be interrupted at any time.

- If the bolus dose is programmed to **d0,00** and the d button is depressed in ON, the error message **Er,d**, will be displayed.

BOLUS DOSE LIMITATIONS

- Time interval between bolus doses (t limitation)
- Number of bolus doses per hours (n limitation)

Bolus doses cannot be delivered before the time (t) has expired or when the number of programmed boluses per hour (n) has already been administered.

The pump will always choose the program - med (t) or (n) that administer the lowest amount of bolus doses in ml.

If a bolus dose is requested during limitation time (t) or after the maximum number of bolus doses (n) has been reached, the display will show error message **Er,t** and **Er,n** respectively.

CLINICIAN BOLUS

The access to the clinical bolus function is reserved to physicians or para - medic staff.

OCCLUSION OF INFUSION SET

The pump has been designed to recognise when the drug delivery is interrupted by external circumstances such as involuntary kink of the infusion set tubing. In this case the pump stops running the infusion, the display will show the symbol for occlusion and the pump will emit an acoustic signal every 10 seconds. Drug administration is interrupted as long as the occlusion remains. Find and remove the reason for the occlusion and press thereafter the ⊕ button to silence the acoustic signal and to resume the infusion.

NOTE

- Search for the occlusion along the infusion set and in the connection point of the set to the patient.
- It is recommended to use kink-free infusion sets to prevent or reduce occlusions to occur.

POST OCCLUSION BOLUS

When the occlusion alarm signal is triggered, the pump has built up a certain overpressure in the administration line(s), which has to be eliminated to avoid an accidental post occlusion bolus that could result in serious injury or death of the patient.

The size of a post-occlusion bolus for Crono Five in combination with an infusion set with 27G needle, 80 cm lenght with very stiff lining is about 0.4 ml.

WARNINGS

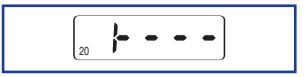
The size of a post-occlusion bolus can increase if there is air in the line, when other catheter sizes, filters and extension set tubing with softer materials are used, or when the lines from the pump are connected to other access devices.
After an occlusion signal use appropriate precaution with the aim to avoid the administration of a post-occlusion bolus to the patient.

END OF INFUSION

Ten and five minutes before the end of infu - sion, the pump will emit an intermittent acou - stic signal lasting two seconds per signal.

At the end of infusion, the pump will emit a acoustic signal and **END** will be displayed.

By depressing the d and the − buttons simultaneously, the acoustic message will be silenced and the pusher will move back to the starting position.



NOTE

- The reversal for a 20 cc volume lasts about 10 minutes; the duration is proportionally shorter for lower volumes.

CAUTIONS

Disconnect the infusion set from the patient or put a clamp on the infusion set before starting the reversal of the pusher to avoid that medication is aspirated from the infu - sion set.

REVERSALS OF THE PUMP PUSHER

Reversal of pusher before the end of infusion.

It is possible to interrupt an infusion in pro - gress and reverse the pusher to its starting position:

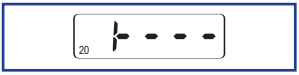
- Depress the ⊖ and the ⊕ buttons simultaneously to switch off the pump.
- Depress the d and the ⊖ buttons simul - taneously, **End** will be displayed for about 10 seconds and the pump will start to reverse the pusher.
- The reversal request of the pusher can be cleared/canceled by depressing the ⊖ and ⊕ button simultaneously during the 10 seconds the screen is displaying **End.**

Reversal of pusher at the end of infusion.

The pump will emit an acoustic signal at the end of infusion and **End** will be displayed. Depress the d and the ⊖ buttons simulta - neously and the pusher will revert to the infu - sion starting position.

Pump pusher movement

When the pump pusher reverses with a conti - nuous movement, a symbol depicting move - ment will be displayed.



NOTE

- The reversal of the pusher before the end of infusion can be interrupted by depressing

the ⊖ and the ⊕ buttons simultaneously; **OFF** will be displayed; **End** and **OFF** will alternate on the screen.
By depressing the ⊕ button, the pump will resume the reversal of the pusher.

- If pump reversal is requested when the pusher already is in the starting position for an infusion, the pump will emit an acoustic signal and **Err** will be displayed.

- The reversal of the pusher at the end of infusion can be interrupted by depressing the ⊖ and the ⊕ buttons simultaneously; **End** and **OFF** will alternate on the screen.
By depressing the ⊕ button, the pump will resume the reversal of the pusher.

CAUTIONS

- Disconnect the infusion set from the patient or put a clamp on the infusion set before starting the reversal of the pusher to avoid that medication is aspirated from the infusion set.
- Do not remove the syringe before the pusher has reached the starting position for a new infusion.

SWITCHING OFF THE PUMP

Depress the ⊖ and ⊕ buttons simultaneously. The display will show **OFF**.

If the pump is switched **OFF** while an infusion is ongoing the device will emit a sequence of 5 short sounds every 5 seconds and **OFF** will flash on the display . To silence the acoustic alarm press down the button ⊖ for 5 seconds. Such a condition will be repeated any time the device is switched of f while an infusion is in progress.

DISPLAYING PROGRAMMED PARAMETERS

To display programmed parameters/values the pump must be running (**ON**). The screen will show either remaining delivery time or **F0,00** if the flow rate is programmed to 0.

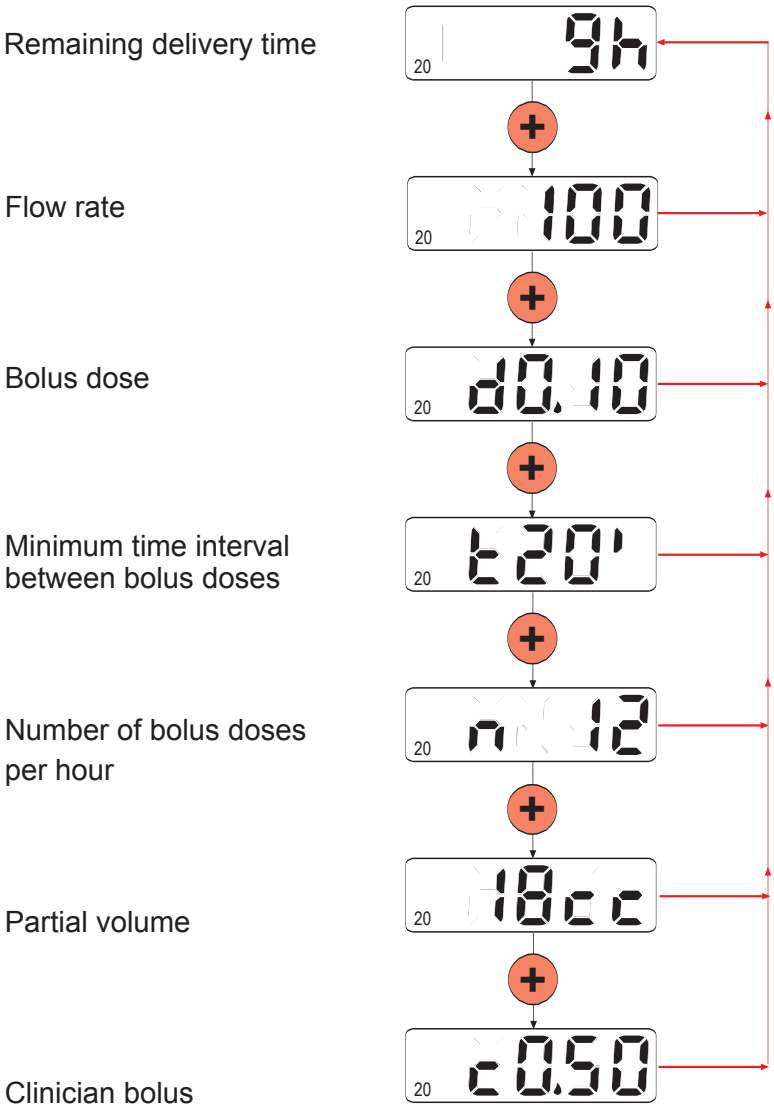
Display procedure:

1. Depress the ⊕ button for about 1 second and the programmed flow rate will be displayed
2. If no button is depressed for 5 seconds, the pump will revert to remaining delivery time or **F0,00.**
3. If the ⊕ button is depressed again within the 5 seconds time interval, the next value of the programming phase will be displayed and so on. The sequence is as follows: **bolus dose, minimum interval between bolus doses, number of bolus doses per hour, partial volume, clinician bolus.**

NOTE

The lock level of the key pad does not interfere with displying programmed parameters.

The chart beside explains the sequence of screens related to the display of the parame - ters.



The screens above are examples of what can be displayed.

DISPLAYING DELIVERED VOLUMES

This display procedure will show the delivered volume in ml since the start of the infusion for the different delivery options.
The pump has to be running (ON) and the screen will either show the remaining delivery time or **F0,00.**

Display procedure:

1. Depress the button for about 1 second and the programmed flow rate will be displayed.
2. If no button is depressed for 5 seconds, the pump will revert to remaining delivery time or **F0,00.**
3. If the button is depressed again within the 5 second time interval, the next value will be displayed as follows: **Volume delivered as bolus doses, Number of bolus doses delivered, Volume delivered as clinician boluses, Total volume delivered.**

NOTE

- The lock level of the key-pad lock out does not interfere with programmed values.
- The values of the volumes delivered are constantly updated during the infusion.
- All values related to delivered volume and number of bolus doses are automatically reset to zero at the beginning of a new or partial new infusion.

The chart beside shows the sequence of the screens related to the volumes delivered by the pump during an infusion.

Remaining delivery time

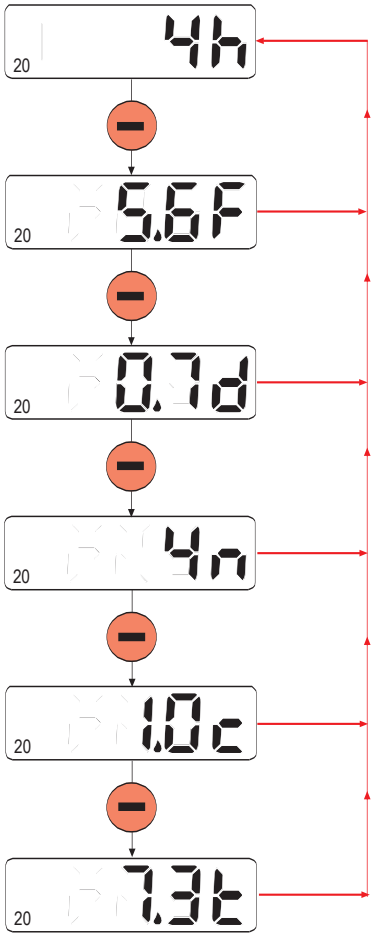
Volume delivered as flow rate during the infusion in progress.

Volume delivered as bolus doses during the infusion in progress.

Number of bolus doses already delive - red.

Volume delivered as clinician boluses during the infusion in progress.

Total volume delivered (flow rate + bolus doses + clinician bolus doses).



The screens above show examples of what can be displayed.

CLEARING THE NUMBER OF BOLUS DOSES DELIVERED

The number of bolus doses delivered can be set to zero at any time, provided that the lock level is **L0**.

Clearing procedure:

1. Depress the d and the + buttons simultaneously for about 4 seconds with the pump in **OFF** and the number of bolus doses delivered will start flashing on the screen.
2. Depress the − button within 5 seconds, the pump will emit an acoustic signal and the number of the bolus doses delivered will be set to zero and **OFF** will be displayed.

WARNING

If the key pad lock-out is programmed to **L1**, clearing the number of bolus doses delivered is not possible. The display will show **L1**, indicating that clearing is not allowed.

DISPLAYING THE NUMBER OF COMPLETE INFUSIONS

The pump has to be in **OFF** to be able to display the number of complete infusions performed by the pump.

Depress the − button for about 5 seconds and the number of complete infusions will be displayed.

Clearing the number of complete infusions performed by the pump.

Clearing procedure:

1. The pump has to be in **OFF** and lock level **L0.**

2. Depress the − button for about 5 seconds and the number of complete infusions will be displayed.

3. Without releasing the − button, depress the d button as well and the number of complete infusions will start flashing on the screen.

4. Depress the + button for about 1 second and thereafter the − button for about 1 second (in sequence) and the d button within 7 seconds. The pump will emit a ticking sound followed by a longer signal. Then the number of complete infusions is cleared.

5. If the clearing sequence is correctly performed, the message **0000** will appear on the screen for about 3 seconds followed by the sound of the buzzer.
   If not, or if no buttons are depressed for more than 7 seconds, the message **UNDO** will appear on the screen (operation not performed correctly).

6. **OFF** will be displayed at the end of zero setting.

WARNING

If the key-pad lock level is in **L1** when the clearing sequence is started to be performed, the pump will emit an acoustic signal and **L1** will be displayed.

LOW BATTERY ALERT

The LOW BA TTERY symbol will be conti - nuously displayed when the battery level is low.
The battery should be changed as soon as the ongoing infusion is completed.

If the battery is completely discharged, BA T-TERY DISCHARGED, the symbol **batt** will be displayed and the pump will emit a short acou- stic signal. The pump will stop and the infusion cannot be completed without changing bat - tery.

CAUTIONS

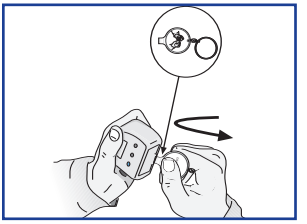
- Avoid that the pump stops during an ongoing infusion by changing the battery as soon as the LOW BATTERY symbol appears and the ongoing infusion is completed.
- Do not replace the bat- tery:
  - during an ongoing infusion.
  - when the infusion set is connected to the patient.

BATTERY INSTALLATION OR REPLACEMENT

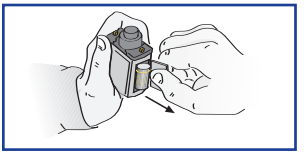
Use only lithium 3 Volt 123 A batteries.
Make sure the pump is in OFF condition (OFF will be displayed), then replace the battery.

Battery exchange procedure:

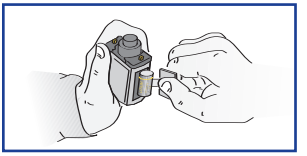
1. Open the battery compartment using the blue key-ring device that is included with the pump.



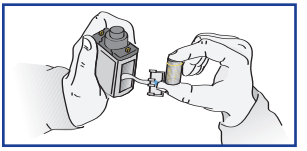
2. Pull out the cover.



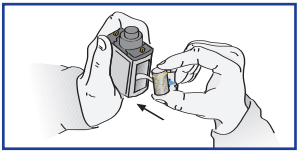
3. Use the small ribbon strap (which lies under the battery) to facilitate the removal of the battery.



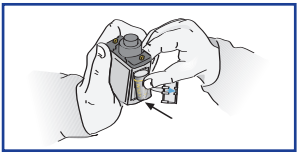
4. Remove the discharged battery and discard it properly.



5. Wait for 10 seconds, then insert the new battery checking that it is placed in the correct position as to polarity indicator and that the ribbon strap is under the battery.



6. Close the cover after the battery has been installed.



If it is difficult to remove the battery using the ribbon strap, do not use any other object to remove the battery but try the following procedure:

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

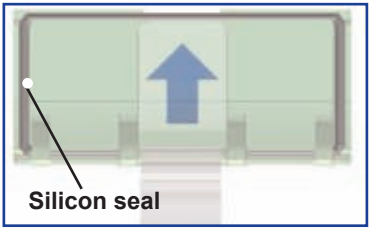
NOTE

- When a battery is installed, the pump performs a self-test during which all symbols will be displayed and the pump will emit acoustic signals.
- Under average operating conditions, each battery should last about six months.
- The pump retains all programmed values. The data are not lost when the battery is replaced or removed or if the pump isn't used for prolonged periods. Programmed partial volume is the only value that is not saved if the battery is removed.

WARNINGS

- Do not use rechargeable batteries.
- The use of batteries of a different type could result in device malfunctions.
- Battery life will vary depending on the battery age, temperature and storage conditions.
- Make sure that a new battery is kept available for emergency replacement.
- Do not store the pump for prolonged periods (1-2 months) with the battery installed.
- Make sure that the battery door is properly closed.
- Dispose of used batteries in an environmentally safe manner and accordingly to any regulations which may apply.

- The door is fitted with a silicone seal that must remain in its lodging as shown in figure.



GENERAL CAUTIONS

The device may be damaged upon contact with any liquid, therefore remo - ve it before taking a bath or shower etc. Should the pump accidentally come into contact with any liquid (drug solution, sweat, bed wetting) the pump has to be checked by CANÈ or CANÈ's local representative.

The pump must be kept away from:
- heating devices (radiators, oven rings, stoves);
- direct sunlight;
- high electromagnetic fields (magnets, loud-speakers, portable radio devices), details are supplied on ANNEX 4;
- ionogenic radiations;
- supersonant devices
- magnetic resonance devices

The pump does not need to be sterilised.

Do not freeze the CRN syringe with the drug inside.

The pump must not be put in the fridge or in the freezer .

The pump must not be put in the oven or in the microwave oven.

Syringes, infusion sets, needles, filters and any disposables used during the infusion process must be properly discarded using the appropriate contai - ners.

USER GUIDE UPDATE

The version and the publication date of the present manual are reported on all pages of the documents. If after one year from the date of publication and the use of the pump, the physician should contact CANÈ S.p.A. or the local representative with the aim to check if there is an updated version of the user guide available.

SECTION 12

MAINTENANCE

Should the device be damaged, the pump has to be checked by CAN È or CANÈ's local representative.
CANÈ S.p.A. recommends an annual check up on all Crono Five pumps with the aim of evaluating the correct function and accuracy Such check ups must be carried out only by CAN È S.p.A. or an authorized distributors.

CLEANING

The exterior shell of the pump can be cleaned with a soft cloth slightly moi - stened with a mild detergent

CAUTIONS

- Do not dip the device into water or detergent solutions.
- Avoid the risk of liquid penetration inside the instrument. Should the device become wet, absorb the liquid with blotting paper.
- Do not clean the pump with acetone, solvents or abrasive detergents.
- Do not sterilise the pump.

STORAGE

If the pump is not going to be used for a long period of time (more than 1 or 2 months), the battery should be removed and put inside the pump case, which should be stored in a dry place.

PUMP LIFE

Pump life is 4 years from the beginning of the purchase date.

DISPOSAL OF THE PUMP

At the end of the period of pump life, contact CAN È or CANÈ's local repre - sentative to get all the necessary information concerning the collection and disposal of the pump.

USER INFORMATION

The pump can only be repaired by CAN È S.p.A. and the pump has the - refore to be sent to CAN È's local representative in the country in which the pump has been sold for further transportation to CAN È S.p.A.

Do not send any pumps for repair before you contact your local repre - sentative:

UNITED STATES:

INTRA PUMP INFUSION SYSTEMS
920 Minters Chapel Road, Suite 200
Grapevine, Texas 76051
Tel: 866-211-7867
Fax: 630-845-2768
Email: info@intrapump.com

MANUFACTURER:

CANÈ S.p.A. MEDICAL TECHNOLOGY
Via Cuorgnè, 42/a 10098 Rivoli (TORINO) Italy
Tel: 0039-011-9574872
Fax: 0039-011-9598880
Email: mailbox@canespa.it

MANUFACTURER'S GUARANTEE

With this consumer 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 period of guarantee 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. This guarantee will be granted only if the defect is brought to the attention of CANÈ S.p.A.

2. This guarantee will not be in effect if the pump and accessories have been damaged as a result of modifications or adjustments made without prior written consent from CANÈ S.p.A.

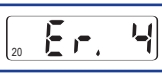
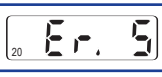
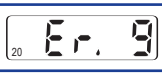
3. This guarantee will not apply if the type or serial number on the product has been altered, deleted, removed or made illegible.

4. This guarantee 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-authorised Service Stations or Dealers, or the Customer himself;
     - Accidental events, dropping, liquid infiltration.
   - Natural calamity, fraudulent or premeditated action.

5. CANÈ S.p.A. will aim to carry out repairs to the device over a period not in excess of 4 (FOUR) years, 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 (FOUR) years from the date of purchase.

6. Once the warranty period has expired, CANÈ S.p.A. will provide the service charging the costs of components being replaced, expenses of labour charges and freight charges.

ALARM MESSAGES

CODE	DESCRIPTION/ACOUSTIC SIGNAL	ACTION
	Unfeasable operation	----------
	Incorrect reset Continuous acoustic signal	Restart device
	Irregularity in the security system Continuous acoustic signal	Press the button
	Irregularity in the motor circuit Acoustic signal repeated every 10 seconds	Press the button
	Mechanical block during “End” phase caused by foreign matter obstructing the pusher’s reversal 7 beeps followed by another 7 beeps after 1 and 2 minutes	1. Remove the cause 2. Restart device
	Irregularity of the pusher advancement Acoustic signal repeated every 10 seconds	Press the button
	Occlusion, pump stopped. Acoustic signal repeated every 10 seconds	Remove occlusion. Press the button
	Reading memory error (EEPROM) Intermittent continuous acoustic signal	Restart device*
	Error within the motor piloting circuit Intermittent continuous acoustic signal	Restart device

CODE	DESCRIPTION	ACTION
	Active limitation of bolus doses number (not possible to deliver bolus doses)	Refer to user guide at page 51
	Bolus dose not available (value set for bolus dose is 0)	Refer to user guide at page 50
	Active limitation of interval between bolus doses (not possible to deliver bolus doses)	Refer to user guide at page 51
	Keypad locked	Unlock the keypad

Alarm messages are accompanied by audible signals.

Re-start

To re-start the device following an alarm message, remove the battery and wait at least 10 seconds before re-inserting it.

***Warning**

After Er,8 signalling, and the subsequent initialization, the standard parameters would be the factory ones (see page 16). Therefore, should this condition take place, you need to re-program the parameters assigned by the physician.

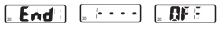
The parameters programmed by the physician have to be recorded on the note-page (see page 82).

SHORT INSTRUCTIONS

INSERTING BATTERY PHASE

BUTTONS	PUMP ACTIVATION	SCREEN
+ / −	• The screen will show all symbols.	
	• Syringe size selection.	
	• Pusher self-adjust.	
	• Pump switches OFF.	

PUMP OFF

BUTTONS	REVERSING OF THE PUMP PISTON NUMBER OF INFUSIONS DELIVERED	SCREEN
d and − depress simultaneously	• Reversing of the pump piston to the start position.	
− depressed for 5 seconds	• Reading the number of infusions delivered.	
d and + depress simultaneously	• Reset the number of bolus delivered (L0).	
−	• Confirm the reset of bolus delivered.	
PUMP ON		
+	• Pump switches ON.	

PUMP OFF

BUTTONS	SETTINGS	SCREEN
	Operations feasible only with key-pad unlocked.	
d 1st depressing	• Setting flow rate	
d 2nd depressing	• Setting bolus dose	
d 3rd depressing	• Setting bolus time limitations	
d 4th depressing	• Setting boluses number limitations	
d 5th depressing	• Setting partial volume	
+ / −	• Decrease/Increase above parameters.	

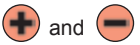
PRIME CONDITION

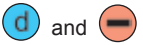
BUTTONS	PRIME	SCREEN
	Priming possible: only at start of a new infusion or start of a new partial infusion.	
+	• Access to PRIME phase.	
d	• PRIME (each depressing administers 0.5 ml - max 1.5 ml).	
+	• PRIME phase finish, infusion start.	
− and + depress simultaneously	• PRIME interruption (if in execution).	
− and + depress simultaneously	• Device switch OFF (if PRIME carried out). In case there is a need to prime one or more times during an already started infusion, the clinician bolus can be used	

	BUTTONS	INFUSIONS	SCREEN
PUMP ON	d	• Bolus dose delivery.	
	− and + depress simultaneously	• Bolus interruption (if in execution).	

	BUTTONS	SCREEN REVIEW OPTIONS	SCREEN
PUMP ON	− 1st depressing	• Administered flow rate in ml since start of infusion.	
	− 2nd depressing	• Administered patient bolus in ml since start of infusion.	
	− 3rd depressing	• Administered number of bolus.	
	− 4th depressing	• Administered clinician bolus in ml since start of infusion.	
	− 5th depressing	• Total administered volume in ml since start of infusion.	

	BUTTONS	SCREEN REVIEW OPTIONS	SCREEN
PUMP ON	+ 1st depressing	• Programmed flow rate.	
	+ 2nd depressing	• Programmed bolus dose.	
	+ 3rd depressing	• Programmed interval time between boluses.	
	+ 4th depressing	• Programmed number of boluses per hour.	
	+ 5th depressing	• Programmed partial volume.	
	+ 6th depressing	• Programmed clinician bolus dose.	

	BUTTONS	PUMP OFF	SCREEN
PUMP ON	 and depress simultaneously	• Pump switches OFF.	

	BUTTONS	END OF INFUSION	SCREEN
END OF INFUSION	 and depress simultaneously	• End of infusion. • Piston automatic reversing. • Automatic switch OFF.	

PUMP ICON TABLE

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

SYRINGE BLISTER PACKAGE ICON TABLE

CE mark	CE 0123
Recyclable	
Do not re-use	
Expiration date	
Sterilised by Ethylene oxide	STERILE EO
Polypropylene	PP
Lot number	LOT

STATEMENT OF CONFORMITY

CE

0476

CANÈ S.p.A. is a registered company with its headquarters in V ia Cuorgnè, 42/a 10098 Rivoli (TO) Italy. CANÈ S.p.A. is the manufacturer of the portable, electrically-operated ambulatory infusion pump Crono Five.

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.

NOTE

GLOSSARY

Alarm
An alarm is a condition that warrants the user ’s attention, and is critical enough that it requires that the pump be shut down or reset.
When an alarm occurs, an alarm beep is sounded and a descriptive mes - sage appears on the display screen.

Bolus
A bolus dose is an additional quantity of drug that can be released under certain defined conditions.

Basal flow rate
The basal flow rate is the quantity of drug delivered by the pump in a time unit.

Clinician bolus
A clinician bolus is an additional quantity of drug that can be released by a physician or other authorized health care staf f and which overrides other programmed bolus restrictions.

Display screen
The pump’s liquid crystal display screen is located on the front panel of the pump, providing the information about the functioning of the pump.

Electromedical equipment BF type
Electromedical equipment manufactured with particular accuracy and care as regards to security . The equipment is suitable for ambulatory use in which the patient can wear the equipment/pump in close contact with the body without influencing the functions of the equipment/pump.

Free Flow
Drug is leaving the syringe in an uncontrolled way due to the force of gra - vity.

Luer-lock connector
A luer-lock connector is a special threaded fitting used to connect the infu - sion set to the syringe.

Occlusion pressure
An alarm beeps when occlusion pressure is reached.

Pyrogen free
It means that the syringe does not contain pyrogenic substances, which cause fever as the ones released, for instance, by leucocytes or produced by bacteria.

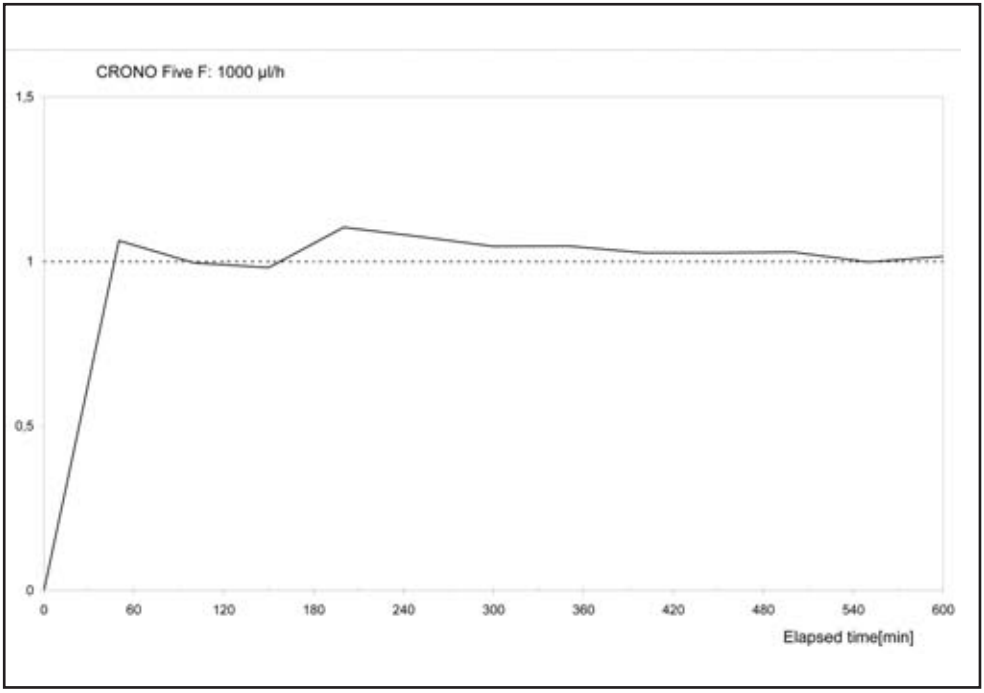
ANNEX 1

ACCURACY TEST

The tests have been carried out in compliance with the standard IEC 60601-2-24 - Medical electrical equipment – Part 2-24: Particular requirements for the safety of infusion and controllers. The following graphics show the accuracy of the pump during the administration.

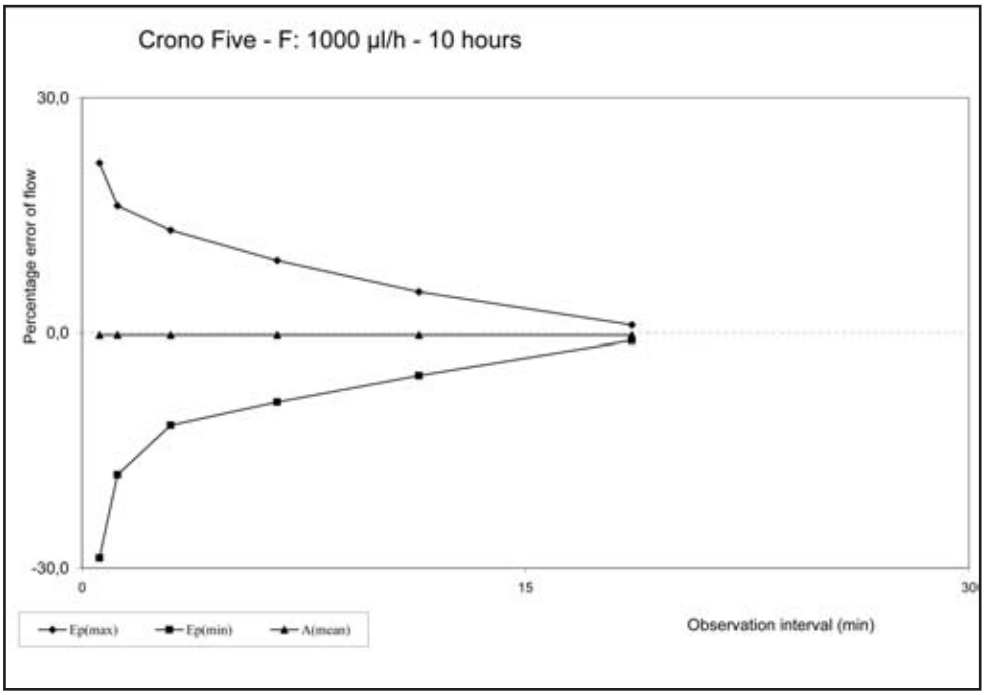
1.1 - Start-up flow rate

• Programmed flow rate: 1000 mcl/h



1.2 - Flow rate error (trumpet curve)

- Programmed flow rate: 1000 mcl/h
- Average error: +/- 2%



Accuracy may deviate from the information in this user guide depending on which type of extension set, tubing and access devices are used for the administration of a medication.

TIME TO AN OCCLUSION ALARM SIGNAL

There is a certain interval time between when an occlusion occurs and the time it takes for the pressure in the administration line to trigger the occlusion alarm signal. The table below is showing the time to an occlusion alarm with different flow rates in combination with an infusion set with 27G needle, 80 cm lenght with very stiff lining.

Flow rate	Time to an occlusion alarm signal
100 mcl/h	About 5 hours
500 mcl/h	About 50 minutes
5000 mcl/h	About 5 minutes

The time to the occlusion signal is a function of the flow rate, the lower the flow rate, the more time the pump will need to trigger the occlusion alarm.

CAUTION

The time to an occlusion alarm signal can increase if there is air in the line, when other catheter sizes, filters and extension set tubing with softer materials are used, or when the lines from the pump are connected to other access devices.

For patients that are likely to be adversely affected by interrupted medication or fluid delivery from Crono Five, close supervision for immediate corrective action should be provided.

POST-OCCLUSION BOLUS

When the occlusion alarm signal is triggered, the pump has built up a cer - tain overpressure in the administration line(s), which has to be eliminated to avoid an accidental post occlusion bolus that could result in serious injury or death to the patient. The size of a post-occlusion bolus for Crono Five in combination with an infusion set with 27G needle, 80 cm lenght with very stiff lining is about 0.4 ml.

Post-occlusion bolus may deviate from the information in this user guide depending on which type of extension set, tubing and access devices that are used for the administration of a medication.

CAUTION

The size of a post-occlusion bolus can increase if there is air in the line, when other catheter sizes, filters and extension set tubing with softer mate - rials are used, or when the lines from the pump are connected to other access devices.

Patients, who are likely to be adversely affected (serious injury or death) by an accidental release of the post-occlusion bolus, should not eliminate the bolus before having instructions how to do the elimination correctly or be trained to eliminate the post-occlusion bolus correctly themselves before the drug delivery is resumed.

ANNEX 4

ELECTROMAGNETIC COMPATIBILITY

The tests have been carried out in compliance with the standard IEC 60601-2-24 - Medical electrical equipment - Part 2-24: Particular requirement for the safety of infusion pump and controllers.

4.1 – Emission tests

The test has been executed with the antenna in horizontal and vertical polarization.

4.1.1

TEST	Coupling port	Range frequency
Radiated Emission	Enclosure	30 - 1000 MHz

4.1.2 - Result
No degradation of performance or loss of function is allowed during the test.

4.2 - Electrostatic Discharge

Discharges in air have been carried out in proximity of the push-buttons, in proximity of two angles of the display and two angles of the battery compartment.
Contact discharges have been carried out on the two eyelets and two points of the anodized metallic body.

4.2.1

TEST	Coupling port	Test level
Electrostatic Discharge	Enclosure	15 kV air discharge, 8 kV contact discharge, pos. and neg.

4.2.2 - Result
No degradation of performance or loss of function is allowed during the test.

4.3 - Radiated immunity

The A test has been executed with horizontal and vertical field polarization.

The B test has been executed with horizontal and vertical field polarization, with steps of equal frequency to 1% of the fundamental one.

4.3.1

TEST	Coupling port	Frequency range	Test level
A - Radiated immunity	Enclosure	26-80 MHz	10 V/m 80% AM 1kHz
B - Radiated immunity	Enclosure	80-1000 MHz	10 V/m 80% AM 1kHz

4.3.2 - Result
No degradation of performance or loss of function is allowed during the test.