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SYMBOLS AND CONVENTIONS

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

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

Notepad
This icon indicates a “NOTE” containing additional information or useful tips about the use of the pump.

Flashing symbol
The graphic symbol shown in the User Guide above the images of the pump display indicates that the information below is flashing.

This User Guide is divided into 5 parts:

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

Part 2 (blue): sections 8 to 10, which describe the functions of the CRONO S-PID 30 device.

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

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

Part 5 (grey): Appendices page 67 to page 86.
INTRODUCTION

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

This User Guide has been prepared to enable you to make the best use of the **CRONO S-PID 30** pump, supplying information on the settings, safe use and maintenance of the device.

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

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

The instructions provided herein are exclusively for the ambulatory infusion pump, model: **CRONO S-PID 30** and are intended for use by the medical and paramedical personnel who need to set up the pump initially, and subsequently by patients who are capable of managing their therapy autonomously, or persons who take care of patients.

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

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

The instructions provided in this User Guide are essential for the safe and correct use of the pump. You are advised to read the whole User guide before starting to use the device and refer to the User Guide for future reference.

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

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

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

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

WARNING: PRECAUTIONS FOR USE

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

INFORMATION

For further information about the CRONO S-PID 30 pump, please contact:

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

The **CRONO S-PID 30** ambulatory infusion pump is designed for subcutaneous infusion of immunoglobulins and drugs in general.

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

NOTE

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

WARNINGS

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

Before using the pump, please evaluate whether its use is appropriate for the type of needs and patients, paying close attention to the following aspects:
- The technical specifications of the pump
- The infusion sets which will be used
- Whether you will be using multiple tube sets and clamps in the infusion line
- The cognitive and psycho-physical conditions of the patient.

Since the clinical procedures are the responsibility of the medical or paramedical personnel, the above list is supplied for example purposes only and is not exhaustive.

The device must be used:
- Under the control of a doctor
- Adopting appropriate procedures and adequate measures when dealing with patients who could suffer serious consequences (injuries or death) in the event of accidents and/or breakdowns which cause an interruption of the administration of the drug.
Do not *prime* the infusion line when it is connected to the patient, because this could cause an overdose of the drug.

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

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

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

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

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

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

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

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

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

**Do not administer immunoglobulins intravenously; if they are accidentally administered to a blood vessel or capillary, the patient could suffer an anaphylactic shock or thromboembolic events. Always check this before continuing with an infusion.**
SECTION 3

PUMP DESCRIPTION

**CRONO S-PID 30** is an ambulatory infusion pump with reservoir for controlled subcutaneous administration of drugs.

**CRONO S-PID 30** is a union of high technology and innovative design. Its reduced dimensions and weight make it ideal for home use, giving the patient the freedom to engage in everyday work and leisure activities during the therapy.

**CRONO S-PID 30** uses 30 ml dedicated reservoirs.
The pump's standout features are:
- the ability to choose between time or flow rate programming modes;
- the ability to divide the drug volume contained in the syringe over several infusion sites (feature only available in flow rate mode).

The pusher mechanism which operates directly on the rubber piston of the reservoir enables the pump to combine high delivery pressure with excellent precision while administering the drug.

**CRONO S-PID 30** is provided with a liquid crystal display (LCD) which shows practical information to the doctor and patient about the settings, operations and diagnostics of the pump.

INFUSION SYSTEM

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pump dimensions</strong></td>
<td>3.14 x 1.85 x 1.18 in (80 x 47 x 30 mm)</td>
</tr>
<tr>
<td><strong>Pump weight</strong></td>
<td>125 g, including the battery.</td>
</tr>
<tr>
<td><strong>Battery</strong></td>
<td>Lithium CR 123A 3V (battery life: about 200 infusions).</td>
</tr>
<tr>
<td><strong>Dedicated single-use reservoirs</strong></td>
<td>With a 30 ml capacity and a &quot;Luer-Lock&quot; universal security attachment.</td>
</tr>
<tr>
<td><strong>Quantities that can be administered</strong></td>
<td>Selectable, from 1 to 30 ml in 1 ml increments</td>
</tr>
<tr>
<td><strong>Time Mode (delivery time)</strong></td>
<td>Selectable, from 25 m. to 300 h.</td>
</tr>
<tr>
<td><strong>Flow rate mode</strong></td>
<td>Selectable, from 0.1 ml/h to 75 ml/h.</td>
</tr>
<tr>
<td><strong>Available priming volume</strong></td>
<td>1.5 ml.</td>
</tr>
<tr>
<td><strong>Flow rate precision</strong></td>
<td>+/-3%</td>
</tr>
<tr>
<td><strong>Occlusion pressure</strong></td>
<td>4.5 bar +/- 2</td>
</tr>
<tr>
<td><strong>Single-shot volume</strong></td>
<td>33 microlitres (shot: quantity administered for every rotation of the motor).</td>
</tr>
<tr>
<td><strong>Time needed to signal an occlusion</strong></td>
<td>See APPENDIX 4.</td>
</tr>
<tr>
<td><strong>Post-occlusion bolus</strong></td>
<td>About 1.2 ml.</td>
</tr>
<tr>
<td><strong>Memory settings</strong></td>
<td>All settings are automatically stored in a flash memory which is retained even if the device is left without a battery.</td>
</tr>
<tr>
<td>Feature</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>Liquid crystal display (LCD) (dimensions: 0.43 x 1.0 in; 11 x 28 mm).</td>
</tr>
<tr>
<td><strong>Motor</strong></td>
<td>Coreless DC motor, the rotation of which is controlled by an infrared system.</td>
</tr>
<tr>
<td><strong>Settings lock</strong></td>
<td>Two configurable levels.</td>
</tr>
<tr>
<td><strong>Electronic circuit with two microcontrollers</strong></td>
<td>Ensures a more reliable and safer infusion system.</td>
</tr>
<tr>
<td><strong>Safety circuits</strong></td>
<td>They check that the device is functioning correctly, intervening in the event of any anomaly with acoustic signals and messages on the display.</td>
</tr>
<tr>
<td><strong>Ingress protection rating</strong></td>
<td>IP 42</td>
</tr>
<tr>
<td><strong>Pump operating conditions</strong></td>
<td>+10°C / +45°C. 30% / 75% RH. 700 hPa / 1060 hPa.</td>
</tr>
<tr>
<td><strong>Storage conditions of the pump</strong></td>
<td>-10°C / +60°C. 10% / 85% RH. 500 hPa / 1060 hPa.</td>
</tr>
</tbody>
</table>
SECTION 4

EQUIPMENT SUPPLIED

1. Ambulatory infusion pump with reservoir CRONO S-PID 30.
2. Infuser carry-case (Code: VAL/01R).
4. Fabric case (Code: CM/02/B).
6. 2 batteries (one of which is already inserted in the pump) (Code: CR/123A).
7. Battery-cover opening tool (Code: CA/02).
8. User guide.
SECTION 5

PUMP PARTS

- Connector for the reservoir wings
- LED
- Display
- Buttons
- Eyelets to fasten the collar strap
- Pusher
- Anti-slip grooves
- Battery compartment
- Serial no.
- Quick reference
- CE marking
- Serial no.
- Anti-slip grooves
- Battery compartment
- Quick reference
- CE marking

Display

 ml/h

30 OFF

OFF

ON

Quick reference

Buttons

CE marking

Anti-slip grooves

Battery compartment

Connector for the reservoir wings

Eyelets to fasten the collar strap

Pusher
SECTION 5

CONTROL BUTTONS

There are 3 control buttons.

The buttons have a built-in safety delay: you must keep them pressed for several seconds before the command takes effect (use only your fingertips, do not use sharp objects).

The buttons make a ticking sound when pressed.

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

WARNING

The buttons have different functions depending on the following operational condition of the pump:

- **OFF**
- **Stop**
- **ON**

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

LED

The red LED on the right of the display activates in the following circumstances:

1 - When inserting the battery and the functioning of the device is checked (see page 33).

2 - When an error has occurred (for further information please refer to pages 25-26).
LIQUID CRYSTAL DISPLAY (LCD)

The liquid crystal display uses text messages and icons to provide the user with the information about the settings, the operation being performed and any errors.

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

**Two secondary digits of the display**
Display:
- The remaining drug volume contained in the reservoir;
- Information related to the parameter being displayed in the four main digits;
- The unit of measurement of the parameter being displayed.
“Low Battery” indicator: Displays when the battery is nearly dead (see related section on page 21).

"Drop" icon: Steady: it separates integers from decimal numbers. Flashing: the hour and minute separator.

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

“Minute” indicator: Flashes when the remaining duration of an infusion is expressed in minutes (time left is less than 60 minutes).

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

The appearance of the “LOW BATTERY” indicator (not flashing) on the display indicates that the battery is nearly low.

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

In these circumstances the device is locked until the battery must be replaced.

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

If the battery needs to be changed during an infusion, the pump must be in the StoP condition.

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

WARNINGS

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

NOTES

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

- When you have completed this phase (replacement of the battery), check that the battery compartment is properly closed.
SECTION 5

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

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

2. Pull back the cover.

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

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

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

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

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

- Hold the pump and the compartment cover firmly in your one hand;
- Strike the palm of your other hand with the pump, to jolt the battery from the compartment;
- The cover is supplied with a gasket which must remain in position as indicated in the illustration.
SECTION 5
SECTION 6

SETTINGS LOCK

The CRONO S-PID 30 pump has 2 access configurations:

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

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

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

WARNINGS

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

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

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

<table>
<thead>
<tr>
<th>DISPLAY</th>
<th>ACOUSTIC SIGNAL</th>
<th>ERROR DESCRIPTION</th>
<th>CORRECTIVE ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Er</td>
<td>Brief beep.</td>
<td>Operation not allowed.</td>
<td>---</td>
</tr>
<tr>
<td>Er.2</td>
<td>Continuous acoustic signal and flashing LED.</td>
<td>Critical problem in the safety system.</td>
<td>Press the button.</td>
</tr>
<tr>
<td>Er.3</td>
<td>Intermittent acoustic signal repeated approximately every 10 seconds.</td>
<td>Anomaly in the motor circuit.</td>
<td>Press the button.</td>
</tr>
<tr>
<td>Er.4</td>
<td>Intermittent acoustic signal repeated approximately every 10 seconds.</td>
<td>Mechanism of the pusher blocked while withdrawing (could be caused by a foreign body preventing its movement).</td>
<td>Eliminate the cause and initialize the device.</td>
</tr>
<tr>
<td>Er.5</td>
<td>Intermittent acoustic signal repeated approximately every 10 seconds.</td>
<td>Pusher mechanism blocked.</td>
<td>Press the button.</td>
</tr>
<tr>
<td>Er.6</td>
<td>Intermittent acoustic signal repeated approximately every 10 seconds.</td>
<td>Motor anomaly.</td>
<td>Initialize the device.</td>
</tr>
<tr>
<td>Er.7</td>
<td>Intermittent acoustic signal repeated approximately every 10 seconds (possibly accompanied by flashing LED).</td>
<td>Communication error between the two microcontrollers.</td>
<td>Press the button.</td>
</tr>
<tr>
<td>DISPLAY</td>
<td>ACOUSTIC SIGNAL</td>
<td>ERROR DESCRIPTION</td>
<td>CORRECTIVE ACTION</td>
</tr>
<tr>
<td>---------</td>
<td>----------------</td>
<td>-------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Er.8</td>
<td>Intermittent acoustic signal repeated approximately every 10 seconds.</td>
<td>When a battery is inserted and at the start of every infusion, the device runs a control algorithm on the parameters stored in the memory. If an error is found, the manufacturer default settings are restored, the motor stops and an error is shown on the display.</td>
<td>Initialize the device.</td>
</tr>
<tr>
<td>Er.9</td>
<td>Intermittent acoustic signal repeated approximately every 10 seconds.</td>
<td>Anomaly in the safety circuit which drives the pump motor. If an error is found, the pump locks and the error is indicated.</td>
<td>Initialize the device.</td>
</tr>
<tr>
<td>Er.11</td>
<td>Intermittent acoustic signal repeated approximately every 10 seconds.</td>
<td>Anomaly in the pusher mechanism.</td>
<td>Initialize the device.</td>
</tr>
<tr>
<td>Occl</td>
<td>Intermittent acoustic signal repeated approximately every 10 seconds.</td>
<td>Mechanism blocked because of an occlusion in the infusion line.</td>
<td>Eliminate the cause and press button +. See page 28.</td>
</tr>
</tbody>
</table>
WARNINGs

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

- Errors messages **Er,2** and **Er,7** are accompanied by the flashing LED.

NOTES

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

- In order to initialize the device when an error has occurred and the device is in the **ON** condition, it is necessary to remove the battery and re-insert it after about 10/15 seconds. If the error is detected again after the corrective action or initialisation of the device, contact the CANÈ S.p.A. Technical Support Service.
INFUSION SET OCCLUSION
The pump is designed to recognise when the administration of a drug has been interrupted by external means, such as, for example, the kinking of the infusion set tube and consequent occlusion. In these circumstances, the pump stops the infusion: the display indicates that an occlusion occurred accompanied by an intermittent acoustic signal every 10 seconds. While the system is still occluded, the drug is not administered: to resume an infusion, press the button after removing the cause of the occlusion.

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

POST-OCCLUSION BOLUS
The occlusion alarm is signalled when the pump detects excessive back pressure in the infusion line. This back pressure must be removed without accidently releasing the post-occlusion bolus, which could cause serious harm to the patient.
The volume of the CRONO S-PID 30 post - occlusion bolus, considering only the combined volume of the pump and reservoirs is approximately 1.2 ml.

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

The pump is supplied with the following default settings:

<table>
<thead>
<tr>
<th>Setting</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery time</td>
<td>10 h</td>
</tr>
<tr>
<td>End of infusion acoustic signal</td>
<td>AL on (active)</td>
</tr>
<tr>
<td>Partial volume</td>
<td>30 ml</td>
</tr>
<tr>
<td>Access level</td>
<td>L 0 (unlocked)</td>
</tr>
<tr>
<td>Number of infusions</td>
<td>0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Setting</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow rate</td>
<td>3 ml/h</td>
</tr>
<tr>
<td>End of infusion acoustic signal</td>
<td>AL on (active)</td>
</tr>
<tr>
<td>Partial volume</td>
<td>30 ml</td>
</tr>
<tr>
<td>Access level</td>
<td>L 0 (unlocked)</td>
</tr>
<tr>
<td>Number of infusions</td>
<td>0</td>
</tr>
</tbody>
</table>
QUICK REFERENCE
The buttons have a built-in safety delay: you must keep them pressed for several seconds before the command takes effect.

WARNING
These quick reference instructions are not an alternative to reading the information contained in this User guide, but offer a basic and rapid summary of the pump’s functions.

<table>
<thead>
<tr>
<th>BUTTONS ACTIVATION DISPLAY</th>
<th>DISPLAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Access all display segments</td>
<td><img src="image1.png" alt="Image" /></td>
</tr>
<tr>
<td>• Show the type of programming (flow rate/time)</td>
<td><img src="image2.png" alt="Image" /></td>
</tr>
<tr>
<td>• Access the flow rate/time selector (only possible with L 0 access level)</td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td>• Change the flow rate/time parameter</td>
<td><img src="image4.png" alt="Image" /></td>
</tr>
<tr>
<td>• Automatic positioning of the pusher at the start of the infusion</td>
<td><img src="image5.png" alt="Image" /></td>
</tr>
<tr>
<td>• Switching off the pump</td>
<td><img src="image6.png" alt="Image" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BUTTONS SETTINGS DISPLAY</th>
<th>DISPLAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The pump is switched off with L 0 access level</td>
<td><img src="image7.png" alt="Image" /></td>
</tr>
<tr>
<td>• Access the end of infusion alarm selector</td>
<td><img src="image8.png" alt="Image" /></td>
</tr>
<tr>
<td>• Access the partial volume selector</td>
<td><img src="image9.png" alt="Image" /></td>
</tr>
<tr>
<td>• Change the value of the preceding settings</td>
<td><img src="image10.png" alt="Image" /></td>
</tr>
</tbody>
</table>
### SECTION 9

<table>
<thead>
<tr>
<th>BUTTONS</th>
<th>SWITCHING ON</th>
<th>DISPLAY</th>
</tr>
</thead>
</table>
| [+]     | • Switching on the pump  
• Priming *phase*  
• Displaying the partial volume (if it has been set)  
• Start of infusion  
• Switches between display of flow rate (only in flow rate mode) and delivery time |
| [+]     | • Switching on the pump  
• Priming *dose* (max 1.5 ml) |
| [−]     | • Switching off the pump |
| [−] / [+] | • Delivery time  
• Setting the delivery time (*t* mode)  
• Decrease/Increase the delivery time |
| [+]     | • Delivery time  
• Display the flow rate (*F* mode)  
• Setting the flow rate  
• Decrease/Increase the flow rate |
| [−]     | • Switching off the pump |

---

**PRIMING**

- Keep pressed

**PUMP SET TO ON**

- Press simultaneously

**SETTING THE DELIVERY TIME (T mode)**

**SETTING THE FLOW RATE (F mode)**

**SWITCHING OFF THE PUMP**
### SECTION 9

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<td></td>
<td>• Switching off the pump</td>
<td><img src="image5" alt="Display Image" /></td>
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</table>
PUMP INITIALISATION

If the battery is removed when the display shows OFF, when you re-insert the battery the pump runs the initialisation sequence, during which it:

1. Runs a self-diagnostic test, emitting a series of brief acoustics signals, flashing the red LED and displaying all the icons.

2. The display shows the previously selected programming mode.

3. The display shows OFF.

NOTES

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

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

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

• If the battery is removed when the display shows StoP, re-inserting the battery makes the pump run a self-diagnostic test (as explained in Step 1). Then, the display shows StoP.

WARNING

The setting of the pump is the doctor's responsibility, who will choose the most suited parameters to carry out the therapy required for the patient.
PUMP SETTINGS WHEN INSERTING BATTERY

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

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

Procedure:

1 - Remove the battery when the device is set to OFF and re-insert the battery.

2 - The display shows all the symbols.

3 - The device simultaneously runs a self-diagnostic tests during which it emits an acoustic signal.

4 - Subsequently, the display shows “F” (flow rate) or “t” (time) programming mode:

5 - After pressing the button the symbol flashes for 9 seconds. By keeping the button pressed it is possible to switch from one option to another one.

6 - If these buttons are not pressed for about 9 seconds, the device memorises the selected parameter.

7 - Subsequently, the display shows OFF.

NOTE

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

WARNING

Choosing whether to program the pump by flow rate or by time is the responsibility of the doctor, who will decide on the most suitable method.
PUMP SETTINGS SEQUENCE WITH THE PUMP OFF CONDITION

When the device is set to OFF, the following parameters can be set:
1 - End of infusion acoustic signal.
2 - Partial volume.

In the OFF condition the parameters can be selected only in the following circumstances:
- Setting lock unlocked;
- At the start of a new infusion (partial or total).

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

Press the button again to display and set the partial volume. You can change the parameter settings (activate/de-activate) while the display is flashing using the and buttons.

NOTE

When the settings lock is on (L 1), if any attempts are made to change the parameter then the display will show the flashing lock symbol and beep several times.
SECTION 10

SETTING OF END OF INFUSION ACOUSTIC SIGNAL

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

2. When the value flashes, select a new value by using the **⇒** and **⇒** buttons. Selecting **off** disables the warning and the end of infusion acoustic signals; selecting **on** activates the warning of end of infusion acoustic signals, which will sound 10 min. and 5 min. before the end of the infusion, and at the end of the infusion.

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

4. By pressing the **P** button while the value of the previous settings is still flashing it is possible to set the following parameter: **SETTING THE PARTIAL VOLUME** (see page 37).

NOTES

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

• The end of infusion acoustic signal can be set also in the **StoP** condition.
SETTING THE PARTIAL VOLUME

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

The partial volume can be set from 1 cc to 30 cc in increments of 1 cc. To set this parameter, press the \( \textcolor{red}{P} \) button again, while the previous parameter is flashing.

The partial volume function can only be set before starting a new infusion, either a complete one (30 ml) or a partial one.

Proceed as follows:

1. The display shows a flashing value of the volume, preceded by \textcolor{red}{cc}, which indicates the unit of volume (1 cc = 1 ml).

2. Press the \( \textcolor{green}{-} \) button to decrease the value and the \( \textcolor{blue}{+} \) button to increase it. Each change is indicated by an acoustic signal.

3. Do not press any button for 10 seconds and the setting phase will end. The display will show \textcolor{red}{P,cc}.

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

5. - When the pusher is in the correct position, the display shows \textbf{OFF}. The selected partial volume value will be shown at the bottom left of the display.
NOTES

• The set partial volume value is automatically saved in the pump memory.

• At the end of the infusion, the pusher returns to the position corresponding to the set partial volume value.

• The partial volume value can be interrupted by simultaneously pressing the \(-\) and \(\textcolor{red}{+}\) buttons.
  - if the pusher was still advancing, the device switches off (the display shows \textit{StoP}) and the pusher remains in the same position when the infusion was interrupted: the partial volume value is not stored in the device memory and the previous value will not be overwritten.
  - If, however, the pusher was in the process of being withdrawn, the display shows \textit{OFF} and \textit{P,cc alternately}. The only possible operation is to continue the withdrawal of the pusher by pressing the \(\textcolor{red}{+}\) button. The pusher withdraws to the position of the partial volume settings.

• Press the \(-\) and \(\textcolor{red}{+}\) buttons simultaneously while \textit{P,cc} is shown to cancel the storing of the partial volume.

WARNINGS

• This operation must not be carried out with the infusion set connected to the patient.
• A partial volume cannot be set while an infusion is in progress.
• The partial volume settings remain in the device memory even if the battery is removed.
• If the battery is removed when the pump is set to \textit{OFF/StoP}, the partial volume remains in the device memory and the pusher is not withdrawn.
• If the battery is removed when the device is in the \textit{ON}, the pusher returns to the infusion start position after a reset and then repositions itself according to the memorised partial volume.

SETTINGS IN ON CONDITION

When the device is set to \textbf{ON}, the following parameters can be set:

1 - Delivery time (if time mode has been selected upon battery insertion).
2 - Flow rate (if flow rate mode has been selected upon battery insertion).
SETTING THE DELIVERY TIME

This function is available only if the “\( t \)” (time) function has been selected upon battery insertion.

Time value can be set from 25 min. to 300 h as follows:
- From 25 min. to 1 h in increments of 5 min.
- From 1 h to 30 h in increments of 15 min.
- From 30 h to 300 h in increments of 120 min. (2 h)

You can change the time parameter during an infusion.

Procedure:
1 - Switch on the pump by pressing the \(+\) button.

2 - Pressing the \(-\) button and the pump allows setting the delivery time – the time displayed begins to flash.

3 - You can change the parameter while it flashes using the \(-\) or \(+\) buttons.

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

NOTES

• If you keep either the \(-\) or \(+\) buttons pressed, it is possible to change the values of delivery time quickly.
• If the settings lock is active, the function to set the delivery time is not available; if attempts are made to change the parameter, then the display will show the flashing lock symbol and will emit an intermittent acoustic signal.

WARNING

If a partial volume is used, the pump can perform an infusion in less time compared to the specified minimum time of 25 minutes.
SETTING THE FLOW RATE

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

The flow rate can be set from 0.1 to 75 ml/h as follows:
- From 0.1 ml/h to 1 ml/h in increments of 0.01 ml/h
- From 1 ml/h to 10 ml/h in increments of 0.1 ml/h
- From 11 ml/h to 75 ml/h in increments of 1 ml/h

You can change the flow rate parameter only during an infusion.

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

2 - Press the  button and the pump allows for setting the flow rate: The display shows the flashing value of the flow rate.

3 - You can change the parameter while it flashes using the  or  buttons.

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

If you press the  button, the display toggles between the delivery time and the flow rate, and vice versa.

NOTES

• If you keep either the  or  button pressed, it is possible to change the values of the flow rate quickly.
• If the settings lock is active, the function to set the flow rate is not available. Any attempt to change the parameter results in the display showing the flashing lock icon accompanied by some short acoustic signals.
SWITCHING ON THE PUMP

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

- **Pr** (priming function) the display shows Pr. (see page 42);

- Having carried out the priming, or if the pump is turned on to resume the infusion from the Stop condition, the display shows the following in sequence:
  - The partial volume value (if it has been set)
  - The value of the delivery time or of the flow rate

THE PUMP IN ON CONDITION

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

- From 300 h to 100 h the delivery time decreases hour by hour.
- From 99.59 h to 1 minute the delivery time decreases minute by minute.

WARNINGS

Before starting an infusion:
- Inspect the infusion line to ensure there are no folds, closed clamps, or other occlusions in the beginning of the line.
- Expel any air bubbles.
PRIMING THE INFUSION SET LINE

The *priming* function allows for filling the infusion set line with the drug contained in the reservoir.

The volume available for *priming* is 1.5 ml.

The *priming* function is enabled when you switch the device on and the pusher is in the infusion start position, regardless of whether the settings lock is on or not.

The *priming* procedure is as follows:

1. Turn on the device by pressing the button.
2. The display shows \text{Pr}. There are three options:
   
   a. Postpone the *priming*.
   b. Cancel the *priming*.
   c. Perform the *priming*.

a. Postpone the *priming*

   Wait for 10 seconds, the pump will turn off automatically.

b. Cancel the *priming*

   Press the button again: the pump begins the infusion and the display shows the time remaining until the end of the infusion.

c. Perform the *priming*

   Press and hold down the button: the pump delivers the *priming* dose until you release the button. The display then shows flashing letter \text{P} in the secondary digits, followed by the number of ml delivered.

   The *priming* function can be interrupted by releasing the button. The display shows \text{Pr} again. In this way it is again possible to postpone, cancel or perform the *priming* function as described above. The procedure can be repeated up to a maximum of 1.5 ml.
NOTES

• If you keep the button pressed, the pump delivers the primary dose, giving an acoustic signal every time 0.5 ml is administered consecutively. (e.g. 0.5 – 1.0 – 1.5 ml).

• Proceed until the infusion set is completely filled and a few drops of the drug leak out of it.

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

WARNINGS

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

• The priming function must only be performed with the reservoir connected to the infusion set, but before inserting the needle into the infusion site.

• Before beginning an infusion, check that there are no air bubbles in the infusion line, and if need be, expel the ones found. Alternatively, use a vented filter.
SECTION 10

END OF INFUSION

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

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

When the withdrawal is complete, the display shows OFF and the pump is ready for another infusion.

NOTE

The pusher withdrawal time for a 30 cc volume is about 6 minutes. It is proportionately less for lower volumes.

SWITCHING OFF THE PUMP

To switch off the pump during an infusion, press the and the buttons simultaneously. The display will show StoP.

If the pump is switched off during an infusion, the device will emit a series of 10 short beeps every 10 seconds, and the display will be flashing with StoP. To stop the acoustic signal, press button . This acoustic signal will be repeated every time the device is switched off during an infusion.
WITHDRAWING THE PUSHER

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

   **To stop an active infusion, do the following:**

   - Stop the pump by pressing the $-$ and $+$ buttons simultaneously.

   - Turn off the pump by pressing the $P$ and $-$ buttons for a few seconds: The display shows **End** for 10 seconds and then begins to withdraw the pusher.

   - During these 10 seconds when the display shows **End** you can cancel the withdrawal request by pressing the $-$ and $+$ buttons together.

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

   The pusher remains still in the infusion end position for about 10 seconds, after which it begins to withdraw until it reaches the infusion start position.

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

   **Pusher in motion**
   While the pusher is being withdrawn, the display shows the “**pusher continuous withdrawal**” icon.
The function to withdraw the pusher can be interrupted by pressing the \(-\) and \(+\) buttons together. The display then alternates between **End** and **OFF**. At this point the only active button is the \(+) button. When you press it again, the pump resumes the withdrawal of the pusher.

**WARNING**

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

This function allows for displaying the programmed pump settings. To display the pump settings, the pump must be set to **OFF** or **StoP**.

If the settings are displayed in the **L 0** mode (settings lock not active) and flash, it is possible to reset them. If the settings are displayed in **L 1** condition (settings lock active with the display showing the lock icon), the parameters will not flash and cannot be modified.

**Proceed as follows:**

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

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

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

The device contains two infusion counters: one for a partial count which can be reset, and another for a total count.

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

1 - Press the button for about 4 seconds, until the display shows the number of partial infusions PC (Partial Counter).

2 - Without releasing the button, press button P: The number of partial infusions shown on the display starts flashing.

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

4 - Press either the or the button to reset the number of partial infusions. Alternatively, press the P button to display the total count of infusions performed: tC (Total Counter).

5 - Press the P button again to display the pump firmware release: rE (Release).

6 - If you do not press anything for about 10 seconds or press the P button again, the display shows OFF.
RESERVOIR PARTS
The **CRONO S-PID 30** pump uses a dedicated 30 ml *reservoir*, model CRN® CRONO® Syringe.

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

![Reservoir Diagram]

**WARNINGS**

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

**LUER-LOCK CAP FUNCTIONS**

- After the *reservoir* has been filled, it facilitates unscrewing of the piston rod, avoiding spillage of the drug.

- It facilitates the correct connection between the pump pusher and the rubber piston of the *reservoir*.

- It protects the drug inside the *reservoir* in case it is not used immediately.
INFUSION SET
You are recommended to use an infusion set with the following characteristics:
• Tube with reduced internal volume (ideal 0.1 ml, maximum 0.62 ml)
• Tube length not more than 90 cm
• Anti-kinking tube

INFUSION SET PARTS

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

WARNING
Refer to the User guide supplied with the device for information on using the infusion sets.

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

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

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

MULTIPLE INFUSION SET

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

MULTIPLE INFUSION SET PARTS

NOTE

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

WARNING

Refer to the User guide supplied with the device for information on using the infusion sets.
PREPARATION OF THE RESERVOIR AND CONNECTION TO THE PUMP

1. Screw the needle into the reservoir in a clockwise direction and remove the needle cover.
2. Fill the reservoir, aspirating the liquid slowly and checking that the quantity of the drug does not exceed its capacity or any partial volume you may have set.
3. Screw the Luer-Lock cap to the reservoir (a) and then unscrew the rod, rotating it counter-clockwise (b) fairly quickly.
4. Insert the reservoir into the pump. The rubber piston will be inserted into the pusher. Rotate it clockwise through 90° and it will click and engage with the pusher.
5. Insert the cone of the infusion set over the reservoir.
INSERTION OF THE RESERVOIR INTO THE PUMP

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

Front view
WARNING

• Before filling the reservoir
Unscrew and screw back the piston rod to facilitate its unscrewing after you have filled the reservoir.

• Filling the reservoir
The liquid must be aspirated slowly.
Do not fill the reservoir more than the maximum level allowed.
The rod must be unscrewed fairly quickly.

• Inserting the reservoir into the pump
To avoid any leakage of the drug while the reservoir is being inserted into the pump, you can use the infusion set as an alternative to the Luer-Lock cap indicated on page 49.

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

While filling the reservoir and inserting it into the pump, a small leakage might occur between the first and second ring on the rubber piston; this does not compromise either the correct operation of the reservoir or the delivery of the drug.
SECTION 11

PUMP CONFIGURATION IMAGES FOR INFUSIONS AT MULTIPLE SITES:

1 - Y-SET PUMP

2 - TWO-WAY PUMP SET
Before preparing for the infusion, you are recommended to adopt the following precautions:

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

**WARNING**
Always work in antiseptic conditions to reduce the risk of infection to the minimum.
The images refer to the Neria™ infusion set from Unomedical, a Convatec Company.

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

Connect the infusion set to the reservoir.

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

**WARNING**

When you are priming the infusion line and are preparing to insert the needle below the skin, hold the set with the needle pointing downwards to ensure that no drug can come into contact with the protecting adhesive paper.

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

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

It is important to lift a fold of skin, to reduce the risk of positioning the needle in a muscle. Pinch the skin with your fingers at the chosen infusion site before inserting the needle, which you do by taking the protective wings of the infusion set with the other hand and inserting the needle vertically.

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

Press firmly on the adhesive to fix it to the skin. Check the infusion site frequently to ensure that the needle remains in the correct position.
HOW TO USE THE ACCESSORIES SUPPLIED
The following figures give an indication of how to use the standard accessories supplied with the pump.

PUMP CARRIED AROUND THE NECK
The pump worn with a collar strap and a fabric case.

FASTENING THE PUMP COLLAR STRAP SEQUENCE

1. 
2. 
3. 
SECTION 12

PUMP ATTACHED AT THE WAIST
The pump worn with an elastic belt and a fabric case.
GENERAL WARNINGS

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

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

The device does not need sterilising.

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

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

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

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

If you do not observe the above instructions, the device could malfunction, with potentially serious consequences for the user.
MAINTENANCE
The technical characteristics of the device make it extremely simple to main-
tain.

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

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

GENERAL WARNINGS

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

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

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

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

EXPECTED PUMP LIFE
The pump is expected to last for 4 (four) years from its purchase date. For safety reasons you should not continue using it after this period.
The device must only be repaired by CANÈ S.p.A. Customer Support Service. You are recommended, before sending the device, to contact:

- **Customer Support Service**  
  CANÈ S.p.A. Medical Technology  
  Via Cuorgnè, 42/a  
  10098 Rivoli (Turin) - Italy  
  Tel. +39.011.9574872  
  Fax +39.011.9598880

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

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

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

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

Conditions:

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

2. This guarantee does not extend to any costs and/or defects following modifications or adaptations made to the product, without prior written authorisation by CANÈ S.p.A. CANÈ S.p.A. disclaims all responsibility either to the purchaser or to third parties for damage that occurs to persons or things as a result of improper operation of the device, for uses of the device for which it was not designed and for the non-observance of the instructions provided in the User guide. The purchaser undertakes to indemnify CANÈ S.p.A. from any claims by third parties with respect to the above.

3. This guarantee is not valid if the model or serial number of the product have been modified, erased, removed or have in any way been made illegible.
4. The following are excluded from the guarantee:

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

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

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

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

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

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

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

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

Rivoli, 13/07/2012

The Chairman

[Signature]
APPENDICES
ICONS USED ON THE PUMP

<table>
<thead>
<tr>
<th>SN</th>
<th>Serial no. of the pump</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP 42</td>
<td>IP protection rating</td>
</tr>
<tr>
<td>1st digit (4) = protection from solid objects larger than 1 mm.</td>
<td></td>
</tr>
<tr>
<td>2nd digit (2) = protection from water droplets sprayed at an angle up to 15° degrees.</td>
<td></td>
</tr>
<tr>
<td>CE 0476</td>
<td>CE marking</td>
</tr>
<tr>
<td></td>
<td>Electromedical device</td>
</tr>
<tr>
<td></td>
<td>Electrical classification: Class I, Type BF.</td>
</tr>
<tr>
<td></td>
<td>Warning: read instructions before use</td>
</tr>
<tr>
<td></td>
<td>Separated waste collection of electrical and electronic equipment</td>
</tr>
<tr>
<td></td>
<td>In accordance with article 13 of Legislative Decree no. 151 of 25 July 2005 “Implementation of Directives 2002/95/EC, 2002/96/EC and 2003/108/EC concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment, as well as the disposal of waste.”</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>📜</td>
<td>Read the instructions</td>
</tr>
<tr>
<td>🌈 0123</td>
<td>CE marking</td>
</tr>
<tr>
<td>🌿</td>
<td>Recyclable</td>
</tr>
<tr>
<td>🧊 2</td>
<td>Use only once</td>
</tr>
<tr>
<td>🌐</td>
<td>Non-pyrogenic</td>
</tr>
<tr>
<td>☔️</td>
<td>Keep dry</td>
</tr>
<tr>
<td>☀️</td>
<td>Keep away from sunlight</td>
</tr>
<tr>
<td>🕒</td>
<td>Expiry date</td>
</tr>
<tr>
<td>🧘‍♂️</td>
<td>Sterilised with ethylene oxide</td>
</tr>
<tr>
<td>PP</td>
<td>Polypropylene</td>
</tr>
<tr>
<td>LOT</td>
<td>Batch code</td>
</tr>
<tr>
<td>REF</td>
<td>Reference No.</td>
</tr>
<tr>
<td>NEEDLE</td>
<td>Needle size</td>
</tr>
</tbody>
</table>
OPTIONAL ACCESSORIES AVAILABLE ON REQUEST

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

**Item code:** CM/15/A

**Colours:**

**Dimensions:** about 16 x 5.5 x 4 cm

**Weight:** about 60 g
2. Horizontal leatherette case, similar to a spectacle case.

Item code: CM/23/A

Colours: 

Dimensions: 16 x 5.5 x 4 cm

Weight: about 50 g
PRECISION TESTS

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

1.1 – Start-up flow
Flow rate setting: 0.3 ml/h.
TRUMPET CURVE

1.2 - Flow rate error (trumpet curve)
Flow rate setting: 0.3 ml/h.

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

Legend:
\[ E_p^{(\text{max.})} \] = maximal percentage variations.
\[ E_p^{(\text{min.})} \] = minimal percentage variations.
\[ A^{(\text{mean.})} \] = mean percentage variations.
APPENDIX 3

PRECISION TESTS

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

2.2 - Flow rate error (trumpet curve)
Flow rate setting: 1 ml/h.

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

Legend:
$E_p^{\text{(max.)}}$ = maximal percentage variations.
$E_p^{\text{(min.)}}$ = minimal percentage variations.
$A^{\text{(mean.)}}$ = mean percentage variations.
APPENDIX 3

PRECISION TESTS

2.1 – Start-up flow
Flow rate setting: 3 ml/h.
TRUMPET CURVE

2.2 - Flow rate error (trumpet curve)
Flow rate setting: 3 ml/h.

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

Legend:
$E_p(\text{max.})$ = maximal percentage variations.
$E_p(\text{min.})$ = minimal percentage variations.
$A(\text{mean.})$ = mean percentage variations.
TIME NEEDED TO SIGNAL AN OCCLUSION

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

<table>
<thead>
<tr>
<th>Flow rate</th>
<th>Time needed to signal an occlusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 ml/h</td>
<td>about 1 h 30 min</td>
</tr>
<tr>
<td>25 ml/h</td>
<td>about 3 minutes</td>
</tr>
<tr>
<td>75 ml/h</td>
<td>about 1 minute</td>
</tr>
</tbody>
</table>

WARNINGS

• The time needed to signal an occlusion is dependant on the flow rate, because the lower the flow rate, the longer the time needed by the pump to detect the occlusion.

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

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

When the occlusion alarm sounds, the pump has detected an excessive back pressure in the infusion line. This back pressure must be removed in order to avoid releasing a post-occlusion bolus, which might cause serious harm to the patient. The volume of a CRONO S-PID 30 post-occlusion bolus, considering only the combined volume of the pump and the reservoir is about 1.2 ml.

WARNINGS

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

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

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

The electromagnetic compatibility tests were performed in compliance with the standards:
• IEC 60601-2-24:2012, Medical electrical equipment, Part 2: Particular requirements for the safety of infusion pumps and controllers.

<table>
<thead>
<tr>
<th>Emission test</th>
<th>Compliance</th>
<th>Electromagnetic environment - User guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>CISPR 11 RF emissions</td>
<td>Group 1</td>
<td>CRONO S-PID 30 uses RF energy only for its internal operation. As a consequence, its RF emissions are very low and would thus not be expected to cause any interference to electronic devices in the vicinity.</td>
</tr>
<tr>
<td>Emissions in RF CISPR 11</td>
<td>Class B</td>
<td></td>
</tr>
<tr>
<td>IEC 61000-3-2 harmonic emissions</td>
<td>N/A</td>
<td>CRONO S-PID 30 is designed for use in all environments, including domestic environments and those environments directly linked to the low voltage mains supplying residential buildings.</td>
</tr>
<tr>
<td>IEC 61000-3-3 emissions in the event of voltage fluctuations or flicker</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

User guide and declaration by the manufacturer - electromagnetic immunity

CRONO S-PID 30 is designed to operate in the electromagnetic environment specified below. The client or user of the CRONO S-PID 30 must ensure that it is operated in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Level of compliance</th>
<th>Electromagnetic environment - User guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>IEC 61000-4-2 electrostatic discharge (ESD)</td>
<td>15 kV in air, 8 kV on contact</td>
<td>15 kV in air, 8 kV on contact</td>
<td>The flooring must be wood, concrete or ceramic. If the floor is covered in a synthetic material, the relative humidity must be at least 30%.</td>
</tr>
<tr>
<td>Magnetic fields</td>
<td>400 A/m, 50 and 60 Hz</td>
<td>400 A/m, 50 and 60 Hz</td>
<td></td>
</tr>
</tbody>
</table>
User guide and declaration by the manufacturer - electromagnetic immunity

**CRONO S-PID 30** is designed to operate in the electromagnetic environment specified below. The client or user of the **CRONO S-PID 30** must ensure that it is operated in such an environment.

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC 60601 test level</th>
<th>Level of compliance</th>
<th>Electromagnetic environment - User guide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiated immunity</td>
<td>80-2500 MHz 10V/m AM 80% 1 KHz</td>
<td>10V/m</td>
<td>Interference could occur in the vicinity of devices marked with the following symbol:</td>
</tr>
<tr>
<td></td>
<td>20-80 MHz 10V/m AM 80% 1 KHz</td>
<td>10V/m</td>
<td></td>
</tr>
</tbody>
</table>

Recommended separation distance between mobile and portable radio communication devices and the **CRONO S-PID 30**.

**CRONO S-PID 30** is designed to operate in an electromagnetic environment in which radiated RF disturbances are under control. The client or user of the **CRONO S-PID 30** can help prevent electromagnetic interference by ensuring a minimum distance between mobile and portable communication devices using RF (transmitters) and the **CRONO S-PID 30**, as recommended below, relative to the maximum output power of the radio-communication devices.

<table>
<thead>
<tr>
<th>Maximum specified output power of transmitter (W)</th>
<th>Separation distance at the transmitter frequency (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>150 kHZ to 80 MHz</td>
</tr>
<tr>
<td>0,01</td>
<td>1,2</td>
</tr>
<tr>
<td>0,1</td>
<td>3,8</td>
</tr>
<tr>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>10</td>
<td>38</td>
</tr>
<tr>
<td>100</td>
<td>120</td>
</tr>
</tbody>
</table>
REFERENCE DIRECTIVES


• **Legislative Decree no. 37 of 25 January 2010**: Implementation of Directive 2007/47/EC.
TECHNICAL STANDARDS

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


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

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

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

• **IEC 62-108: 2000-05.** User guide to the maintenance of infusion pumps and control systems.

• **IEC EN 62353:2008-11.** Medical electrical equipment - recurrent checks and tests after repair of medical electrical equipment.

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


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

For further information about the CRONO S-PID 30 pump, please contact:

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