

MEDICAL TECHNOLOGY

ABOUT CANÈ

Based in north-west Italy, Canè SpA is a leading manufacturer of ambulatory infusion pumps for the administration of pharmaceuticals.

Canè was founded in 1978 as a manufacturer of ambulatory infusion pumps for treating thalassaemia. Over the last 35 years it has grown to become the leader in the segment addressing drug deliveries ranging from 10 to 100 mL. Starting from the first syringe drivers, which were relatively bulky thus causing patient compliance to suffer, Canè's products have evolved into the Crono line of miniature pumps which may be worn without impacting patients' normal daily routine.

THERAPEUTIC AREAS

Canè's Crono series is comprised of the ambulatory infusion pumps and the dedicated CRN[®] CRONO[®] Syringes which are used with them. Depending upon the therapy the syringes may have volumes of 10, 20, 30, 50 or 100 mL. Most of the pumps are designed for a specific therapy, so that their features and programmability are tailored to the way in which the drug will be used by the patient.

The Crono series of ambulatory infusion pumps addresses four main therapeutic areas: primary immunodeficiency; Parkinson's disease; pain control; and thalassaemia. In addition, Canè has models dedicated to pulmonary hypertension and fertility treatment, and it is working with partners in areas as diverse as hormone replacement therapy, radiopharmacology and skin care.

The majority of the pumps are intended for use by patients at home, and are designed to allow them to receive medication almost continuously while maintaining as normal a life as possible.

Crono PAR

Crono PAR pumps (Figure 1) are for the subcutaneous infusion of apomorphine in the treatment of Parkinson's disease. There are models for reservoirs with volumes of 20 mL, 30 mL, and 50 mL, and they offer two different programming modes:

- Free mode which allows the patient to freely select one of the three available flow rates pre-programmed by the physician
- Auto mode, which automatically administers a daily flow rate profile, pre-programmed by the physician. The profile may be programmed hourly over a 24-hour period.

The Crono PAR pumps also have priming, bolus dose and partial volume functions.

Crono S-PID

Crono S-PID pumps (Figure 2) are for controlled subcutaneous administration of immunoglobulins. Models are available for 20 mL, 30 mL, 50 mL and 100 mL. This therapy generally requires rapid infusions, and flow rates of up to 300 mL/h are available, depending upon the model. The main features of the pumps are:

- The possibility of selecting between time or flow rate programming mode (50 mL and 100 mL models)
- The possibility of automatically pausing the infusion in order to allow the patient to divide the syringe contents over several infusion sites (50 mL and 100 mL models, available in flow rate mode only)
- Flow rate and infusion time can be varied during the infusion
- Priming and partial volume functions.

Crono SC

Crono SC pumps are designed for use in pain treatment. The two models of Crono

SC, with 20 mL and 50 mL syringes, have several features which allow the control and, if necessary, the limitation of drug administration such as:

- The display of the volume administered thus far through the basal rate
- The display of the total volume administered through bolus doses
- The display of the total volume administered thus far in an infusion
- A bolus dose counter
- The display of the total volume administered using clinician's bolus doses (bolus administration generally only accessible to the clinician)
- Limitation of the number of bolus doses administrable in an hour
- Limitation of minimum time between bolus doses.

The Crono SC 20 has a 5 mL/h maximum flow rate, and therefore uses a 5 μ L shot size so that at low infusion rates the concentration of drug is kept as constant as possible.

The Crono SC 50 has a maximum flow rate of 35 mL/h and delivers 20 μL shots (Figure 3).

DESIGN AND MANUFACTURING

All pump R&D and design work is done in-house, as are final assembly and testing. Canè's dedicated syringes are designed

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in-house and are manufactured by an Italian partner. Canè prides itself on the fact that where possible all components are locally sourced, which carries the added advantage of being able to maintain the highest standards of quality.

While Canè has its own series of products, it also provides ODM services to pharmaceutical companies who require customised pumps, be it in limited numbers for clinical trials or for mass-produced, private-labelled devices.

CUSTOMISATION

Canè's products are developed using a platform-based approach, in which the same hardware is used as a basis for many different models. It is therefore easy for us to provide pharmaceutical companies and other medical device manufacturers with customised solutions which perfectly match their specific device requirements.

Canè can produce limited numbers of special pumps for clinical trials or for investigatory purposes which then become a part of Canè's standard product range. One example is the Crono P (Figure 4) which was developed for hormone infusion according to strict circadian and ultradian rhythms, mimicking the body's normal hormone production cycles. It is the only ambulatory infusion pump of this type on the market today.

Another example is the Crono Twin, (Figure 5) developed for the delivery of immunoglobulins into two infusion sites. Normally infusion into two infusion sites is via a Y-set, which has the disadvantage that if one branch becomes occluded the entire volume is delivered via the unoccluded branch. The Crono Twin has two syringes, so that it is impossible to deliver more than 50% of the total volume to each infusion site.

In other cases Canè has developed privately labelled models which it manufactures exclusively for the customer. These can be either based on its standard platforms or can be completely new designs. Pump characteristics which may be customised include:

- Programmability in terms of flow rate or infusion time
- Bolus doses volume and interval control
- Partial volume function (for partially filled syringes)
- Selectable occlusion alarm pressure
- Infusion line priming and anti-freeflow systems
- · Lockable keyboard, so patients can't



Figure 1: The Crono PAR (shown with the protective syringe guard), for the treatment of Parkinson's Disease, has both manual and automatic flow profile operating modes.



Figure 2: The Crono S-PID 50, for the subcutaneous infusion of immunoglobulins, has a maximum infusion volume of 50 mL which can be administered in just 30 minutes.



Figure 3: The Crono 50 SC is for the subcutaneous infusion of drugs in the treatment of pain. It has a series of functions for controlling the number and interval between bolus doses, and for verifying how the pump has been used during an infusion. The shot size is 20μ L, and the maximum flow rate is 35 mL/h.

change medical practitioners' settings

- Multiple pre-programmed flow rates which are selectable by the patient during an infusion
- Automatic flow rate profiles through the day
- Bluetooth interface.

Our latest product: Crono S-PID 100

The Crono S-PID 100 ambulatory infusion pump is designed for the subcutaneous infusion of immunoglobulins and drugs in general, and is a union of high technology and innovative design. Its reduced dimensions and weight make it ideal for home use, giving the patient the freedom to engage in everyday activities during the therapy. The main features of the pump are:

- 100 mL reservoir with luer lock connector
- The possibility of selecting between time or flow rate programming mode:
 o Delivery time from 20 m to 500 h
 o Flow rate from 0.2 mL/h to 300 mL/h
- Partial volume Selectable, from 1 to 100 mL in 1 mL increments
- Available priming volume 3.0 mL
- Pump dimensions 88 x 59 x 56 mm, weight 140 g (including CR 123A battery).
- Ingress protection rating IP 42
- Flow rate precision +/-3%
- The possibility of automatically pausing the infusion in order to allow the patient to divide the syringe contents over several infusion sites (this feature is available in flow rate mode only).

The pusher mechanism, which operates directly on the rubber piston of the reservoir, enables the pump to combine high maximum delivery pressure (to maintain flow rate even with a partially occluded or kinked infusion set) with excellent precision. The pump administers micro doses (shots) of fixed volume, and the interval between them determines the flow rate and the configured delivery time.



Figure 4: The Crono P is a pump for the infusion of hormones following the body's natural rhythms. The infusion takes the form of a series of boluses at intervals of either 90 or 180 minutes, with a volume which may be programmed from 5 μ L to 1000 μ L. The day can be divided into up to three periods, with a different bolus volume programmed for each, such that the circadian and ultradian cycles may be reproduced as required.



Figure 5: The Crono Twin uses two 20 mL syringes working in tandem to administer immunoglobulins in two or more infusion sites.





Crono[®] Ambulatory infusion pumps



Small size, great solutions

Sterne 10m 10m	tacrn ^e un littlitti		20 CTP 'VALENTER 30 40	5 ² cm. em3 ⊗0
4	15 W	 30ml	₹_ 50 ml	100 ml
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