T34™ Syringe Pump

(3rd Edition)

Directions For Use

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Section 1: General Information

1.1 Preface

Duplication or distribution of this *Directions For Use* and any information contained within is strictly prohibited without the express written permission of CME Ltd. This *Directions For Use* and any information contained within, may not be reproduced, distributed, or transmitted in any form, or by any means, for any purpose, without the express written permission of CME Ltd. To order additional copies of this *Directions For Use* , or other related manuals, contact your BD representative.

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1.2 About this Directions For Use

The operator must be thoroughly familiar with the T34™ Syringe Pump described in this *Directions For Use* prior to use, and in particular must read and understand any warnings and precautions stated herein.

All illustrations used in this *Directions For Use* show typical settings and values that may be used in setting up the functions of the syringe pump. These settings and values are for illustrative use only. The complete range of settings and values are listed in the specifications section of this *Directions For Use*.

This *Directions For Use* has been developed with consideration to the requirements in relevant Harmonised Standards. Data presented in the technical specifications reflect specific test conditions defined in this standard. Other external factors such as varying back pressure, temperature, head height, syringe extension set usage, fluid restrictions, solution viscosity or combinations of these factors, may result in deviations from the performance data enclosed.

Note: Keep this *Directions For Use* for future reference during the syringe pump's operational life.

1.3 Advisory Terms and Warnings

WARNINGS, CAUTIONS AND NOTES

Warnings, cautions and notes will be seen throughout this *Directions For Use*. These are defined as follows:

Warnings **advise of circumstances that could result in injury or death to the patient or operator.**

Read and understand this *Directions For Use* and all warnings completely before operating the T34™ Syringe Pump.

Cautions **advise of circumstances that could result in damage to the T34™ Syringe Pump.**

Read and understand this *Directions For Use* and all cautions completely before operating the T34™ Syringe Pump.

Note: A *Note* indicates that the information that follows is additional important information, a tip that will help you recover from an error or refer you to related information within the *Directions For Use*.

OPERATING PRECAUTIONS AND WARNINGS

Read the entire *Directions For Use* before using the syringe pump, since the text includes important precautions.

Only trained service personnel should open the syringe pump cover.

A kinked or occluded syringe extension set may impair the operation of the syringe pump and the accuracy of the infusion. Before operation, verify that the syringe extension set is not kinked or occluded.

Unsafe operation may result from using improper accessories. Use only accessories and options designed for this system and supplied or recommended by the T34™ Syringe Pump distributor.

Do not use this equipment with other infusion systems or accessories that are not designed to be used with this pump system.

Do not let the syringe pump operate when battery is fully depleted. Pump may turn off during operation on fully depleted battery. Before beginning infusion, ensure the battery is fully charged.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the T34™ Syringe Pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Although the T34™ Syringe Pump has been designed and manufactured to exact specifications, it is not intended to replace trained personnel in the supervision of infusions.

The specified accuracy of the syringe pump can only be maintained if the syringe pump is used in accordance with the *Directions For Use* and is maintained and serviced by a certified CME technician.

Adjustments, maintenance, or repair made by un-certified service personnel may impair the operation of the syringe pump and/or the accuracy of the infusion. Make sure any adjustments, maintenance, or repair of the syringe pump are carried out only by authorised and skilled technicians.

Refer all service, repair and adjustments only to qualified and certified technical personnel. Unauthorised modifications or the use of any spare parts, other than those supplied by the manufacturer or their distributor, will void any warranty.

If the syringe pump is subjected to excessive moisture, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by qualified personnel.

The syringe pump has been designed to be as safe as possible to handle; however, care should be exercised to avoid trapping of fingers or other body parts in the mechanism.

The T34™ Syringe Pump should be operated within the recommended environmental operating range. Operation at temperatures and/or humidity outside this range may adversely affect accuracy.

This syringe pump is designed for use and should withstand everyday handling. If the syringe pump is dropped onto a hard surface, or is suspected of being dropped, the operation and calibration should be checked by a qualified technician.

Pump should be stored with the battery removed to prevent battery corrosion and decay.

CME Ltd. will assume no responsibility for incidents which may occur if the product is not used, stored or transported in accordance with the environmental conditions stipulated in this document or on the package labelling.

INFUSION PRECAUTIONS AND WARNINGS

Carefully read and follow accompanying syringe extension set instructions for priming the set and the recommended set change interval.

The syringe and syringe extension set should be disposed of in an appropriate manner, considering the nature of the residual fluid that may be contained within and in accordance with the hospital/homecare provider's disposal practices.

Drugs for infusion to be used with the syringe pump may only be prescribed by a qualified medical practitioner. Caution must be exercised in the selection of drugs and the amount and rate intended to be delivered via syringe pump.

If the drug contained in the syringe will be exposed to extreme environmental conditions for prolonged time periods, it is important to select drugs that will not change pharmacologically upon such exposure.

As with all automatic syringe pumps, whenever a toxic or dangerous level of drug is stored in the reservoir, constant/frequent monitoring of the infusion is required.

In all applications, time to alarm under occlusion or other fault conditions will depend on the infusion rate and levels of alarm settings. It is recommended to consider these parameters when using drugs requiring infusion stability or low flow rates and therefore a quick time to alarm.

Do not use Slip-tip syringes. Luer Lock syringes must always be used to ensure secure connection of the syringe extension set and the syringe pump.

GENERAL PRECAUTIONS AND WARNINGS

The maximum volume that may be infused under single fault condition is 0.1 ml.

Potential strangulation may occur if the cables/tubing are of excessive length.

Potential choking may occur if small parts are inhaled or swallowed.

Potential allergic reactions may occur due to materials used in the syringe pump.

The T34™ Syringe Pump is not certified for use in oxygen-enriched environments.

Do not operate the syringe pump near high-energy radio-frequency emitting equipment, (e.g. Imaging equipment (i.e., X-Ray, MRI, CT Scan, etc.), High Frequency (RF) Surgical Equipment, Defibrillator, etc.) as this may cause degradation in performance of the syringe pump, which may affect proper infusate delivery.

Do not use hard or sharp objects on the keypad.

Do not bathe or shower whilst using the syringe pump. The syringe pump is resistant to a limited amount of splashing, but its construction does not make it resistant to large amounts of spraying or immersion in liquids. Damage to the internal components may result.

1.4 Intended Use

The T34™ Syringe Pump is designed for infusion of medications or fluids requiring continuous or intermittent delivery at precisely controlled infusion rates through all clinically acceptable routes of administration including intravenous, subcutaneous, percutaneous, in close proximity to nerves, and into an intraoperative site (soft tissue/body cavity/surgical wound site). The system is intended for patients who require maintenance medications, analgesics, Immunoglobulins, biosimilar, chemotherapeutic agents and general fluids therapy in hospital and homecare environments.

1.5 Contraindications

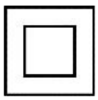
- Infusion of blood and blood products
- Infusion of insulin
- Infusion of critical medications whose stoppage or interruption could cause serious injury or death
- Use in ambulatory regimens by patients who do not possess the mental, physical or emotional capability to self-administer their therapy, or who are not under the care of a responsible individual

1.6 System Symbols

The following symbols are used on the T34™ Syringe Pump and components. Labels on the syringe pump or statements in this *Directions For Use* preceded by any of the following words and/or symbols are of special significance and/or are intended to help you to operate the syringe pump in a safe and successful manner.

System Symbol Identification and Description

Symbol	Description
Syringe Pump	
	Warnings advise of circumstances that could result in injury or death to the patient or operator. Read and understand this *Directions For Use* and all warnings completely before operating the T34™ Syringe Pump.
	Cautions advise of circumstances that could result in damage to the T34™ Syringe Pump. Read and understand this *Directions For Use* and all cautions completely before operating the T34™ Syringe Pump.
	Refer to *Directions For Use*: Read the entire *Directions For Use* before using the syringe pump.
CE 0344	CE mark indicates conformance to Medical Device Directive 93/42/EEC.
	Do not dispose of in municipal waste. Symbol indicates separate collection for electrical and electronic equipment. (WEEE Directive 2012/19/EU). NOTE: Does not apply to the battery.

	Type CF applied part.
	Class II Medical Electrical Equipment providing double insulation for operator and patient safety.
IP22	Symbol for degree of protection against ingress of water and solid objects.
	Battery.
	Direct current.
	Manufactured by.
	Date of manufacture.
	Serial number.
	Reference number. Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the authorised representative in the European Community.
	Indicates the acceptable upper and lower limits of atmospheric pressure (altitude).
	Indicates the acceptable upper and lower limits of relative humidity.
	Indicates the range of temperatures to which the medical device can safely be exposed.
	Indicates a medical device that should not be used if its packaging has been damaged or opened.
	Indicates the number of drops per millilitre.

Disposables	
	The use of single-use disposable components on more than one patient is a biological hazard. Do not reuse single-use disposable components.

	Expiry date (consumables).
	Lot number (consumables).
	Sterilized with Ethylene Oxide (applies to syringe extension sets).

1.7 Syringe Pump Inspection and Unpacking

INSPECTING THE SYRINGE PUMP BEFORE USE

Remove the T34™ Syringe Pump from the packaging and inspect for damage during shipment or storage.

Make sure you have the following items:

- T34™ Syringe Pump
- *Directions For Use*
- Quick Reference Guide for homecare

If any items are missing or damaged, contact your supplies department.

Visually inspect packaging and contents before each use.

Do not use the T34™ Syringe Pump and accessories if there are any obvious signs of damage. Return for inspection by authorised service personnel.

ACCESSORIES (IF PURCHASED)

- Lockbox (supplied with two keys)
- Carry Pouch (re-usable or disposable)

Refer to the product catalogue for more details.

If any items are missing or damaged, contact your supplies department.

Unsafe operation may result from using improper accessories. Use only accessories and options designed for this system and supplied or recommended by the T34™ Syringe Pump distributor.

1.8 Syringe Pump Specifications

T34™ SYRINGE PUMP SPECIFICATIONS

Type:	Linear syringe driver mechanism, pulsed motion (540 pulses per mm).	
Flow Rate:	Flow rate is adjustable between 0.1 ml/h and 650 ml/h	0.1–10 ml/h in 0.01 ml/h increments; 10–29.9 ml/h in 0.1 ml/h increments; 30–49.5 ml/h in 0.5 ml/h increments; 50–299 ml/h in 1 ml/h increments; 300–650 ml/h in 5 ml/h increments.
Bolus Parameters:	Bolus flow rate 1–650 ml/h: 1–10 ml/h in 0.01 ml/h increments; 10–29.9 ml/h in 0.1 ml/h increments; 30–49.5 ml/h in 0.5 ml/h increments; 50–299 ml/h in 1 ml/h increments; 300–650 ml/h in 5 ml/h increments.	Bolus volume: 0–20 ml in 0.1 ml increments. Maximum bolus volume is 20 ml.
Actuator Travel:	67 mm available.	
Syringe Sizes:	2 ml to 50 ml (most commonly used manufacturers).	
Accuracy:	± 5% system accuracy (syringe pump and set combined) by volume under nominal conditions, defined as follows: Flow rates: 1 ml/h and 5 ml/h; Tested with syringe extension set model M100-172SB; Needle: 18 gauge; Solution Type: Distilled water; Temperature: 22°C ± 3°C; Back Pressure: 0 ± 10 mmHg; Syringe size and brand: BD Plastipak 20 ml. Accuracy measured using the trumpet curve test method defined in EN/IEC60601-2-24.	
Occlusion Pressure:	200–1500 mmHg configurable (10 mmHg increments).	
Battery:	9 V alkaline, IEC 6LR61 type.	
Operating Time:	Rate	Approximate battery life
	1 ml/h	25 hours
	5 ml/h	20 hours
Indicators:	4 line LCD display (122 × 32 pixels), dual color operation LED.	
Alarms:	When a problem is detected, the T34™ displays the following alarm messages, sounds an audible alarm and the LED lights red:	
	Occlusion or Syringe Empty	Syringe Displaced during infusion
	End Program	System Error
	End Battery	
Dimensions:	167 × 68 × 39 mm (L x W x H)	
Classification:	Type CF Equipment, degree of protection against electrical shock; IP22 protection against ingress of water and solid objects. Definition of code: I = Ingress P = Protection 2 = Protection from solid objects ≥12.5 mm 2 = Protection from dripping water (15° tilted)	
Housing:	ABS (fire retardant). Complies with standard UL94V-1.	
Weight:	230 g without battery.	
Electrical Safety:	Complies with: IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, IEC 60601-2-24.	
Standards:	Manufactured in accordance with ISO 13485, IEC 62304 and IEC 62366. CE marked in accordance with the Medical Devices Directive 93/42/EEC.	

Environmental Specifications:	**Operating Environment Range:** Ambient Temperature: 5°C to 40°C Relative Humidity: 15% to 90%, non-condensing Ambient pressure: 70 kPa to 106 kPa.
	Transport and Storage Conditions: Ambient Temperature: –25°C to 70°C Relative Humidity: 0% to 90%, non-condensing Ambient pressure: 48 kPa to 110 kPa.

EMC Specifications:	The T34™ Syringe Pump is designed to be in compliance with IEC 60601-1 (safety), IEC 60601-1-2 (EMC), and IEC 60601-2-24 (infusion pump). The T34™ Syringe Pumps have been tested and found to comply with the limits for a Class B digital device. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: • Reorient or relocate the receiving antenna. • Increase the separation between the equipment and receiver. • Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. • Consult the dealer or an experienced radio/TV technician for help. The T34™ Syringe Pump has been tested to comply with the requirements of IEC 60601-1-2:2014.			
EMC – Emissions Compliance	**EMC Standard**		**Range**	**Compliance**
Radiated emissions	CISPR 11:2015		30 MHz – 1 GHz	Class B, Group 1
EMC – Immunity Compliance	**EMC Standard**	**Test level**		**Compliance**
Electrostatic Discharge (ESD) Immunity	IEC 61000-4-2	Contact discharge	± 2 kV, ± 4 kV, ± 6 kV	No degradation of performance
		Air discharge	± 2 kV, ± 4 kV, ± 8 kV	
	IEC 60601-2-24	Contact discharge	± 8 kV	Operator intervention may be required as the syringe pump may intermittently reset, requiring user to restart the infusion.
		Air discharge	± 15 kV	
Radiated RF Immunity	IEC 61000-4-3:2006 +A1:2007 +A2:2010	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz		Yes
Proximity fields from RF wireless communications equipment	IEC 61000-4-3:2006 +A1:2007 +A2:2010	380 – 390 MHz 27 V/m 430 – 470 MHz 28 V/m 704 – 787 MHz 9 V/m 800 – 960 MHz 28 V/m 1.7 – 1.99 GHz 28 V/m 2.4 – 2.57 GHz 28 V/m 5.1 – 5.80 GHz 9 V/m		Yes
Conducted RF Immunity	IEC 61000-4-6:2013	3 V/m 0.15 MHz – 80 MHz 6 V/m in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz		Yes
Power Frequency Magnetic Field Immunity	IEC 61000-4-8:2009	30 A/m 50 Hz		Yes

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Do not operate the syringe pump near high-energy radio-frequency emitting equipment, (e.g. Imaging equipment (i.e., X-Ray, MRI, CT Scan, etc.), High Frequency (RF) Surgical Equipment, Defibrillator, etc.) as this may cause degradation in performance of the syringe pump, which may affect proper infusate delivery.

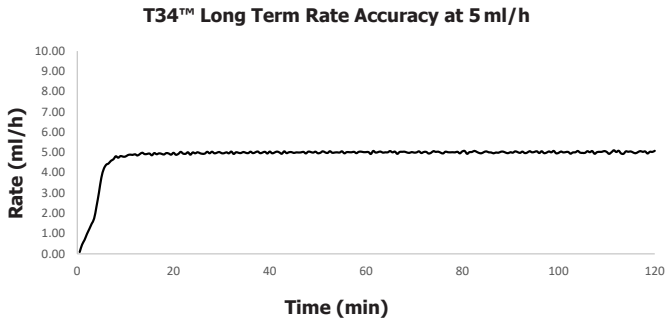
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the T34™ syringe pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

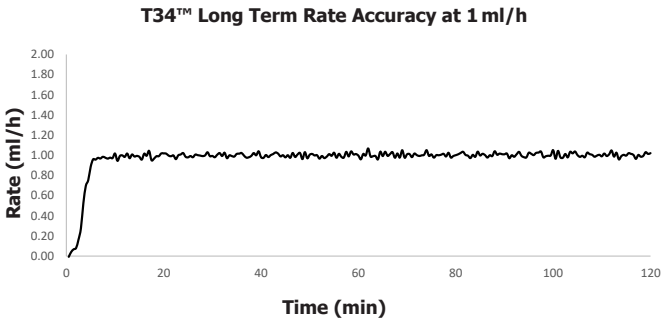
PUMP ACCURACY

The following graphs and curves were derived from testing described in IEC60601-2-24. Testing was performed under normal conditions at room temperature (72°F or 22°C). Any deviations from normal conditions and room temperature may cause changes in the accuracy of the syringe pump.

Start-up Curves

The Start-up curves represent continuous flow versus operating time for two hours from the start of the infusion, measured for infusion rates of 5 ml/h and 1 ml/h. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Tests performed according to IEC 60601-2-24 standard.





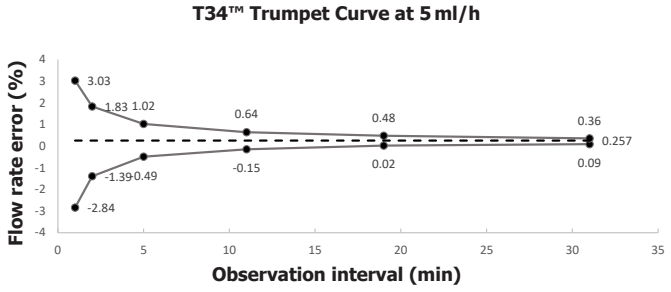
Trumpet Curves

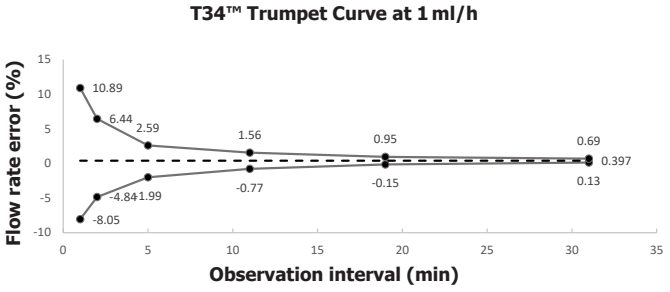
With the T34™, as with all infusion systems, variations cause short term fluctuations in rate accuracy.

The following curves show typical performance of the system in two ways:

1. The accuracy of fluid delivery over various time periods is measured (trumpet curves).
2. The delay in onset of fluid flow when infusion commences (start up curves).

Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or 'Observation windows', not continuous data versus operating time. Over long observation windows, short-term fluctuation has little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effects as represented by the 'mouth' of the trumpet. Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short-term fluctuations in rate accuracy may have clinical impact depending on the shelf life of the drug being infused and the degree of inter-vascular integration. The clinical effect cannot be determined from the trumpet curves alone.





Section 2: Disposables and Accessories

2.1 Syringe Brands and Sizes

The T34™ Syringe Pump is programmed to recognize most commonly used syringes from 2 ml to 50 ml. Luer Lock syringes should always be used to ensure secure connection of the syringe extension set and syringe.

To avoid accidental selection of an incorrect brand of syringe during setup, it is recommended to disable all syringe types not in regular use. Unused syringe types can be disabled by an authorised technician.

Do not use Slip-tip syringes. Luer Lock syringes must always be used to ensure secure connection of the syringe extension set and the syringe pump.

Should you need to operate the T34™ Syringe Pump with a syringe manufacturer and/or brand other than those listed here, please consult either your local medical engineering department or CME Ltd. Technical Services.

Default Syringe Brands Configured for Use with T34™

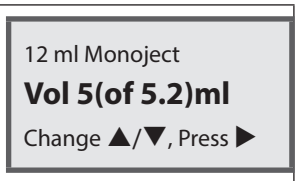
Manufacturer	Syringe Sizes (ml)						
Braun Omnifix	2		5	10	20	30	50
BD Plastipak		3	5	10	20	30	50
Monoject		3	6	12	20	35	
Codan/Once				10	20	30	50
Terumo			5	10	20	30	50
Nipro			5	10	20	30	50

Syringe Volumes

Due to the physical length of the screw that drives the syringe plunger forward there are limits to the maximum amount of infusate that can be delivered from larger syringes and on some smaller syringes there is an undeliverable volume of infusate that will remain in the syringe once the actuator has driven to the zero position.

Braun 2 ml, BD 10 ml, Codan 10 ml, Monoject 3 ml, Monoject 12 ml, Monoject 35 ml, Nipro 10 ml and Nipro 20 ml syringes cannot empty completely, potentially a small volume of infusate will be left in the syringe due to limitations of the syringe pump and the syringes design. The T34™ Syringe Pump will display the volume as, for example, Vol 5 (of 5.2)ml. In this example the syringe pump can only deliver 5 ml of the 5.2 ml in the syringe and when the syringe pump has driven the syringe plunger as far forward as possible, 0.2 ml will remain in the syringe. The potential volumes that might remain in the syringes are listed in the table below:

Syringe size and brand		Undeliverable infusate volume
Braun Omnifix	**2 ml**	0.000 ml to 0.114 ml
BD Plastipak	**10 ml**	0.000 ml to 0.177 ml
Codan/Once	**10 ml**	0.000 ml to 0.043 ml
Monoject	**3 ml**	0.000 ml to 0.007 ml
Monoject	**12 ml**	0.000 ml to 0.388 ml
Monoject	**35 ml**	0.000 ml to 0.348 ml
Nipro	**10 ml**	0.000 ml to 0.094 ml
Nipro	**20 ml**	0.000 ml to 0.006 ml



Some manufacturers have several brand names within their ranges (e.g. Braun Omnifix and Braun Perfusor). Only use the brands named above with the T34™, as failing to do so could result in an under- or over-infusion.

Maximum Fill Volume for Syringes 20 ml to 50 ml

Syringe brand	Syringe size		
	20 ml	30 ml	50 ml
Monoject	18.7 ml	—	—
Braun Omnifix	20 ml	24.4 ml	37.7 ml
BD Plastipak	18 ml	23.5 ml	34.9 ml
Terumo	18.6 ml	24.5 ml	38.0 ml
Codan	20 ml	22.5 ml	35.9 ml

Time to Alarm from Occlusion

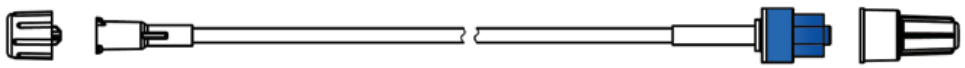
Flow Rate	Pressure Threshold	Time to Alarm (TTA) (hh:mm:ss)
5 ml/h	200 mmHg	TTA < 00:06:00
1 ml/h	200 mmHg	TTA < 00:35:00
0.1 ml/h	200 mmHg	TTA < 06:00:00
5 ml/h	1500 mmHg	TTA < 00:25:00
1 ml/h	1500 mmHg	TTA < 03:45:00
0.1 ml/h	1500 mmHg	TTA < 24:00:00

Note: Tested at flow rates and occlusion thresholds as described in the table above, using a BD Plastipak 20 ml syringe.

2.2 Syringe Extension Sets

INTRODUCTION

The T34™ Syringe Pump can be operated with any syringe extension set with a Luer connection. However, it is recommended, to optimise system accuracy and performance, that proprietary syringe extension sets from CME Ltd. are used. All CME Ltd. syringe extension sets have siphon/free flow protection.



FEATURES AND CHARACTERISTICS

Feature	Description
Materials	The syringe extension sets are manufactured using PVC materials that do not contain latex or di-2-ethylhexyl phthalate (DEHP).
Tubing	Micro-bore: require small priming volumes. Anti-kink: to prevent kinking or occlusion particularly in configuration. Various lengths available.
Slide clamp	Clamps: to prevent fluid flow to patient (optional on some syringe extension sets).
Pressure activated anti-siphon/anti-reflux valve 	All CME Ltd. syringe extension sets contain an anti-syphon valve to prevent uncontrolled flow of fluid either into or from the patient. The syringe extension set with pressure activated anti-siphon/anti-reflux valve reduces the potential for uncontrolled flow and backflow (backtracking). The pressure-activated anti-siphon valve requires pressure to open. The syringe pump occlusion pressure setting may require adjustment to prevent occlusion alarms. The anti-syphon valve enhances pump functioning by: • Preventing siphoning (uncontrolled flow) in the event the syringe extension set is detached from the syringe pump or mechanical malfunction, and • Preventing reflux (back-flow) in the event several infusion pumps are connected simultaneously to the same patient.

Luer Lock end connector 	The syringe extension set is designed to be connected to Luer Lock syringes. Luer Lock syringes allow a connection between male and female Luer. This provides a secure connection and prevents accidental removal.

Ensure the syringe extension set is NOT connected to the patient during priming.

A kinked or occluded syringe extension set may impair the operation and accuracy of the syringe pump. Before operation, verify that the syringe extension set is not kinked or occluded.

Note: The recommended syringe extension set change interval is maximum 72 hours.

ADVISORY WARNINGS AND NOTES FOR SYRINGES AND SYRINGE EXTENSION SETS

Component damage may occur if the syringe extension set is not correctly attached to the syringe. Assure all connections are secure: Do not over-tighten connection. This will help minimise leaks, disconnection and component damage.

Disposables (as with any infusion) used with the syringe pump must be compatible with the drug/fluid being delivered. Check with the manufacturer of the disposables before use. Consult the fluid or drug manufacturer's information for precautions, guidelines, and instructions for preparation and use of disposables.

Replace the syringe and/or syringe extension set in accordance with local guidelines.

Use aseptic technique when filling the syringe and priming the syringe extension set. Patient infection may result from the use of non-sterile components. Maintain sterility of all syringe extension set components and do not re-use single-use syringe extension sets.

Syringes and syringe extension sets should be disposed of in an appropriate manner, considering the nature of the residual fluid that may be contained within, in accordance with the hospital/homecare provider's disposal practices.

2.3 Battery Power Supply

Refer to section 7.1 for checking battery levels

BATTERY TYPES AND USE

Always use a 9 volt alkaline disposable battery with the following attributes:

Designation: IEC: 6LR61

Body Size: 46.4 mm × 26.5 mm × 17.5 mm

Impedance: 1700 milli-ohms @ 1 kHz

Do not use batteries marked 6LP3146 or 6LF22 with the T34™ Syringe Pump. 6LP3146 and 6LF22 batteries can cause issues with the operation of the syringe pump, as the physical construction and internal resistance of this type of battery are different to the 6LR61 battery. Issues arising from use of 6LP3146 and 6LF22 batteries can include End Battery messages during Pre-Load, volume test fails, pressure test/calibration issues and reduced amount of infusions from a battery.

Nominal voltage	9 V
Impedance	1700 milli-ohms @ 1 kHz
Typical weight	45 g (1.6 oz)
Typical volume	22.8 cm^3 (1.4 in^3)
Terminals	Miniature snap
Storage temp. range	5°C to 30°C (41°F to 86°F)
Operating temp. range	–20°C to 54°C (–4°F to 130°F)
Designation	ANSI: 1604A IEC: 6LR61

Note: Tested at flow rates and occlusion thresholds as described in the table above, using a BD Plastipak 20 ml syringe.

If a battery is too tight, do not try to force it into the battery compartment as this may damage the battery contacts.

Only use accessories designed for the system. Unsafe operation may result from using improper accessories. Use only accessories and options designed for this system and supplied or recommended by the T34™ Syringe Pump distributor.

BATTERY LIFE

Factors that affect battery life include:

- Pump settings,
- Infusion rate,
- The number of interventions that occur (e.g. stopping/starting infusions, manual movement of actuator and backlight activation),
- The number of key presses that occur, and
- Frequency of LED green light flashing.

The syringe pump battery meter displays battery life remaining as a percentage (%).

- When the battery power is low a low battery alert will activate.
- When the battery power is almost depleted, an end of battery alarm will activate.
- The end of battery alarm will continue until the user presses ▶ key to confirm or the battery power is fully depleted.

Refer to alerts, alarms and troubleshooting section for further information on alerts, alarms and troubleshooting.

INDICATIONS TO CHANGE A BATTERY

Guidance for battery changing may vary for different areas according to local policy and where the syringe pump is to be used and who is managing the syringe pump (healthcare professional or patient).

If the syringe pump is being managed in an environment where designated personnel are available at all times to change a battery if necessary, the low battery alert can be used as an indication to change a battery.

Note: If the syringe pump is being managed in an environment where designated personnel are unavailable to change a battery if necessary, the following rule applies: To ensure delivery of 24 hours at flow rate of up to 1ml/h, always change to a new battery.

BATTERY FITTING AND REMOVAL

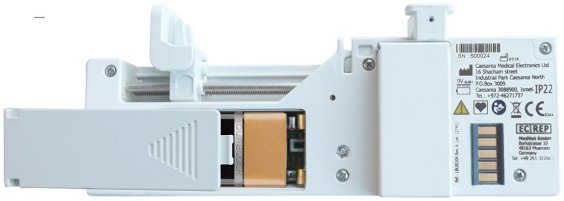
Inserting and removing a battery

The battery should fit securely to ensure good electrical contact.

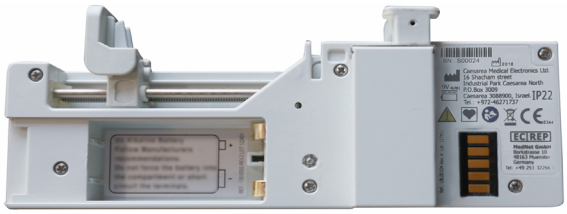
DO NOT use scissors or metal objects to remove a battery.

To insert the battery into the syringe pump:

1. Slide the compartment cover off at the back of the syringe pump.

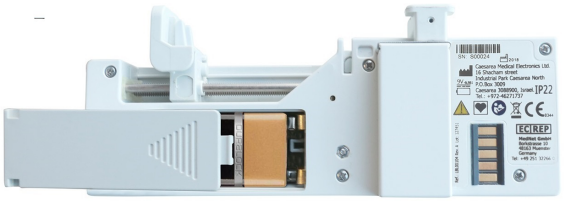


2. This reveals the empty battery compartment, with insertion instructions.



3. Push the battery into the compartment taking care to ensure that the battery + / – contacts are aligned on the label inside the compartment.

4. Slide the cover back on.



To remove the battery from the syringe pump:

1. Slide the compartment cover off at the back of the syringe pump.
2. Remove the battery
3. Slide the cover back on.

2.4 Lockbox (Optional)

USES AND FEATURES

Lockboxes are designed to help protect the syringe from displacement and/or tampering.

Lock boxes are made from polycarbonate due to its high impact, temperature resistance and optical properties.

TYPES AND SIZES

Lockboxes are available in clear plastic.

- The clear lockbox can be used with any drug delivery route.
- The lockbox will fit most commonly used syringe brands and sizes up to 30 ml.

Refer to your local sales representative for any product-related information.

After the syringe is loaded on the T34™ Syringe Pump and the syringe extension set is connected, place the syringe pump into the lockbox and carry pouch:

1. Open the lockbox using the standard key that operates all T34™ Syringe Pump lockboxes.
2. Place the syringe pump into the lockbox so that the LCD display and keypad line up with the cut out opening.
3. Close the lockbox, guiding the syringe extension set out of the slot at the side of the top section of the lockbox.
4. Place the lockbox (or the syringe pump without the lockbox) into the carry pouch and secure to the patient.

Note: You can use the lockbox only with syringes which size is 30 ml or smaller.

Note: Lockboxes are designed for the use with CME Ltd. syringe extension sets. If using an alternate brand of syringe extension set with a commonly used 30 ml syringe, the syringe extension set design may prevent the lockbox from fully closing and locking.

2.5 Carry Pouches (Optional)

CARRY POUCH USE AND TYPES

Disposable and reusable (washable) pouches are available.

Refer to your local sales representative for any product-related information.

Refer to Section 7.7 for re-usable pouch cleaning/washing instructions.

Using the syringe pump with a CME Ltd. carry pouch or similar receptacle during transportation or patient ambulation whilst the syringe pump is infusing protects the syringe pump functionality and the medication in the syringe. The carry pouch will also protect the syringe pump from damage or syringe displacement.

When using the CME Ltd reusable (washable) carry pouch, it is possible to access the screen and keypad of the syringe pump during infusion by lifting the Velcro flap of the carry pouch whilst the syringe pump remains in the carry pouch.

When using either a CME Ltd reusable (washable) or disposable (single patient use) carry pouch it is possible to remove the forward part of the syringe pump during infusion from the carry pouch to inspect the syringe without removing the rear section of the syringe pump. CME Ltd carry pouches can be carried on the shoulder or around the waist for convenience.

Section 3: Pump Features and Description

3.1 Overview

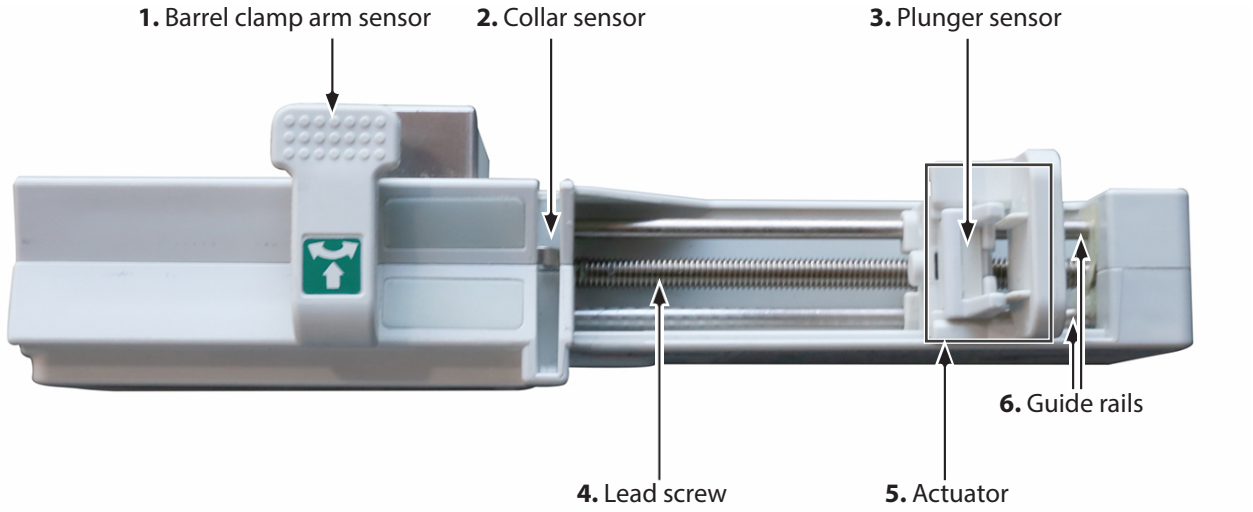
The T34™ Syringe Pump provides the following features:

- Accommodates a range of commonly used syringe brand and sizes
- Three-point syringe detection system
- Capable of small ml/h rate delivery
- Configurable occlusion pressure setting
- LCD display screen with backlight
- Green LED indicator light to indicate if infusion is in progress
- Event log

The following safety features are available:

- Access code protected pump configuration
- Lockable infusion program
- Post Occlusion Bolus Reduction System
- Comprehensive range of alerts and alarms
- Keypad lock
- Lockable lockbox (optional)

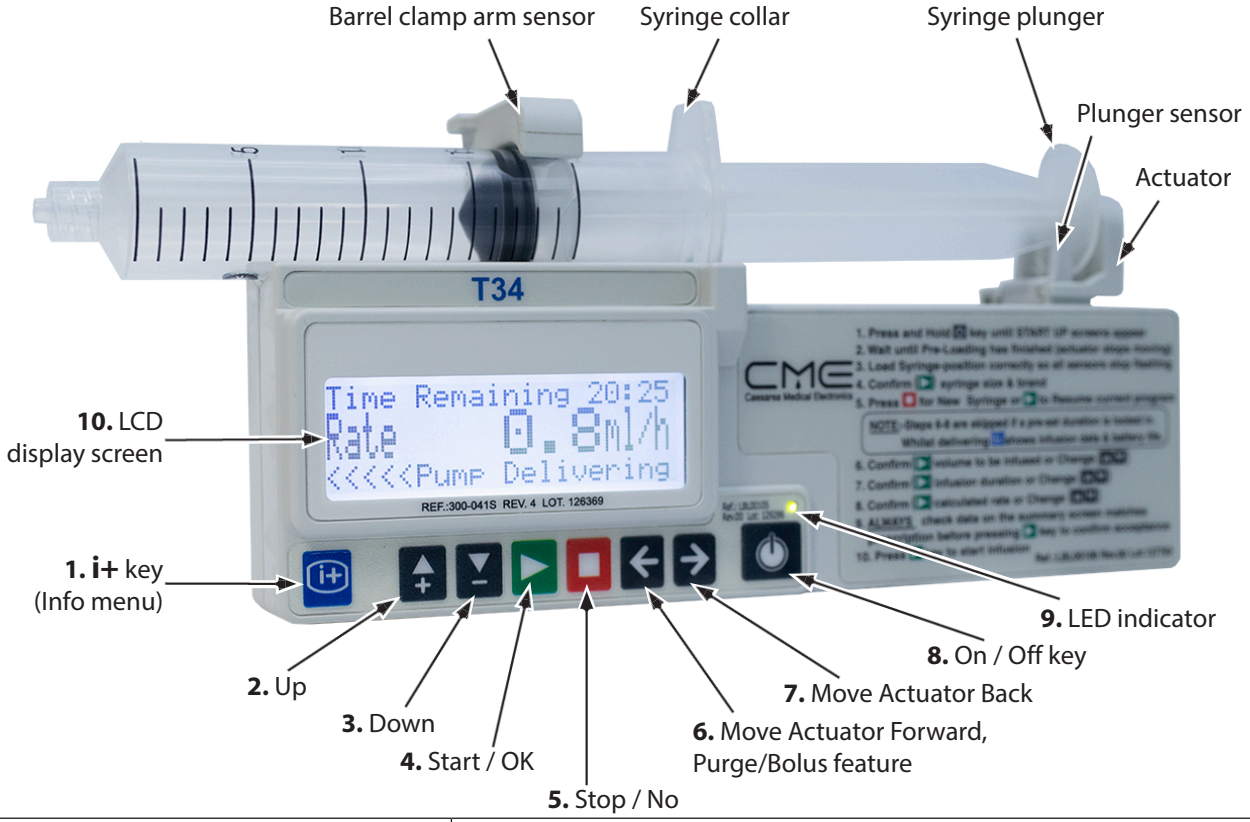
3.2 Pump Description



TOP OF PUMP: SYRINGE FITTING

No.	Area	Function
1.	Barrel clamp arm sensor	Detects syringe barrel loading and secures syringe in place.
2.	Collar sensor	Detects correct loading of the syringe collar.
3.	Plunger sensor	Detects correct loading of the syringe plunger.
4.	Lead screw	Moves actuator.
5.	Actuator	Drives the syringe plunger to deliver syringe contents.
6.	Guide rails	The two guide rails support the actuator position.

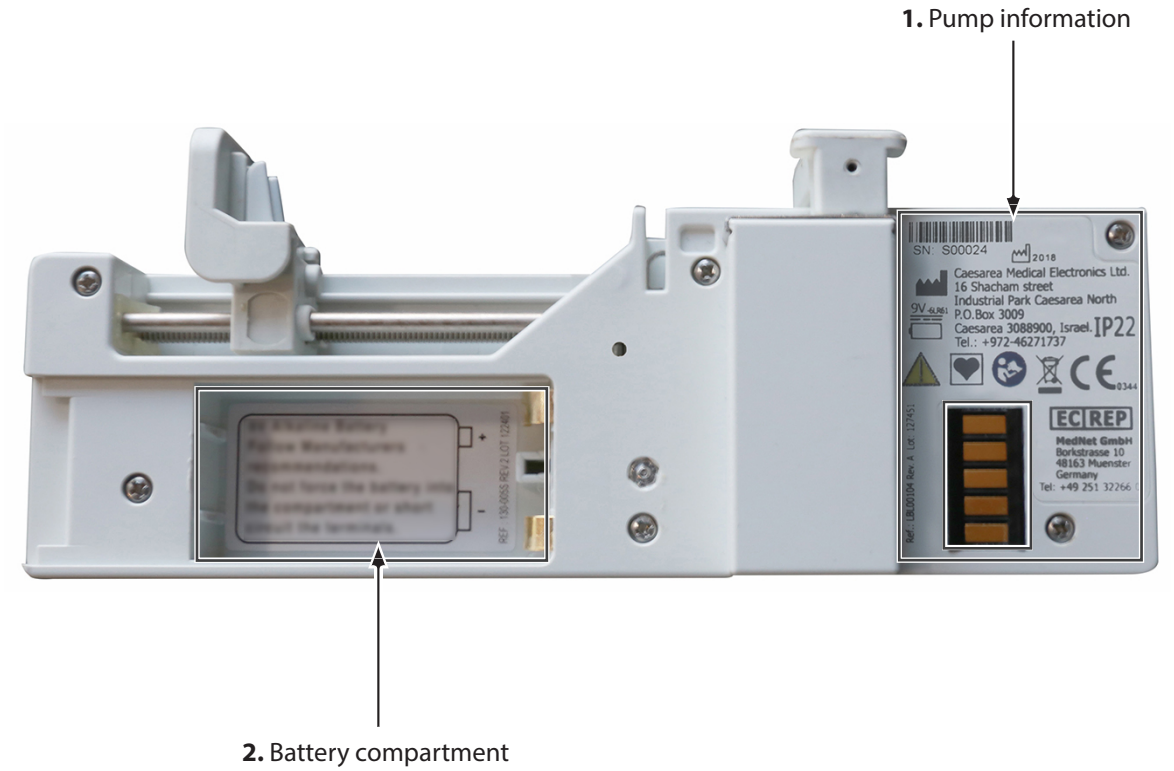
FRONT OF PUMP: KEYS AND DISPLAY SCREEN



No.	Area	Function
1.	**Info Menu** key	• Pressing once during infusion displays an infusion summary. • Pressing a second time during infusion displays the current battery level. • When pump is in standby mode, accesses the main (Info) menu. • Activates/deactivates keypad lock.
2.	**Up** key	• Scrolls between options. • Increases infusion parameters during programming/titration.
3.	**Down** key	• Scrolls between options. • Decreases infusion parameters during programming/titration.
4.	**Start / OK** key	• Confirms selection. • **Starts** infusion.
5.	**Stop / No** key	• Takes user back one step during programming. • **Stops** infusion.
6.	**Move Actuator Forward** key	• Moves actuator forward when no syringe in place and the barrel clamp arm is down. • Accesses purge function (if enabled). • Accesses bolus function (if enabled).
7.	**Move Actuator Back** key	• Moves actuator backward when no syringe is in place and barrel clamp arm is down.
8.	**On / Off** key	• Powers the syringe pump on and off.
9.	LED indicator	• The LED indicator light is a steady green during system self-tests. • The LED indicator flashes green to indicate infusion delivery. • The LED indicator is a steady yellow when the syringe pump is in standby mode or indicates low priority alarm. • The LED indicator flashes yellow to indicate medium priority alarm. • The LED indicator flashes red to indicate a high priority alarm.
10.	LCD display screen	• Displays pump and infusion status, programming choices and instructions.

Note: Instructions on the pump label are for reference only and do not reflect all possible settings. Please, refer to this *Directions For Use* for full instructions.

BACK OF PUMP: BATTERY AREA AND PUMP MARKINGS



No.	Area	Function
1.	Pump information and symbols	Labelling (including universal symbols) identify a pump, its manufacturer, and communicates information on safety, use and performance.
2.	Battery compartment	Includes instructions for inserting the battery correctly.

3.3 Event Log

The event log shows a complete time and date stamped record of the last 512 pump events along with a record of pump status (volume infused, rate, etc.) at the time of the event. Event log data cannot be deleted or altered and it is not patient-specific. i.e. the 512 events are likely to span multiple patients treated with that particular pump.

Each event is assigned a new number and the syringe pump stores the most recent 512 events in memory. When more than 512 events have occurred, the oldest event will be deleted each time a new event occurs.

For example, after some time, the first event to appear when you enter the events history might be number 754. This means there have been 754 events in this pump's life and events 242–754 are currently stored. When event 755 occurs, the oldest event, number 242, will be deleted and the syringe pump will store events 243–755, then 244–756, and so on.

Events recorded include hourly self-testing when an infusion is running and certain key presses.

When the syringe pump is infusing, the syringe pump will record pump status every hour regardless of any key presses.

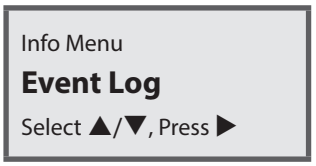
The event log can be viewed via the syringe pump menu:

Event log access and navigation

The event log cannot be accessed whilst an infusion is running. If necessary, stop the infusion and remove keypad lock.

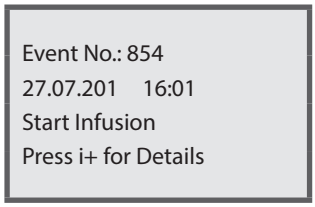
1. Press the key:

2. Use / keys to scroll to **Event Log**



3. Press key.

The most recent event displays:



Line 1: Event Number

Line 2: Date and time of event

Line 3: Event description/operating state

Line 4: View details on this event

Either use / keys to scroll up/down through events or,
Press key to display detailed data for the event.

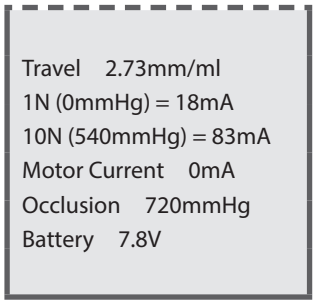
When key is pressed:

VI = Volume infused

VTBI = Volume to be infused

Rate = ml/h rate

30 ml BD Plastipak = Syringe brand and size confirmed



Travel = Actuator travel distance (mm) to deliver 1 ml (for syringe size/brand confirmed)

1 N = Minimum actuator travel force (related to start up motor movement)

10 N = Maximum actuator travel force (related to start up motor movement)

Motor current = Motor current level in mA

Occlusion = Pump occlusion alarm setting

Battery = Battery voltage

Either use / keys to display further information or to return to the previous screen, press key.

The event information that displays when key is pressed will vary depending on the operational status of the syringe pump for that event.

Some events may only record one or two parameters, while other events record numerous parameters.

Note: The syringe pump does not automatically change for daylight saving. The date and time can be updated manually via the syringe pump Change Set up menu.

Event Log examples

Switched ON	Syringe Removed	Anti-bolus Reverse	Keypad Lock ON
Switched OFF	Occlusion / End	Stop Infusion	Keypad Lock OFF
Volume Change	Purge	Pump Operating	System Error

Note: Other events may be recorded relating to technical information. Refer to the *Technical Service Manual* for details.

3.4 Post Occlusion Bolus Reduction System (POBRS)

POST OCCLUSION BOLUS REDUCTION SYSTEM

During an occlusion, the pressure in the downstream section of the syringe extension set and/or inside the syringe can increase above the occlusion pressure defined in pump settings. When the syringe pump alarms the user must check the syringe extension set and attempt to clear the occlusion. During an occlusion the syringe pump's Post Occlusion Bolus Reduction System feature will reverse the operation of the motor and drive the actuator to avoid an unintended bolus on release of the occlusion.

When the infusion is resumed, the volume to be infused (VTBI) increases and the volume infused (VI) decreases to indicate the syringe pump back off feature and the infusion time remaining increases; this protects the ml/h infusion rate.

Following activation of the POBRS and if the user presses ▶ to resume the infusion VTBI increases and the VI decreases to indicate the syringe pump back off feature.

Intermediate Rate	**Occlusion Pressure**	**Unintended Bolus Volume**
5 ml/h	200 mmHg (minimum) 1500 mmHg (maximum)	<= 0.5 ml <= 0.5 ml

An occlusion may pressurize the syringe extension set and syringe, which can result in an unintended bolus of infusate when the occlusion is resolved. In order to prevent unintended bolus, disconnect the syringe extension set or relieve the excess pressure through a stopcock, if present.
The clinician should weigh the relative risks of syringe extension set disconnection with the risks of an unintended bolus.

OCCLUSION PRESSURE

The occlusion pressure of a pump is the pressure in the system, registered at the syringe pump, when the syringe pump is still operating but cannot sustain the flow rate. The resultant build-up of pressure sets off the occlusion alarm.

OCCLUSION AND RESPONSE

An occlusion alarm can be activated by:

- A blockage in the syringe extension set – often inadvertently caused by kinking or leaving a roller clamp or a tap closed.
- A clotted-off cannula.
- A partially occluded cannula – if it causes the required driving pressure to rise above the occlusion alarm level.
- A very long or narrow bore cannula or/with syringe extension set.

Occlusion response is characterised in terms of three measurable parameters:

1. Pressure to alarm
2. Time to alarm
3. Bolus release when occlusion is resolved

1. Pressure to alarm

If an occlusion occurs the syringe pump attempts to maintain sufficient pressure on the infusate to cause it to flow through all restrictions and overcome any additional resistance. Although infusate is incompressible, the syringe extension set and other components of the system have some give (compliance) and the syringe extension set can expand under the increasing pressure. Other components of the system, such as the syringe stopper, become compressed. This expansion and compression takes some time to occur.

2. Time to alarm

If the occlusion is present from the beginning of the infusion, the time to alarm will increase. The pressure in the syringe and syringe extension set increases from zero at the start of the infusion up to the alarm level. Leaving a clamp closed is the most likely cause of occlusions. Generally, shorter time to occlusion alarm occur with high flow rates and small syringes. Refer to section *Time to Alarm from Occlusion* on page 14 for time-to-alarm specifications.

3. Unintended bolus release

In the case of a complete occlusion, there is no flow to the patient whilst pressure in the system is increasing. When the occlusion is released, the build-up of infusate in the syringe extension set can result in an unintended bolus.

Section 4: Modes of Operation

4.1 Modes of Operation

DURATION INFUSION

The primary setting is duration (volume over time infusion) which can be configured with a locked or changeable duration time. Once the duration time is confirmed, the syringe pump will calculate the ml/h rate.

RATE INFUSION (ML/HOUR)

The primary setting is ml/h rate (rate over time infusion) which can be configured with a locked or changeable ml/h infusion rate. Once the ml/h rate is confirmed, the syringe pump will calculate the duration time.

COMMON PUMP CONFIGURATIONS

Four common pump configurations are:

- Lock On mode – fixed duration
- Lock Off mode – adjustable duration
- Rate mode (Lock On) – fixed ml/h rate
- Rate mode (Lock Off) – adjustable ml/h rate

Each of these modes can have additional functions enabled or disabled, to suit local requirements.

The syringe pump default mode of operation is Lock On 24 hour duration.

For the correct pump configuration, mode of operation and start-up sequence, you must refer to your local policies.

RESUME

The T34™ Syringe Pump can be configured for a continuous infusion with Rate as the primary setting. The primary setting (e.g. Rate) is then used to calculate duration. If the Rate is the primary setting it is saved for the current program when Resume is selected after therapy interruption (e.g. syringe displacement or occlusion). See KEY PRESS OPTIONS OF RESUME AND NEW SYRINGE section for further instructions.

LOCK ON MODE (FIXED DURATION)

The syringe pump will deliver the syringe volume over the fixed (locked) duration. Once a syringe is detected and confirmed, the syringe pump calculates the ml/h infusion rate:

$$\frac{\textit{syringe volume}}{\textit{fixed duration}} = \textit{ml/h infusion rate}$$

- With the Program Lock On, rate change (titration) during infusion **cannot** be enabled.
- KVO and purge can be enabled if required.

Note: During programming, the user must check and confirm the infusion summary screen. This includes checking the syringe volume, duration, and the calculated rate matches the prescription and what is required for that infusion before it is commenced.

LOCK OFF MODE (ADJUSTABLE DURATION)

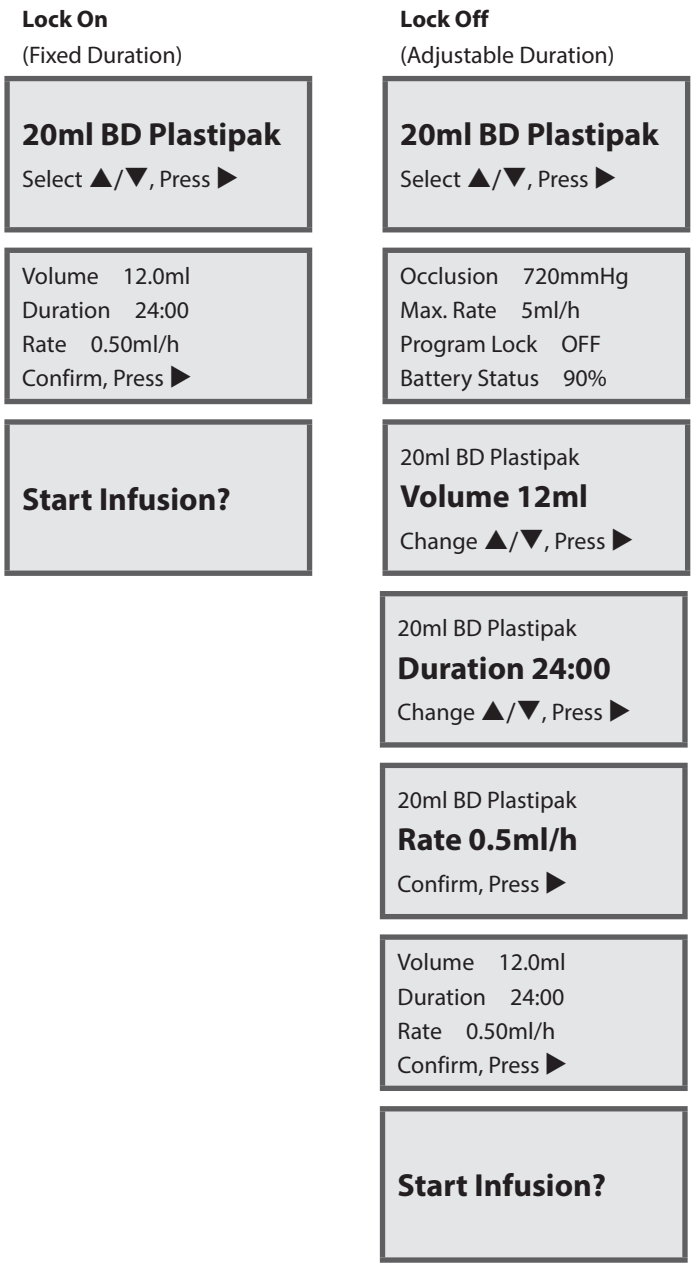
The syringe pump will deliver the syringe volume over the confirmed default duration or the duration inputted and confirmed by the user during programming. The syringe pump then calculates the ml/h infusion rate:

$$\frac{\textit{syringe volume}}{\textit{default or duration entered}} = \textit{ml/h infusion rate}$$

- With Program Lock Off, rate change (titration) during infusion **can** be enabled if required. There is no option to re-program the infusion duration during delivery.
- KVO, purge and rate titration can be enabled if required.

Note: During programming, the user must check, change and/or confirm infusion information and programming screens. This includes checking that the program summary screen (syringe volume, duration, and the calculated rate) matches the prescription and what is required for that infusion before it is commenced.

COMPARISON OF LOCK ON AND LOCK OFF (DURATION) MODES PROGRAMMING SCREENS



If the default duration is changed and/or titration is enabled additional screen prompts will display.

Note: There are two alternatives methods for starting an infusion when using a duration (volume over time) mode of operation: prime and load or load and prime methods. The method chosen relates to the priming volume of the syringe extension set. Your local policy will state which method to use.

Note: In Duration mode we recommend using "Prime and Load" and not "Load and Prime". Please be aware if using Load and Prime instead of Prime and Load sequence, the rate of delivery will be automatically adjusted to compensate for the lost priming volume while maintaining the preset duration. If you wish to maintain the rate, please work in Rate mode.

RATE MODE (LOCK ON) – FIXED ML/HOUR RATE

The syringe pump will deliver the syringe volume over the fixed (locked) ml/h rate. Once a syringe is detected and confirmed, the syringe pump calculates infusion delivery duration:

$$\frac{\textit{syringe volume}}{\textit{fixed ml/h rate}} = \textit{duration}$$

- With the Program Lock ON, rate change (titration) during infusion **cannot** be enabled.
- KVO and purge can be enabled if required.

Note: During programming, the user must check and confirm the infusion summary screen. This includes checking the syringe volume, duration, and the rate matches the prescription and what is required for that infusion before it is commenced.

RATE MODE (LOCK OFF) – ADJUSTABLE ML/HOUR RATE

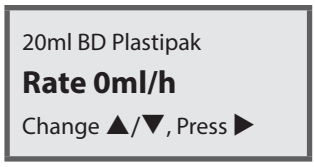
The syringe pump will deliver the syringe volume over the ml/h rate inputted and confirmed by the user during programming the syringe pump calculates the infusion delivery duration:

$$\frac{\textit{syringe volume}}{\textit{confirmed ml/h rate}} = \textit{duration}$$

- With Program Lock OFF, rate change (titration) during infusion **can** be enabled if required.
- KVO, purge and rate titration can be enabled if required.

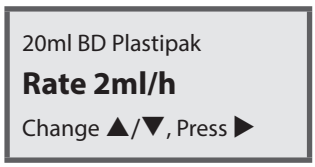
RATE MODE PROGRAMMING SCREENS

a) If the syringe pump is configured with Rate Setting disabled, the default is 0 ml/h.



This example shows the default rate is 0 ml/h. The user enters the rate required.

b) If the syringe pump is configured with Rate Setting enabled, the programmed rate becomes the default.



This example shows the default rate is 2 ml/h. The user can either confirm or change the rate.

Note: During programming, the user must check, change and/or confirm infusion information and programming screens. This includes checking that the program summary screen (syringe volume, duration, and the calculated rate) matches the prescription and what is required for that infusion before it is commenced.

Section 5: Pump Configuration

5.1 Pump Configuration

CONFIGURATION AUTHORISATION

Pump configuration must only be carried out by designated and authorised personnel, you must check with your technical department and/or line manager if you are designated and have the authority to change the syringe pump configuration.

When configuring a pump, the following must be taken into account, to ensure that:

- The pumps are configured for the required application, e.g. occlusion pressure settings correct for drug delivery route.
- The mode of operation (lock on, lock off and rate modes) configured is correct for the drug prescription. e.g. duration (volume-over-time) or a ml/h infusion
- Optional features and functions that may be required are configured (e.g. Purge, KVO, titration, pump maximum ml/h rate)

Any program/pump changes that are made must be fully documented checked with a second person and against a pump setting authorisation form which is available from local or CME Ltd. technical service staff.

5.2 Pump Access Codes

ACCESS CODES FOR PUMP CONFIGURATION

The T34™ Syringe Pump has three areas of access code protection to prevent unauthorised changes to set up, configuration or programming. Certain settings and features may be configured and locked based on patient or clinical need or to configure the syringe pump for a specific clinical application.

No access code is required to turn the syringe pump on and run an infusion. In normal clinical use the syringe pump user will not see these fields or be prompted for access codes.

The Change Set Up and Rate Settings menus are available via the syringe pump menu.

The Technician menu code is only provided to fully trained, (by CME Ltd.) and authorised electrical biomedical engineering personnel.

Do not attempt to access code protected areas if you are not trained or authorised to do so. Authorised personnel should not share codes with un-authorised personnel and should only give code access to designated personnel.

Note: Codes will only be provided by CME Ltd. to designated and authorised clinical or technical staff when they have been trained and certified in their use. No access codes are contained in this *Directions For Use*.

Note: Technical staff must refer to CME Ltd. Technical Services department for access codes and information on pump configuration and training.

5.3 Pump Info and Configuration Menus

PUMP INFO MENU

The syringe pump Info menu enables the user to navigate to various functions. This includes accessing the syringe pump configuration settings (Change Set Up and Rate Setting areas).

ACCESSING THE INFO MENU

The menu cannot be accessed during an infusion or with the keypad lock activated.

- With no infusion running, press the key.
- Use / keys to scroll up/down the menu to select the option required, then press key to view the contents.

The tables describes the functions in the menu.

Option	Description
Info Menu **Battery Level** Select ▲/▼, Press ▶	View battery life percentage (graph)
Info Menu **Exit** Select ▲/▼, Press ▶	Exits Info menu
Info Menu **Rate Setting** Select ▲/▼, Press ▶	Change and configure Rate Setting function (access code protected)
Info Menu **Event Log** Select ▲/▼, Press ▶	View pump event log
Info Menu **Change Set up** Select ▲/▼, Press ▶	Change and configure programming functions (access code protected)

RATE SETTING MENU

The tables shows the configurable parameters in the Rate Setting area.

Parameter	Default	Range	Description
Rate Setting	0 ml/h	0.1 ml/h – (maximum rate)	Sets the default rate on Rate Setting Mode. **Note:** Maximum rate can be changed from the technician menu (**Maximum Rate** parameter). Default: 5 ml/h. Range: 0.1 ml/h to 650 ml/h.

CHANGE SET UP MENU

The tables shows the configurable parameters in the Change Set Up menu

Parameter	Default	Range	Description
Exit	—	—	Exit the Change Set Up menu.
Language	English	English, local language	The syringe pump can be set to English or one local language which varies according to where the syringe pump is sold.
Set Time and Date	Current date/time	Month/year Hour/minute	Sets a date and time stamp for the event log. This does not automatically change for daylight saving.
Key Operation	5 mm	0.1–100 mm	Limits the forward movement of the actuator when the key is pressed with no syringe in place and barrel clamp arm down.

Backlight Duration	5 seconds	0 (OFF)–60 seconds	Limits the screen backlight duration following key presses.
Info Duration	5 seconds	1–20 seconds	Limits the screen information duration which displays when the key is pressed during an infusion.
Bolus Dose Rate	300 ml/h	1–650 ml/h	1–10 ml/h in 0.01 ml/h increments; 10–29.9 ml/h in 0.1 ml/h increments; 30–49.5 ml/h in 0.5 ml/h increments; 50–299 ml/h in 1 ml/h increments; 300–650 ml/h in 5 ml/h increments.
Bolus Maximum Volume	0 ml (Disabled)	0 (OFF)–20 ml	0–20 ml in 0.1 ml increments.
Titration Option	Disabled	Enabled/Disabled	Enables rate change during infusion. Maximum rate is the syringe pump max. ml/h rate. Minimum is 0.1 ml/h. Can only be enabled if program lock is OFF.
Default Duration	24:00 hours	0:00 hours (ml/h) 0:01–99:00 hours (volume over time)	With default duration set to 0:00 hours, the syringe pump runs as an ml/h infusion. With a nonzero default duration set, the syringe pump runs as a volume over time infusion.
Occlusion Pressure	720 mmHg	200–1500 mmHg	Sets the pressure level at which the occlusion alarm will activate.
KVO Operation Rate	0 ml/h	0 (OFF)–5.0 ml/h	0–5.0 ml/h in 0.1 ml/h increments. Activates Keep Vein Open infusion at end program.
Program Lock	ON	OFF/ON	With lock on, prevents alteration of default duration or ml/h rate.

5.4 Pump Configurable Settings for Modes of Operation

CONFIGURATION SETTINGS FOR LOCK ON AND LOCK OFF (DURATION) MODES

	Lock On (Fixed duration)	**Lock Off (Adjustable duration)**
Titration Option	Disabled	Enable if rate change during infusion is required
Default Duration	e.g. 24:00 hours	e.g. 24:00 hours
Program Lock	On	Off
Rate Setting	0 ml	0 ml
Occlusion Pressure	Set the pressure for the infusate delivery route e.g. subcutaneous, IV.	
KVO	Set KVO ml/h if required.	
Max. Rate	Change if required. Pump default 5 ml/h.	
Purge	Set purge volume if required. Pump default 0 ml.	

CONFIGURATION SETTINGS FOR RATE (ML/HOUR) MODES

	Rate Mode (Lock ON) (Fixed ml/h rate)	**Rate Mode (Lock OFF) (Adjustable ml/h rate)**
Titration Option	Disabled	Enable if rate change during infusion required
Default Duration	0:00 hours	0:00 hours
Program Lock	On	Off
Rate Setting	e.g. 2 ml/h	e.g. 2 ml/h
Occlusion Pressure	Set the pressure for the drug delivery route e.g. subcutaneous, IV.	
KVO	Set KVO ml/h if required. Pump default 0 ml.	
Max. Rate	Change if required. Pump default 5 ml/h.	
Purge	Set purge volume if required. Pump default 0 ml.	

Note: A Pump Configuration Authorisation form is available from CME Ltd. to record authorisation and document pump settings. Contact your local Sales or Clinical representative.

Note: Pump maximum ml/h rate and purge volume are configured via the syringe pump Technician Menu. If these settings need to be changed, you must consult technical staff.

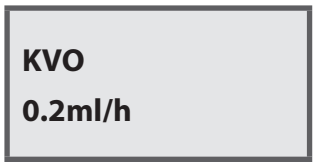
Note: The syringe pump uses an indirect method of pressure detection.

5.5 Optional Configurable Settings

KVO (KEEP VEIN OPEN) OPERATION

The T34™ Syringe Pump can be configured to deliver a KVO infusion to commence at the end of the infusion to keep the patients access device patent. With KVO enabled the syringe pump applies the KVO rate set until the syringe is empty or to a maximum of 5 ml.

KVO rate can be configured in the syringe pump Change Set Up Menu.



When configuring KVO infusion rate, Medium priority alarm will be heard to confirm the syringe pump is still infusing in KVO mode.

When the KVO volume is delivered the end program alarm activates.

PURGE

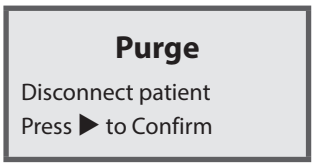
In order to eliminate/reduce mechanical slack (visible spaces at the syringe collar and plunger loading points) and ensure a faster start up time (time to start delivering the fluid to the patient/reach the programmed infusion rate) the user can purge the system.

- The purge function is available (if enabled) once only, after pre-loading prior to commencing an infusion.
- The purge function is disabled by default (0 ml) and the maximum deliverable is 2.0 ml.
- The purge rate is 650 ml/h.
- The purge function can be configured via the syringe pump Technician menu.
- The purge function can be used with any mode of operation.

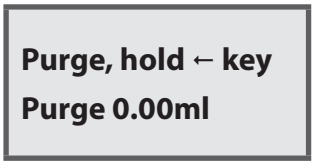
Purge sequence (all modes of operation)

1. Turn the syringe pump on without syringe and wait until the preloading process is complete.
2. Load the syringe.
3. Press the ← key after confirming the syringe size/brand.

4. Ensure the syringe extension set is disconnected to the patient, confirm by pressing ▶ key.



5. Press and hold the ← key until the slack is removed and purge volume is delivered (a purge volume will be configured, e.g. 0.2 ml).



6. Wait for the next screen to display.

7. If the syringe size/brand displayed matches the one used, confirm by pressing ▶ key. (Use ▲ / ▼ keys to select the matching syringe if necessary).

Rate Titration

If enabled, you can titrate (change) continuous infusion flow rates during infusion, it is recommended that the keypad lock is used as an additional protection against accidental rate change during infusion.

The maximum ml/h rate limit will be the syringe pump maximum rate which is configured via the syringe pump Technician menu. The minimum rate is 0.1 ml/h. If this setting needs to be changed, you must consult technical staff.

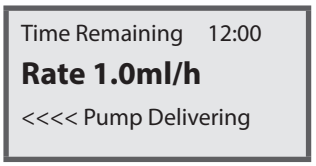
Rate change can be enabled in the following modes of operation:

- Lock Off Mode (duration)
- Rate Mode (ml/h)
- Rate Setting Mode (ml/h, Lock Off)

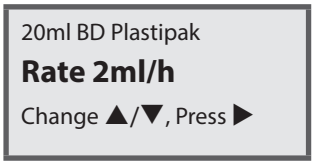
Rate change cannot be enabled in Lock On mode.

To titrate the ml/h rate during infusion

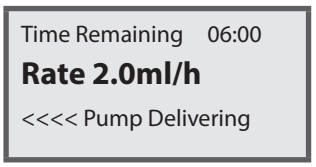
1. Deactivate keypad lock.
2. With infusion running, press ▲ / ▼ keys to change the rate.



3. Enter infusion rate required using ▲ / ▼ keys, confirm by pressing ▶.



4. Check that the rate change completed and is correct. (Note change to time remaining).



5. Activate keypad lock.

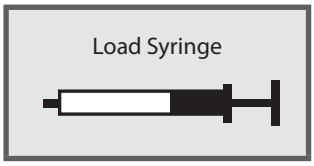
5.6 Practice Scenarios for Changing Pump Configuration

Changing configuration will affect the operation/functionality of the T34™ Syringe Pump. Set up parameters should only be changed by clinical or technical staff with user code access rights only and the authority to change pump settings. It is advisable that any configuration changes are carried out with no syringe in place and barrel clamp arm down.

SCENARIO 1: CHANGE DATE AND TIME

Scenario: Change date and time from 4th February 2009, 16:15 to current date/time.
(10th December 2011, 12:30 is demonstrated below)

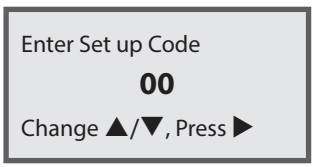
1. To power on, press key. Wait until pre-loading completes and screen prompt displays:



2. Press the key.

3. Scroll to **Change Set Up**.

4. Press key.



5. Enter access code using / keys, confirm by pressing . To obtain a suitable access code, please contact your local service centre.

When the arrow is pressed and held down the syringe pump will count up in single digits to ten, then in tens to one hundred and then in thousands thereafter. Scroll to the nearest point in tens and then release the key. Press either the or arrow individually, until the correct code displays then press to confirm.

6. Scroll to **Set Time and Date,** press key.

7. Change year using / keys, confirm by pressing key.

8. Change month using / keys, confirm by pressing key.

9. Change date using / keys, confirm by pressing key.

10. Change hour using ▲/▼ keys, confirm by pressing ▶ key.

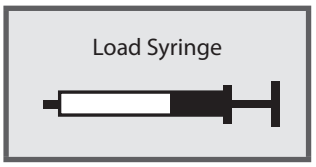
11. Change minutes using ▲/▼ keys, confirm by pressing ▶ key.

12. Press ▶ to exit Set Up.
13. Check changes by powering off and on, with barrel clamp arm down and observing start up screen information.

SCENARIO 2: CHANGE PROGRAM LOCK ON TO LOCK OFF

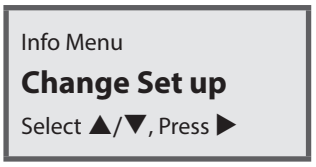
Scenario: Current pump set up: pump default, Lock On 24:00

1. To power on, press ⏻ key. Wait until pre-loading completes and screen prompt displays:

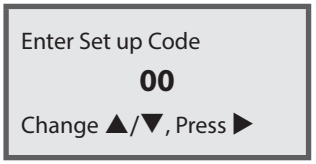


2. Press the ⓘ key.

3. Scroll ▼ to **Change Set Up**.



4. Press ▶ key. Contact your local service centre to obtain a suitable access code.

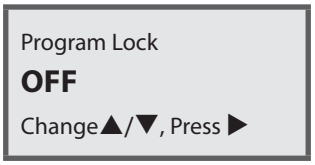


5. Enter access code using ▲/▼ keys, confirm by pressing ▶ key.

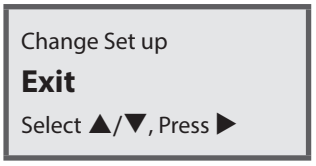
When the ▲ arrow is pressed and held down the syringe pump will count up in single digits to ten, then in tens to one hundred and then in thousands thereafter. Scroll to the nearest point in tens and then release the key. Press either the ▲ or ▼ arrow individually, until the correct code displays then press ▶ key to confirm.

6. Scroll ▼ to **Program Lock**

7. Press ▶ key. Change to **OFF** using ▲/▼ keys, confirm by pressing ▶ key.



8. Scroll ▼ until **Exit** displays, confirm by pressing ▶ key.

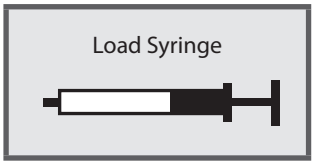


9. Check changes by powering off and on, with barrel clamp arm down and observing start up screen information (Program Lock status).

SCENARIO 3: CHANGE FROM LOCK ON MODE TO RATE SETTING (LOCK ON) MODE

Scenario: Change from Lock On Mode with default duration of 24:00 to Rate Setting (Lock On) Mode with 2 ml/h rate. Change Default Duration to 0 hours in Change Set-Up Menu and enter 2 ml/h in Rate Setting Menu.

1. To power on, press key. Wait until pre-loading completes and screen prompt displays:



2. Press the key.

Info Menu
Battery Level
Select ▲/▼, Press ▶

3. Scroll to **Change Set Up,** press key.

Info Menu
Change Set up
Select ▲/▼, Press ▶

4. Enter access code using / keys, confirm by pressing key. Contact your local service centre to obtain a suitable access code.

Enter Set up Code
00
Change ▲/▼, Press ▶

5. Scroll to **Default Duration**.

Change Set up
Default Duration
Select ▲/▼, Press ▶

6. Change to **00:00** using / keys, confirm by pressing key.

Default Duration
00:00
Change▲/▼, Press ▶

7. Scroll until **Exit** displays.

Change Set up
Exit
Select ▲/▼, Press ▶

8. Press the key.

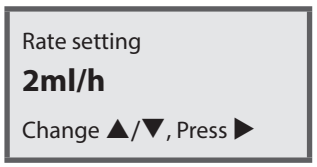
Info Menu
Battery Level
Select ▲/▼, Press ▶

9. Scroll to **Rate Setting**, press key.

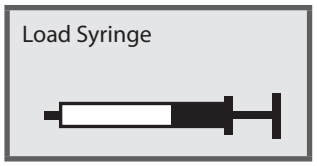
Info Menu
Rate Setting
Select ▲/▼, Press ▶

10. Enter access code using / keys, confirm by pressing key. Contact your local service centre to obtain a suitable access code.

Enter Rate Code
0
Change ▲/▼, Press ▶



11. Change to **2 ml/h** using ▲ / ▼ keys, confirm by pressing ▶ key.



12. The **Load Syringe** screen prompt displays.

13. Check if all setting changes completed by simulating starting an infusion.

Section 6: Starting A New Infusion

6.1 Sequence for Starting an Infusion

This section explains the user actions needed for starting a new infusion. The 'Prime and Load' method of syringe extension set priming is described. This is suitable for the low priming volumes of all CME syringe extension sets.

A. PREPARE SYRINGE AND MANUALLY PRIME THE SET

Prepare syringe with drug(s) as per prescription and local policy, attach drug label, ensuring the label lies flat.

Do not over-label the syringe or apply anything that changes its external diameter at the point where the barrel clamp is applied as incorrect syringe detection may result.

Manually prime the syringe extension set

Preparing the syringe and the syringe extension set:

1. Select the correct syringe extension set, and remove from packaging.
2. Attach the syringe extension set to prepared Luer Lock syringe, maintaining sterility.
3. Remove cap from end of syringe extension set.
4. Gently push syringe plunger forward until air is expressed from the syringe extension set.
5. Cap the end of the syringe extension set.

B. CHECK THE SYRINGE PUMP

Ensure that the syringe pump is clean, visually intact, appropriate for intended use, and within service date. It is good practice to inspect medical equipment and accessories between patients and certainly immediately before use (e.g. whilst setting it up on the patient).

Inspection of the syringe pump and/or accessories should include checking that the:

- Pump is undamaged
- Lockbox is locked and intact (if in use)

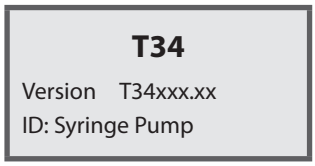
C. POWERING ON AND PRE-LOADING

Do not insert foreign objects around or near the actuator during automatic actuator movement (pre-loading) or when manually adjusting the actuator. The procedure for releasing a foreign object from the actuator is in section 6.2.

Powering On

With no syringe in place and the barrel clamp arm down, press the key until the screen illuminates and the first screen displays.

When the syringe pump is powered on, pre-loading commences.



Pre-loading

Pre-loading is a simultaneous sequence of screen information displaying and automatic actuator movement. During pre-loading:

- The syringe pump performs an internal self-test
- The screens display important pump information
- The actuator moves forwards/backwards automatically

Pre-loading deletes any program in the syringe pump memory and at the end of the pre-loading sequence the actuator returns to the start position of the last infusion. If the user regularly uses the same syringe brand, size and fills to the same volume, powering off and on allows automatic actuator movement which returns the actuator to the correct position each time.

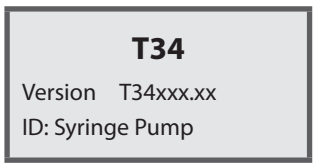
Pre-loading only takes place when no syringe is in place and the barrel clamp arm is in the down position.

Note: If the syringe pump is powered on with no syringe in place but with the barrel clamp arm raised, pre-loading does not take place.

The actuator will only move automatically or manually by using the and keys (with no syringe in place and barrel clamp arm down). Do not use force to try to move the actuator manually as this could cause damage to the syringe pump and/or affect calibration.

If the keypad lock is on, when a pump is powered on (with no syringe in place and barrel clamp arm down), pre-loading will not take place and the actuator cannot be moved manually using the / keys.

During pre-loading the following screens display in sequence:



Pump identification

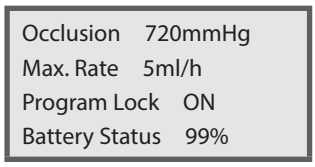
The syringe pump displays the model name, software version number and pump identification.

The default identification name (ID) is **Syringe Pump**. This name can be changed by an authorised technician, e.g. to an asset number or site name. Up to 17 characters are permitted.

Advisory notice

It is advisable not to interrupt the automatic actuator movement to ensure that a previous program is deleted.

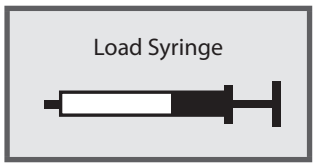
If the user pressed ■ key, the actuator stops moving and the **Load Syringe** screen will display.



Pump default settings

Line 1 – Occlusion pressure setting
Line 2 – Pump maximum ml/h Rate that can be set
Line 3 – Program lock status
Line 4 – Battery status*

*During actuator movement this value may fluctuate. Do not rely on this figure as the true battery percentage.



On completion of pre-loading the screen displays.

This screen displays and flashes until a syringe is detected in all three syringe sensors.

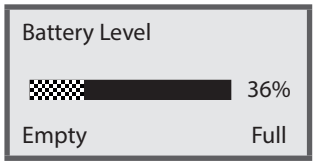
D. CHECK THE BATTERY LEVEL

Check the battery level via the menu

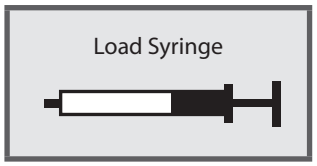
The LED light will display red (no infusion running)

1. Press key.

2. Press key.



3. Wait a few seconds for this screen to display:

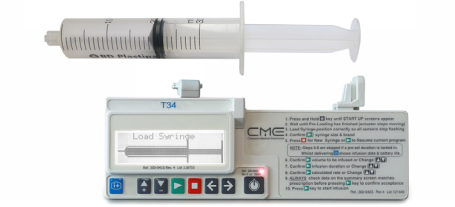


Instructions for changing the battery when necessary are given in section 2.3.

E. SYRINGE LOADING, DETECTION AND CONFIRMATION

Manual adjustment of the actuator

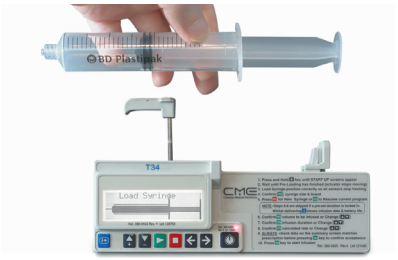
1. Ensure the barrel clamp arm is down.
2. Place the prepared syringe above the syringe pump to visually align the syringe collar to the collar sensor.
3. Use the ◀ / ▶ keys (if required), to move the actuator to the correct position for placing the syringe collar and plunger into the matching pump sensor areas.



Syringe loading

1. Lift the barrel clamp arm fully and turn the arm 90° (either way).
2. Place the syringe collar vertically (long side) into the syringe pump collar slot and the syringe plunger into the syringe pump plunger slot,
   the syringe should click into position.
3. Turn and lower the barrel clamp arm onto the syringe.

As each point of the syringe is correctly seated, the flashing indicator becomes solid on the screen display. When the collar and plunger sensors detect a syringe, its size and brand will display. If the syringe is not detected, the display will show 'Check Plunger Sensor' or 'Check Collar Sensor'.



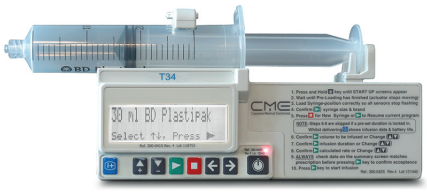
Check Plunger Sensor

Check Collar Sensor

Syringe detection and confirmation

The syringe pump identifies the syringe brand, size and volume by measuring the syringe dimensions from the three sensors.

Check that the syringe brand and size inserted into the syringe pump matches the syringe brand and size displayed. If they match, confirm by pressing ▶ key.



Incorrect syringe size/brand detected

The syringe pump may sometimes misidentify a syringe as a different type or brand from the one being inserted. Common causes are:

- The syringe is not correctly fitted into the 3 sensor areas and the syringe pump has wrongly detected another syringe with very similar dimensions. (Within ±1 mm of another syringe brand in the syringe library.)
- Over-labelling of the syringe or applying anything that changes its external diameter at the point where the barrel clamp is applied.

To rectify:

- Scroll between syringe brands of similar dimensions using the ▲ / ▼ keys.
- When the correct syringe displays, press ▶ key to confirm and continue programming.

Failure to detect a syringe

Failure to detect any brand/size of syringe can be caused by:

- The syringe is positioned incorrectly or not fully engaged with any or all of the sensors.
- The syringe brand or size being fitted is not configured into the syringe pump.

To rectify:

- Reposition or refit the syringe ensuring the syringe is firmly placed into the 3 sensor areas. The screen prompt will indicate which sensor or sensors are affected. For the collar sensor, ensure that the collar of the syringe is facing downwards into the slot because the sensor is positioned at the bottom of the slot.

- Either use a compatible syringe brand or arrange for the new size or brand of syringe to be configured into the syringe pump. This change can only be performed by authorised personnel.

Never take a syringe that is not empty off the syringe pump if it is still connected to the patient. The syringe extension set must be disconnected or clamped before removing the syringe to prevent uncontrolled flow and the risk of serious injury or death to the patient.

If the Volume to be Infused displayed on the syringe pump LCD after confirming the syringe varies by more than 5% of the actual syringe volume visually confirmed on the syringe scale, remove the syringe, turn off the syringe pump and, with the barrel clamp arm down, turn the syringe pump on to allow pre-loading to occur. Repeat the syringe placement and detection steps and ensure the correct syringe size and brand are confirmed. If the calculated volume reading is still significantly different from the visually confirmed contents, remove the syringe pump from use and return to an authorized service center for inspection, testing and calibration.

Using a syringe not approved by the syringe pump manufacturer or a syringe type which is not compatible with syringe pumps, could affect pump performance, resulting in over-delivery or under-delivery of medication to the patient.

F. ENTERING/CONFIRMING THE PROGRAM

When programming the syringe pump for a mode of operation, specific screens and user interactions will depend on the syringe pump configuration for local use.

This section demonstrates typical programming using the prime and load method for the following modes:

- Lock On mode – fixed duration
- Lock Off mode – adjustable duration
- Rate mode (Lock ON) – fixed ml/h rate
- Rate mode (Lock OFF) – adjustable ml/h rate

Lock On mode – fixed duration

Following syringe confirmation, the program summary displays:

Volume 12.0ml
Duration 24:00
Rate 0.5ml/h
Confirm, Press ▶

Review the infusion/program summary to check that the parameters displayed match the prescription: Visually check the volume/duration/rate. To confirm infusion, press the ▶ key.

The ml/h rate displayed has been calculated from the syringe volume and fixed duration.

Lock Off mode – adjustable duration

Following syringe confirmation, the program sequence commences:

Review pump configuration settings and wait for next screen prompt.

Occlusion 720mmHg
Max. Rate 5ml/h
Program Lock OFF
Battery Status 90%

Visually check if the volume in the syringe matches the volume displayed.
Change if necessary, confirm by pressing ▶ key.

20ml BD Plastipak
Volume 12ml
Change▲/▼, Press ▶

Change duration if necessary, by using ▲ / ▼ arrow keys, confirm by pressing ▶ key.

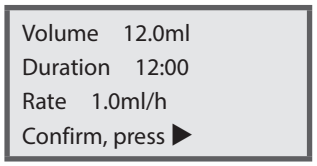
20ml BD Plastipak
Duration 24:00
Change▲/▼, Press ▶

If the default duration is changed this screen displays for a few seconds.

Duration Changed,
Please Check Rate

The rate displays (calculated from the syringe volume divided by the duration confirmed), check and confirm by pressing ▶ key.

Review the infusion/program summary to check that the parameters displayed match the prescription: Visually check the volume/duration/rate. To confirm infusion, press the ▶ key.

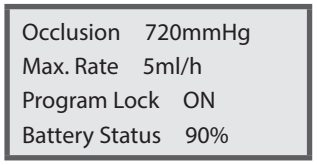


The ml/h rate is calculated from the syringe volume and confirmed duration.

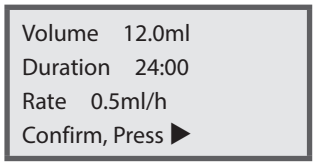
Rate mode (Lock ON) – fixed ml/h rate

Following syringe confirmation, the program sequence commences:

Review pump configuration settings and wait for next screen prompt.



Review the infusion/program summary to check that the parameters displayed match the prescription. Visually check the volume/duration/rate, to confirm infusion, press ▶ key.

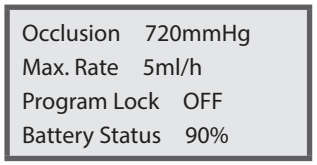


(The duration has been calculated from the syringe volume and fixed ml/h rate).

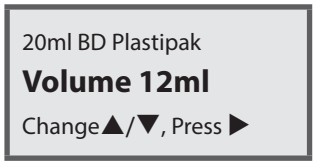
Rate mode (Lock OFF) – adjustable ml/h rate

Following syringe confirmation, the program sequence commences:

Review pump configuration settings and wait for next screen prompt.

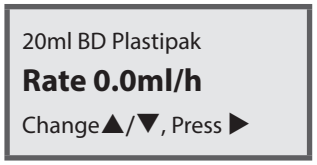


Visually check if the volume in the syringe matches the volume displayed. Change if necessary, confirm by pressing ▶ key.



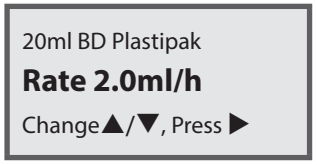
If adjustable rate setting is enabled, but no value has yet been entered, then an initial default value of 0 ml/h will display.

Enter the infusion rate required and confirm by pressing ▶ key.

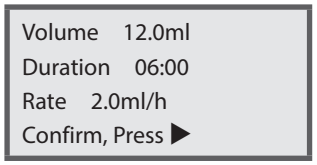


If a rate setting has been entered, then the ml/h rate will display.

Adjust the infusion rate if necessary, and confirm by pressing the ▶ key.



Review the infusion/program summary to check that the parameters displayed match the prescription. Visually check the volume/duration/rate. To confirm infusion, press ▶ key.



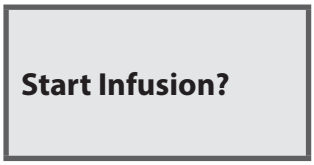
Duration is calculated from the syringe volume and confirmed ml/h rate.

G. START INFUSION (ALL MODES)

Connect the syringe extension set to patient

At this point, site/connect the cannula/syringe extension set to the patient. Follow local policy for the recommended cannula and set to use.

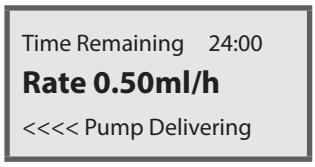
To commence the infusion, press ▶ key.

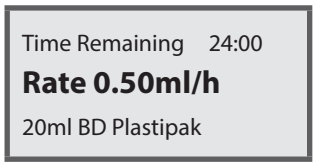


Check and confirm infusion is running

Visually check that the infusion running screen is visible and the green LED light flashes intermittently.

When the syringe pump is operating, note that the bottom line alternates between the syringe brand and size confirmed and **<<<< Pump Delivering** (with moving chevrons):





Note: An alternative sequence which may be used is the 'Load and Prime' method, which involves priming the set after loading the syringe pump. This method is more suitable for pumps which require a large priming volume. Which method to use should be decided based on which syringe extension sets are available, local circumstances and hospital policy. Consideration must be given to clinical risk, ease of use for the syringe pump user and consistency in start-up procedure for all wards/departments and clinical areas.

Note: In Duration mode we recommend using "Prime and Load" and not "Load and Prime". Please be aware if using Load and Prime instead of Prime and Load sequence, the rate of delivery will be automatically adjusted to compensate for the lost priming volume while maintaining the preset duration. If you wish to maintain the rate, please work in Rate mode.

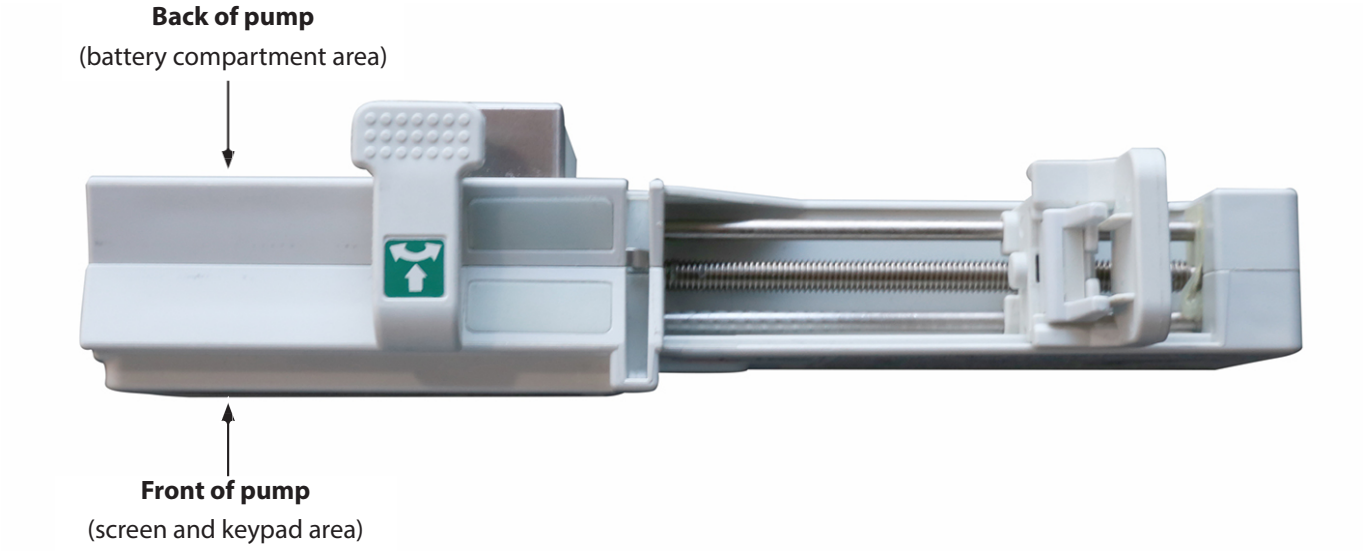
6.2 Releasing a Trapped Foreign Object from the Actuator

If an object /finger is trapped either during pre-loading or when manually adjusting the actuator, the alarm and screen prompt that displays will depend on the battery % level and the force/resistance moving against the actuator. Alerts or alarms that may display include low battery alert, end battery alarm, system failure alarm or a high motor current alarm.

If a foreign object /finger is trapped in front of, or behind the actuator during pre-loading (automatic actuator movement) or when manually adjusting the actuator, the user should:

Option 1 (manual adjustment of actuator)

1. Power the syringe pump off
2. With the syringe pump positioned with front of pump facing.
   - To move the actuator towards the barrel clamp arm, place finger on guide screw and roll finger towards the syringe pump screen/ keypad.
   - To move the actuator towards the front of the syringe pump, place finger on guide screw and roll finger towards the battery compartment.



Option 2 (adjustment of actuator using ◄ / ► keys)

1. Power the syringe pump off.
2. Power on.
3. Use the ◄ or ► key to release the object.

Event log interpretation of alarms

Interpretation of the syringe pump event log can assist in identifying the effects on the syringe pump with an object being trapped in front of, or behind the actuator. Recorded events will reflect the alarm that was activated at the time. If a low or end battery alarm was activated you may see that the battery voltage has dropped substantially and the activation of a low or end battery alarm is dependent on the battery % level at the time of the alarm.

Section 7: Monitoring and Managing Infusions

7.1 Pump and Infusion Safety Checks

Ensure that the syringe pump is clean, visually intact, appropriate for the intended use, and within service date. It is good practice to inspect medical equipment and accessories between patients and certainly immediately before use (e.g. whilst setting it up on the patient).

It is recommended that procedures are established for regular checks on the syringe pump, accessories and the progress of the infusion.

Inspect the lead screw prior to use (refer to section *3.2 Pump Description* on page 19, item 4). If there is white plastic debris on the lead screw, this is an indication of wear on the syringe mechanism. Therefore, discontinue use and send the syringe pump for service.

Inspect for signs of physical damage to the syringe pump, and to lockbox and carry pouch (optional).

PUMP POSITIONING

It is good practice to minimise disturbance to the pumps and to maintain the syringe pump at the same height level throughout an infusion as far as possible. Optimal operation occurs with positive pressure infusion devices are positioned at the same height level as the infusion site.

If a pump has been accidentally damaged, dropped or subject to fluid ingress/spillage it should be withdrawn from service immediately and a suitable replacement pump located. Contact your local service centre.

TO CONFIRM THE INFUSION IS IN PROGRESS

- The indicator LED will flash green.
- The LCD screen will display the following information:
  - Line 1 – infusion time remaining
  - Line 2 – ml/h infusion rate
  - Line 3 – alternates between the syringe size and brand confirmed by the user during set up and Pump Delivering

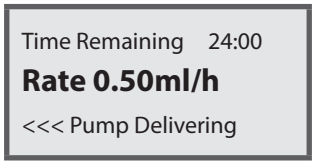
Regular monitoring should include checking:

- All connections between the syringe and the syringe extension set are secure.
- There are no kinks in the syringe extension set.
- There are no signs of physical damage to the syringe pump, lockbox or carry pouch.
- The keypad lock is on.
- Infusion is in progress.
- Volume history and battery status are as expected.

Note: Follow local guidance for a full list of infusion monitoring checks.

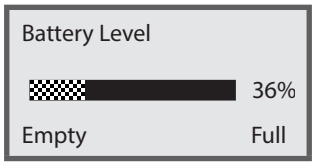
CHECKING THE BATTERY LEVEL DURING INFUSION (LED LIGHT IS GREEN)

Press key twice.



The battery level displays as a percentage (%).

Wait a few seconds for the screen to default back to infusion running screen again or press the key again, to display infusion volume history screen.



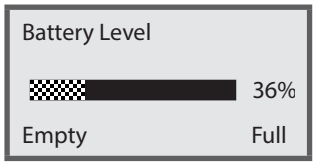
Note: With the infusion running, repeated key presses on the key cycles through volume history, battery level and infusion running screen. Excessive key presses or usage of the feature will reduce battery life. Use only as required to optimize battery performance.

CHECKING THE BATTERY LEVEL WITH INFUSION PAUSED (LED LIGHT IS RED)

1. Stop infusion by pressing key.
2. Press key once.
3. Press key.

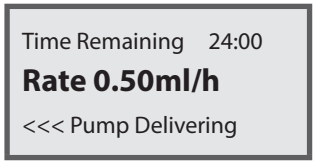
4. The battery level displays as a percentage (%).

Wait a few seconds for the default display to reappear, or press the key to exit the battery screen immediately.



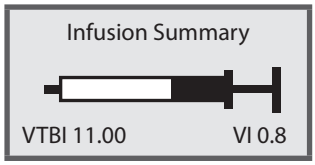
TO CHECK THE VOLUME HISTORY DURING INFUSION

Press key once.



The syringe volume to be infused (VTBI) and volume infused (VI) are displayed.

The total of VTBI + VI equals the starting volume.



Note: After pressing the key either a third press or waiting a few seconds returns the display to the base display screen.

Note: Excessive key presses or usage of the feature will reduce battery life. Use only as required to optimize battery performance.

7.2 Keypad Lock

FEATURES AND USES

The keypad has a locking feature that prevents unintentional powering off of the unit, as well as the ability to lock or limit certain infusion parameters or pump settings. The T34™ Syringe Pump allows users to lock the operation of the keypad if concerned about patients, relatives or untrained personnel tampering with the syringe pump.

The key and key are active as there may be a need to stop/pause the infusion short-term (e.g. in an emergency situation or for other clinical interventions).

If the syringe pump is stopped/paused for longer than 2 minutes, the **Pump Paused Too Long** alarm will activate to alert the user to the syringe pump status. In this instance, the Event Log records these events.

When the syringe pump is used with the keypad lock activated:

The user can stop and start an infusion, and with the infusion running use the key to review the infusion status. If the infusion is stopped/paused, the only option available is to restart the infusion.

- The syringe pump cannot be powered off using the Power key.
- The user cannot scroll through the menu to access the available options
- The user cannot change rate during continuous infusion (if enabled in Lock Off or Rate Modes).

Note the following principles with keypad lock:

- If the power supply is interrupted during an infusion and the user powers the syringe pump on again (with syringe in place): if the **Press to Resume, for New Syringe** screen displays, the infusion can be resumed.
- The use of the / keys for manual actuator adjustment is not accessible (when no syringe in place and barrel clamp arm is down).
- The syringe brand and size displayed cannot be changed using the and arrow keys as this would delete the current program.
- The purpose of pre-loading, (automatic actuator movement) is to delete the current program in the syringe pump. Pre-loading will not take place even when there is no syringe is in place and the barrel clamp arm is down.
- If the power supply is interrupted during an infusion and the user powers the syringe pump on again (with no syringe in place and the barrel clamp arm down) Pre-loading does not take place. Because pre-loading (automatic actuator movement) has not occurred, the program is still available to be resumed. Use of the keypad lock prevents automatic actuator movement.
- If the user then loads and confirms a syringe, the **Press to Resume, for New Syringe** screen displays, and the infusion can be resumed.

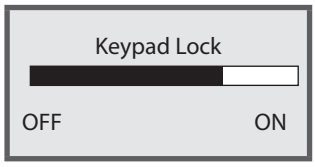
Note: It is recommended that the keypad lock is used if rate change (titration) is enabled. This gives additional protection against unintentional rate change during infusion.

APPLYING AND REMOVING THE KEYPAD LOCK

The keypad lock can be activated and deactivated at any time by pressing and holding the key.

To activate the keypad lock

With the syringe pump infusing, press and hold the key down for approximately 5 seconds. The lock indicator graphic will fill up from left to right. When the progress bar is completely black the syringe pump will beep to confirm that the lock has been activated.



To deactivate the keypad lock

Press and hold the key down for approximately 5 seconds. The lock indicator graphic will empty from right to left. When the progress bar is completely white the syringe pump will beep to confirm that the lock has been deactivated.

7.3 Program Protection and Resume

Program Protection

The current *program* (infusion) is the only one available in the syringe pump memory for use. In certain situations, it is possible to continue use of the current program using Resume after therapy interruption. Program protection and the ability to Resume applies specifically to the programmed ml/h rate. Pre-loading (automatic actuator movement) will clear a program from the syringe pump memory. For detailed information on pre-loading, refer to Section 6, Stage C. Powering on and Pre-Loading.

RESUME AND NEW SYRINGE OPTIONS

An infusion can be interrupted, for example by alarm activation (e.g., occlusion), syringe change, or power interruption. Depending on the cause of interruption, 'Resume' and 'New Syringe' are the two options that may be presented.

Press ▶ to Resume
■ for New Syringe

RESUME

The Resume option saves the current infusion rate and eliminates the need to reprogram/confirm settings (volume, duration, and rate) after therapy interruption. The Resume option is available to continue an infusion in the following situations:

- Syringe displacement or occlusion alarm
- Power supply interruption or failure

Resume is **not** available in the following situations:

- A different syringe brand and/or size is placed in the syringe pump
- The volume in the syringe is changed during therapy interruption

To Resume therapy press ▶ to confirm syringe brand and size then press ▶ to Resume. Follow the prompts to confirm the settings summary and press ▶ to start infusion.

Note: Pressing ■ for New Syringe immediately deletes the current program. A new program is then calculated or entered (depending on mode of operation).

NEW SYRINGE

A program (infusion) may be interrupted to change the syringe (i.e. brand, type, or increase/decrease syringe volume) which requires programming infusion settings (i.e. volume, duration, and rate). This type of interruption deletes the previous program, rate is not saved, and the options ▶ to Resume, ■ for New Syringe will not be provided.

Following an interruption, verify the syringe brand and size displayed matches the syringe placed into the syringe pump. If they match, press ▶ to confirm. Follow the prompts to change and/or confirm each setting for the current infusion, review the setting summary, and if correct press ▶ to start infusion. If incorrect, press ■ to go back.

Note: Follow local policy/procedure for the appropriate option to press when the ▶ to Resume, ■ for New Syringe screen displays following purge.

Syringe fitting and confirmation:

1. The syringe pump will automatically attempt to detect the syringe brand and size, but if it identifies a syringe incorrectly, lift the barrel clamp arm and re-seat the syringe.
2. If the incorrect syringe brand and size continue to be displayed, use the ▲ and ▼ arrows to scroll and select the correct syringe. When the correct syringe is displayed, to confirm press ▶. The options ▶ to Resume, ■ for New Syringe will be provided.
3. If the options for ▶ to Resume, ■ for New Syringe are **not** provided, then there is no current program available and a new program must be entered.

7.4 Stopping/Pausing the Infusion and Powering Off

TO STOP THE INFUSION (PUMP PAUSED)

If the user presses ■ key during an infusion the syringe pump is paused (stopped) for two minutes, the LED light changes from green to yellow and a screen message displays:

Either press ▶ key to restart the infusion or ■ key to pause for another two minutes.

If the paused state continues with no key presses, after two minutes the syringe pump will alarm and a 'Pump Paused Too Long' screen message displays.

Either press ▶ key to restart the infusion or ■ key to pause for another two minutes.

POWERING OFF

1. Remove keypad lock and stop/pause the infusion if running.
2. Press and hold down the ⏻ key until the progress graphic (moving from left to right) fills completely black, a beep is heard and the display screen power is removed.
3. Disconnect the syringe extension set from patient access device.
4. Remove syringe from the syringe pump and place the barrel clamp arm down.
5. Remove battery if the syringe pump is no longer required.

7.5 Alerts, Alarms and Troubleshooting

Alarm Condition

When the syringe pump detects a problem, four things may occur:

- If a High priority alarm occurs, infusion will stop. For lower priority alarms, infusion continues.
- An audible alarm is activated,
- A message appears on the display screen indicating the cause of the alarm, and
- The LED indicator will change to red/yellow.

Note: See the *Technical Service Manual* for test procedures to check Alarms functionality.

Note: During the power on sequence the audible speaker is activated and LEDs will illuminate to verify alarm functionality. No action is required during this self-test.

Note: Alarm tone settings are normally preserved in the case of power loss, however some system faults will result in loss of alarm settings.

Note: When you turn off the syringe pump, an event is recorded by the event log, while unexpected power loss events (for example, if you change the battery while the pump is on) are not recorded.

Note: In the event of complete loss of power supply, the backup audio alarm will sound, but there will be no visual indicators.

The operator should ensure that the current alarm presets are appropriate to use on each patient.

Avoid setting pump limits to extreme values. This may render the alarm system ineffective.

Infusion settings and other setup parameters should only be changed by clinical or technical staff with user code access rights and the authority to change pump settings.

ALARMS

The syringe pump will activate an alarm when:

Description	Alarm Type	Audio Signal as per 60601-1-8	Visual Signal as per 60601-1-8 Operational LED
Down Occlusion	High priority alarm Requires immediate user response	High priority 5 tones Volume min. 45 dBA	Red flashing visual Operation LED flashes red
End Battery			
End Of Infusion			
Syringe displaced during infusion			
Restart Pump **Switch off & On** **ERROR XX**			
End Of Infusion **(Keep Vein Open)**	Medium priority alarm Requires prompt user response	Medium priority 3 tones Volume min. 45 dBA	Yellow flashing signal Operation LED flashes yellow
Pump Paused Too Long	Low priority alarm Requires user awareness	Low priority 3 tones Volume min. 45 dBA	Yellow solid visual Operation LED is solid yellow (Not flashing)
Low Battery			
Near End			
Bolus Started / Completed	Informational signal Provides information that may, or may not require action from user	1 or 2 pulses	No visual
Keypad Lock / Unlock			
Syringe plunger at the limit of travel			

Syringe loaded	Informational signal Provides information that may, or may not require action from user	1 or 2 pulses	No visual
Purge Start / End			
Power On / Off			
Infusion started / resumed / stopped by user			
KVO stopped by user			
Service interval alert			

WHEN THE ALARM ACTIVATES:

- If a High priority alarm occurs, infusion will stop. For lower priority alarms, infusion continues.
- The alarm sounds until either the syringe pump is paused or the problem is rectified.
- A screen message indicates the cause of the alarm.

SCREEN PROMPTS

In certain situations screen prompts display to prompt the user and provide information:

Screen prompt	Result/cause	Possible actions
Keypad Locked	Only the ■, ▶ and ⏻ keys are accessible.	Disengage keypad lock if further access required.
Press ▶ to Resume, ■ for New Syringe	The current program has been interrupted and two options are available for programming.	Press ▶ key resumes the current program. Press ■ key to delete the current program (to allow a new program to be set up).
Pump Stopped Press ▶ to Resume	The infusion has been stopped.	Press ▶ key to resume the infusion or press ■ key to continue stopped state.

TROUBLESHOOTING ALERTS AND ALARMS

Screen information	Result/cause	Possible actions
Program Nearly Complete	Alert: Program is about to end/syringe is almost empty.	Prepare to change syringe or discontinue pump use.
Low Battery	Alert: Battery is almost depleted.	Prepare to change battery.
Pump Paused Too Long	Alarm: The syringe pump has been stopped/paused for more than 2 minutes without any key presses.	Either press ▶ key to resume the infusion, press ■ key to continue pause for another two minutes or turn the power off.
Syringe Empty, Remove Syringe	Alarm: Current infusion program has completed/syringe is empty.	Prepare to change syringe or discontinue pump use.
End Battery	Alarm: Battery will fail imminently.	Change battery.
Syringe Displaced, Check Syringe	Alarm: One or more of the syringe detection sensors is not detecting.	Check the syringe and re-seat as necessary Check screen messages for assistance.
Occlusion/Empty Syringe, Check Line	Alarm: Clamped set, occluded or kinked. Actuator has reached the minimum travel position.	Release the clamp, flush/replace the access device or clear the occlusion.
System Error (High Priority alarm) Press and hold ⏻ key for details. If problem persists send pump for service.	Alarm: An internal system error has occurred. (Two examples of system failure screen messages are shown here).	If error recurs: Take pump out of use. Press ⏻ key to obtain error message. Record error code and summary of fault and return pump to designated service centre.
ERROR. Startup MotMov Fail, If problem persists send pump for service.		

Technical problem/error and failure identification.

- The syringe pump alarms if an internal system fault has been detected and the unit will be inoperative.
- The user may be prompted to power off and restart, which may rectify the error.
- If the problem cannot be rectified: power off and remove from patient use.
- Refer to the *Technical Service Manual* for full details of all technical alarms.
- Follow local policy and/or contact your authorised Medical Engineering Department for advice.

The Event Log will record the error/alarm event.

7.6 Bolus

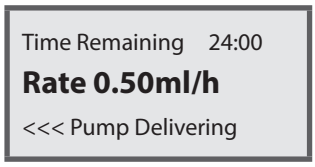
INTRODUCTION

Bolus Administering a controlled volume of fluid or drug at an increased rate for diagnostic or therapeutic purposes. The syringe pump should always be infusing and always attached to the patient. (Drugs given by an IV bolus could achieve immediate and high drug concentration levels.)

Note: Bolus delivery can only be used during an infusion.

When the infusion is in progress, this screen displays.

To deliver a bolus, press ◀ key and follow the screen prompts.



BOLUS DELIVERY SETUP

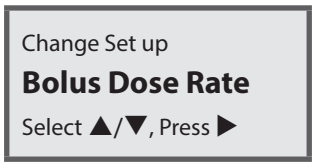
Bolus delivery cannot be performed unless the bolus delivery feature has been configured. Bolus delivery setup is configured via the Change Set up menu. Note that a suitable access code will be needed.

Press the ⓘ info button and select Change Set up from the menu.

Enter the access code and press ▶.

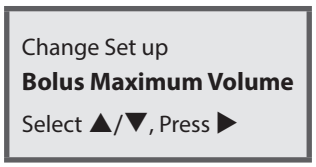
Use the ▲ / ▼ arrow keys to select Bolus Dose Rate and press ▶ when selected.

The default Bolus Dose Rate is 300 ml/h. Bolus Dose Rate can adjusted from 1 ml/h to 650 ml/h. Use the ▲ / ▼ arrow keys to enter the desired rate and press ▶ to confirm.

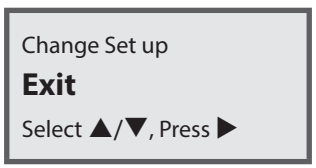


Use the ▲ / ▼ arrow keys to select Bolus Maximum Volume and press ▶ when selected.

The Bolus Maximum Volume is preset to 0 ml, and can be configured from 0 to 20 ml in 0.1 ml intervals. Use the ▲ / ▼ arrow keys to enter the desired volume and press ▶ to confirm.



Once the bolus dose rate has been adjusted, use the ▲ / ▼ arrow keys to select the Exit option and the ▶ key to exit the setup menu.



DELIVERING A BOLUS

Once the bolus delivery settings have been configured, boluses may be delivered during infusion. In order to deliver a bolus during an infusion, press the ◀ key. This brings up a confirmation screen:

Press ◀ key to activate the bolus menu. To confirm delivery of the bolus, press the ▶ key. Once delivery has been confirmed, the ◀ key must be held down continually to deliver the bolus.

Note: After confirming the bolus, the ◀ key must be held continuously. If the ◀ key is released, bolus delivery will stop and the syringe pump will change back to normal infusion.

7.7 Changing Syringes/Syringe Extension Sets

INTRODUCTION

This section provides options for managing an infusion in the form of checklists. They are intended as guidance only, not user instructions.

The way the infusion is managed in your own clinical area will vary, depending on, for example, local policy, types of syringe extension sets and drugs being infused. You must refer to your local policy for specific infusion management requirements and instructions for managing infusions.

CHECKLIST FOR CHANGING A SYRINGE (NEW PROGRAM, SAME SET)

Remember to de-activate and activate the keypad lock as necessary.

1. Stop infusion.
   a) If the infusion complete alarm has activated, press key to confirm the end of the infusion.
   b) If the Program Nearly Completed alert has activated, press the key to access volume history and record the VI (Volume Infused) then press key to stop the infusion.
2. Power off.
3. Clamp and disconnect the set from the empty syringe.
4. Raise the barrel clamp arm, remove the empty syringe and lower barrel clamp arm.
5. Prepare a new syringe and attach the syringe extension set.
6. Power on, observe pre-loading and wait for the screen to display **Load Syringe**.
7. Check battery level.
8. Load the new syringe into the syringe pump, check syringe brand/size is correct and to confirm press key.
9. Enter/check new program, if correct, press key.
10. The screen will display **Start infusion?** Connect set to syringe and when ready to do so, press key.
11. Check that the infusion is running.

CHECKLIST FOR PRIMING A NEW SYRINGE EXTENSION SET FROM THE SAME SYRINGE

Remember to de-activate and activate the keypad lock as necessary.

1. Stop the infusion.
2. Do not power the syringe pump off.
3. Disconnect set from cannula.
4. Remove syringe and set.
5. Attach new set to existing syringe and prime.
6. Align the syringe above the syringe pump and use the key to resize the syringe to the actuator.
7. Raise the barrel clamp arm.
8. Load the new syringe into the syringe pump, check syringe brand/size is correct and to confirm press key.
9. When the screen prompt **Press to Resume, for New Syringe** displays, press key to resume.
10. Check the program summary screen. If correct, press key.
11. The screen will display **Start infusion?** Connect set to cannula and when ready to do so, press key.
12. Check that the infusion is running.

CHECKLIST FOR DISCONTINUING THE INFUSION AND PUMP

Remember to de-activate the keypad lock

1. Stop infusion.
   a) If the infusion complete alarm has activated, press key to confirm the end of the infusion.
   b) If the **Program Nearly Complete** alert has activated, press the key to access volume history and record the VI then press key to stop the infusion.
2. Power off.
3. Disconnect the set/cannula from patient.
4. Raise the barrel clamp arm, remove the syringe and lower barrel clamp arm.
5. Remove the battery from the syringe pump.
6. Dispose of the syringe and set according to local policy.
7. Clean and store the syringe pump as per local policy.

Section 8: Servicing and Maintenance

8.1 Servicing, Maintenance and Periodic Checks

Periodic maintenance (PM) is recommended every **1 year**. In between maintenance the syringe pump requires only cleaning between patients (or as necessary; refer to section *8.2 Cleaning* on page 54 for complete cleaning instructions). The syringe pump will display a maintenance reminder alert for the user to send the syringe pump for service yearly. The PM is designed to assure the syringe pump's accuracy and detect and repair any potential pump inconsistencies prior to their occurrence in the field. During the PM, a biomedical engineer or trained technician should perform the following procedures:

- Clean the syringe pump thoroughly.
- Visually inspect the syringe pump to verify its structural integrity.
- Perform all the manual tests in the Change Set Up menu.
- Perform calibration procedures as per the *Technical Service Manual*.
- Run the syringe pump for several hours to make sure no abnormalities occur during infusion such as alarms, inaccurate infusion, and battery inconsistencies.

Note: Service and maintenance should be performed by a CME technician. The only maintenance a patient can perform is cleaning the device.

Note: It is the CME technician's responsibility to repair any faults found during the Periodic Maintenance.

Note: Do not service the syringe pump while it is in use and/or attached to a patient.

8.2 Cleaning

PUMP CLEANING - MRC Protocol

IMPORTANT!

- The Manufacturer Recommended Cleaning (MRC) protocol is **NOT intended to replace** local Infection Prevention and Control Policy. The decision about the level of decontamination required depends not only on how the device is used, but also on the risk of the device transmitting infection or acting as a source of infection.
- Best prevention practices against HAI (Hospital Acquired Infections) recommend a 2 steps process: Step 1. Removing unwanted soils from all surfaces with a cleaning agent (pathogens can use soils for harborage limiting accessibility to disinfectant agents). Step 2. Disinfecting the freshly cleaned surfaces.

MRC Protocol

INTENT:

- To preserve pump performance.
- To remove soil, particles and chemical residue that could accumulate over time on pump surface. Soil, particles and chemical residue result from normal use and from the "disinfection protocol" developed by users at point of use.

INSTRUCTIONS

- To clean the pump, wipe the external pump surface using a disposable alcohol wipe impregnated with isopropyl alcohol (IPA) 70%, to minimize pump exposure to excessive quantities of liquids.
- Isopropyl alcohol (IPA) is volatile and leaves no residue upon evaporation, therefore surfaces are left dry quickly after wiping.

FREQUENCY:

- It is recommended to apply the MRC protocol to the pump after each disinfection sequence as a preventive measure to maintain pump performance and longevity (removal of chemical residue).
- Note: Preventive maintenance also helps to maintain pump performance over time. This should be performed as recommended in the Periodic Maintenance section.

Turn off the syringe pump before cleaning.
When fluid ingress is suspected, stop using the syringe pump and request pump verification through maintenance to identify potential need of corrections.
Immersing the syringe pump into liquid could cause damage to components. Do not soak or immerse any part of the syringe pump or the syringe pump charger in any type of liquid.
If other chemical cleaning agents are used for "disinfection protocol / regime", ensure to follow the manufacturer recommended cleaning to preserve pump performance, after completing the "disinfection protocol /regime".
Do not spray or rinse cleaning solutions directly on pump surfaces or in potential liquid retention areas or open ports such as electrical connections.
Avoid using chemicals that can damage the surfaces of the instrument (for example chlorinated solvents).
When using cleaning solutions containing chemicals (such as corrosive agents), do not use concentrated solutions and do not expose surfaces above the recommended dwell time. After application, rinse surfaces with IPA disposable wipes to eliminate chemical residue.
Do not steam, autoclave, EO (ethylene oxide) sterilize, immerse the syringe pump or pump charger in any type of fluid, or allow fluids to enter the syringe pump case.

LOCKBOX CLEANING

CME Ltd. recommends the use of alcohol sprays and wipes to decontaminate the lockbox. Other products may be used but users should be aware that extended usage could result in the lock box becoming brittle and susceptible to damage. The substances listed below may adversely impact products constructed from polycarbonate:

- Alkali bleaches such as sodium hypochlorite
- Butyl acetate

- Methanol
- Acetone
- Sodium hydroxide
- Methyl ethyl ketone
- Acrylonitrile
- Chloroform
- Styrene
- Ammonia
- Dimethylformamide
- Tetrachloroethylene
- Amyl acetate
- Concentrated hydrochloric acid
- Toluene
- Benzene
- Concentrated hydrofluoric acid
- Concentrated sulphuric acid
- Bromine
- Iodine
- Xylene

RE-USABLE POUCH CLEANING

Clean fabric made products according to need with wet wipes containing water or alcohol. When thorough cleaning is required, use machine laundry at 60°C.

- Do not spin wash.
- Do not bleach.
- Do not heat dry.
- Do not iron.

8.3 Pump Storage

If the syringe pump is to be stored for an extended period it should be cleaned and the battery removed. Store in a clean, dry atmosphere at room temperature and, if available, use the original packaging or a suitable alternative, for protection.

8.4 Disposal/Decommissioning

When the time comes to dispose of the pump, accessories or packaging do so in the best way to minimise any negative impact on the environment. You may be able to use special recycling or disposal schemes. To find out about these contact your technical service department or local waste disposal service. Existing national or local regulations concerning waste disposal must take precedence over the above advice.

Used syringe extension sets should be considered bio-hazardous and treated (handled, disposed or processed) as potentially posing significant risks of infection transmission to humans or harming the environment. Please follow any applicable national and institutional guidelines for bio-hazardous materials treatment.