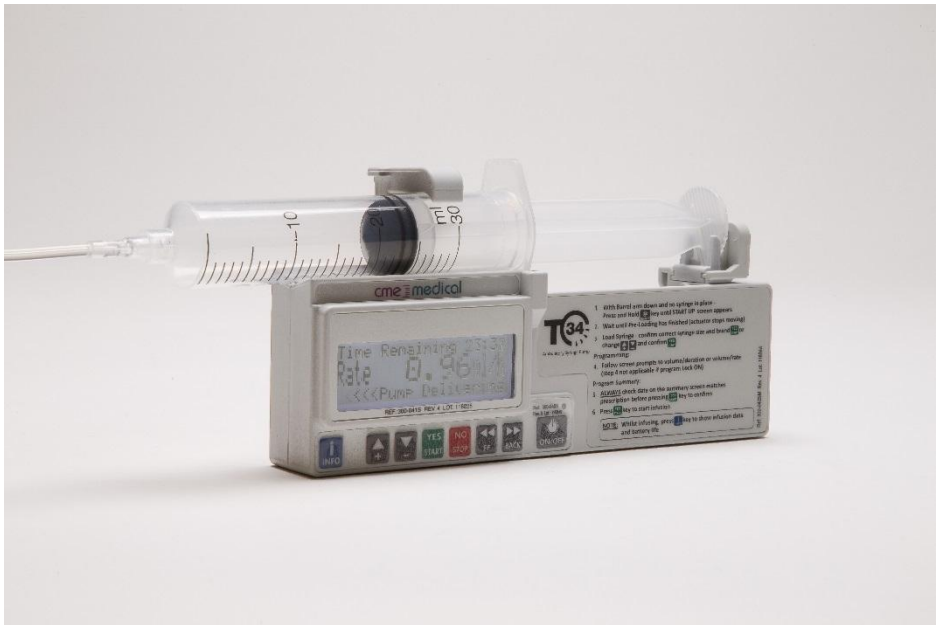

T34™

Syringe Pump System

Operator Manual

Caesarea Medical Electronics

CE 0344

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Contents

SECTION 1: GENERAL INFORMATION

1.1 Preface

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1.2 About this manual

The operator must be thoroughly familiar with the T34™ ambulatory syringe pump described in this manual prior to use, and in particular must read and understand any warnings and precautions stated herein. If a software change occurs and the operation/specification for the pump changes, new or additional operating instructions will be issued, if needed.
All illustrations used in this manual show typical settings and values that may be used in setting up the functions of the 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 manual.
This operation manual document 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, set usage, fluid restrictions, solution viscosity or combinations of these factors, may result in deviations from the performance data enclosed.

1.3 Advisory terms and operating precautions and warnings

Warnings, precautions and notes

Warnings and notes will be seen throughout this manual. These are described as:

NOTE: Indicate that the information that follows is additional important information, a tip that will help you recover from an error or point you to related information within the manual.

PRECAUTION: Indicates that the information is a precaution. Precautions advise you of circumstances that could result in damage to the device. Read and understand this manual and all precautions completely before operating T34™ ambulatory syringe pump.

WARNING: Warnings advise of circumstances that could result in injury or death to the user/operator or circumstances that could result in damage to the device. Read and understand this manual and all warnings before operating the T34™ syringe pump.

Operating precautions and warnings

- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference (2) this device must accept any interference received, including interference that may cause undesired operation.
- 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.
- 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.
- This syringe pump is designed for ambulatory use and should withstand everyday handling. If the pump is dropped onto a hard surface, or is suspected of being dropped, the operation and calibration should be checked by a qualified technician.
- The specified accuracy of the pump can only be maintained if the pump is used, maintained and serviced in accordance with the instructions given in this manual. If the pump has failed to calibrate during the servicing procedure, it must be returned for repair or disposal.
- Adjustments, maintenance, or repair made by un-certified service personnel may impair the operation of the pump and/or the accuracy of the infusion. Make sure any adjustments, maintenance, or repair of the device 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 pump is dropped, 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 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 system should be operated within a temperature range of -15°C (-59°F) to +45°C (+113°F). Operation at temperatures outside this range may affect accuracy.

Infusion precautions and warnings

- Carefully read and follow accompanying set instructions for priming the set and the recommended set change interval.
- The syringe and administration 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 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 any infusion 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 infusion devices, 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.

General precautions and warnings

- The T34™ syringe pump must always be used in a CME Ltd pouch or similar receptacle if used in direct sunlight. If the pump is exposed to direct sunlight, it may affect functionality.

- Do not use hard or sharp objects on the keypad.
- Do not bath or shower whilst using the pump. The 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.
- If the pump is dropped, subjected to excessive moisture, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by qualified personnel.
- Do not operate the pump near high-energy radio-frequency emitting equipment, such as electro-surgical cauterising equipment as this may result in false alarm signals or error messages being displayed.

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, epidural in close proximity to nerves, and into an intra-operative site (soft tissue/body cavity/surgical wound site). The system is intended for patients who require maintenance medications, analgesics, 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 pump or statements in this manual preceded by any of the following words and/or symbols are of special significance and/or are intended to help you to operate the pump in a safe and successful manner.

System symbol identification and description

Symbols	Description
Pump	
	Attention, consult the accompanying instructions.
	Attention, refer to operating instructions.
	CSA mark.
	CE mark indicates conformance to Medical Device Directive 93/42/EEC.
IPX3	Symbol for degree of protection against ingress of water.
	Do not dispose of battery in municipal waste. Symbol indicates separate collection for battery is required.
	Type CF applied part.
	Date of manufacture.
	Manufacturer.
SN	Serial number.
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	Lot number (consumables).
STERILE **EO**	Sterilized with Ethylene Oxide.

1.7 Syringe pump specifications

T34™ syringe pump specifications	
Type:	Syringe Pump with motor driven linear actuator, pulsed motion (540 pulses per mm).
Flow Rate:	0.05- 10mL/h in 0.01mL increments, 10 to 650mL/h in 1 mL increments (1000 mL/hr available).
Actuator Travel:	c.67 mm available.
Syringe Sizes:	2 mL to 50 mL (most commonly used manufacturers).
Accuracy:	± 5 % system accuracy (pump and set combined).
Occlusion Pressure:	100-1500mmHg configurable (10mmHG increments). Max. actuator force 50N (5 Kgf).
Battery:	9V alkaline, IEC 6LR61 type (or Lithium for extended life).
Battery Operation:	7 full deliveries depending on infusion and set up parameters.
Indicators:	4 Line LCD display (122 x 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 — Pump Paused Too Long End Program — Syringe Displaced End Battery — Syringe Empty
T34™ Dimensions:	169 x 53 x 23mm.
Classification:	Type CF Equipment, degree of protection against electrical shock, IPX3 protection against ingress of water.
Housing:	ABS (fire retardant).
Weight:	210 gr. Without battery.
Electrical Safety:	Complies with IEC 60601-1 (Medical Electrical Equipment Safety), IEC 601-2-24 (Infusion pumps and controllers), IEC 60601-1-4 (Programmable Electrical Medical Systems).
Standards:	Manufactured in accordance to ISO 9001:2008 and ISO 13485:2003. CE marked in accordance with the Medical Devices Directive 93/42/EEC.
EMC:	CME Ltd. T34™ syringe pump is designed to be in compliance with EN60601-1 (Safety) and IEC 601-1-2 (EMC).
Environmental Specifications:	**Non-Operating Conditions** (Transportation and Storage): Temperature: -25°C to 55 °C (-13 °F to +131 °F) Humidity: 5 % to 100% R.H., non-condensing Air pressure: 48kPa to 110kPa **Operating Conditions:** The system may not meet all performance specifications if operated outside of the following conditions: Temperature: +15°C to +45 °C (+59 °F to +113 ° Humidity: 20 % to 85% R.H. at +40 °C, non-condensing Air pressure: 70kPa to 110kPa

1.8 Limited Warranty

The T34™ syringe pump has been carefully manufactured from the highest quality components. Caesarea Medical Electronics Ltd. (CME) guarantees the pump against defects in material and workmanship for twelve (12) months from date of purchase.

CME's obligation, or that of its designated representative under this Limited Warranty, shall be limited, at CME's option, or that of its designated representative, to repairing or replacing pumps, which upon examination, are found to be defective in material or workmanship. The repair or replacement of any product under this Limited Warranty shall not extend the abovementioned Warranty period.

All repairs under this Limited Warranty should be undertaken only by qualified, trained service personnel. In the event that a pump is found to be defective during the warranty period, the purchaser shall notify CME or its designated representative within thirty (30) days after such defect is discovered.

The defective pump should be sent immediately to CME or its designated representative for inspection, repair or replacement. Shipping costs are the purchaser's responsibility.

Material returned to CME or its designated representative should be properly packaged using CME shipping cartons and inserts. Inadequate packaging may result in damage to the pump.

This Limited Warranty shall not apply to defects or damage caused, wholly or in part, by negligence, spilt fluids, dropping of the pump, misuse, abuse, improper installation or alteration by anyone other than qualified, trained personnel; or to damage resulting from inadequate packaging in shipping the pump to CME or its designated representative. If, after inspection, CME or its designated representative is unable to identify a problem, CME or its designated representative reserves the right to invoice purchaser for said inspection.

This Limited Warranty is the sole and entire warranty pertaining to CME's products and is in lieu of and excludes all other warranties of any nature whatsoever, whether stated, or implied or arising by operation of law, trade, usage or course of dealing, including but not limited to, warranties of merchantability and warranties of fitness for a particular purpose. Purchaser expressly agrees that the remedies granted to it under this limited warranty are purchaser's sole and exclusive remedies with respect to any claim of purchaser arising under this Limited Warranty.

Managing Director
Caesarea Medical Electronics Ltd.

CE 0344

Caesarea Medical Electronics

1.9 Pump inspection and unpacking

Inspecting the pump before use

Remove the T34™ syringe pump and accessories from the packaging and inspect for damage during shipment or storage.

Make sure you have the following items:

- T34™ syringe pump
- Operations Manual (hard/electronic copy)

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

WARNING: Visually inspect packaging and contents before each use.

WARNING: 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)

- Alkaline 9V batteries
- Lockbox (supplied with two keys)
- Carry Pouch (re-usable or disposable)

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

WARNING: 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.

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 infusion set and syringe. For homecare applications it is recommended that all but the brand of syringe in regular use are disabled per the technician menu to prevent accidental selection of the incorrect brand during set up.

WARNING: DO NOT USE Slip-tip syringes. Luer Lock syringes must always be used to ensure secure connection of the infusion set and the pump is calibrated to Luer Lock. Failure to do so may result in under or over infusion as the dimension of some manufacturers slip-tip syringes differ from their own Luer Lock variants.

It is recommended that all but the brand of syringe in regular use are disabled via the BodyComm™ Communication Software to prevent accidental selection of the incorrect brand during set up.
Should the need arise to program the T34™ syringe pump to operate with a manufacturer and/or brand other than one of those listed above you should consult either your local medical engineering department or CME Ltd. Technical Services.

Default syringe brands configured for use

- Braun Omnifix 2, 5, 10, 20, 30 & 50mL
- BD Plastipak 3, 5,10, 20, 30l & 50mL
- Monoject 6, 12, 20, 35 & 50mL
- Codan/Once 2.5, 5, 10, 20, 30 & 50mL
- Terumo 5, 10, 20, 30 & 50mL

It is possible to disable default syringes from the memory or replace them with one not listed above. This procedure is not detailed in this manual as it should only be undertaken by trained, certified service centres or biomedical engineers. Please consult a biomed engineer or your local T34™ syringe pump distributor should this need arise.

Syringe volumes

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

NOTE: Braun 2mL, Codan 2.5mL and Monoject 6mL syringes exhibit a slight undeliverable volume of 0.1mL due to their design. The T34™ will display the volume as “VOLUME 2.4 (of 2.5mL)”. In this example the pump can only deliver 2.4 of the 2.5mL in the syringe and when the pump has driven as far forward as possible 0.1mL will be left in the syringe.

WARNING: 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 20mL to 50/60mL

Syringe brand	Syringe size		
	20mL	30mL	50/60mL
Monoject	18.7mL	-	33.6mL
Braun Omnifix	20mL	24.4mL	37.7mL
BD Plastipak	18mL	23.5mL	34.9mL
Terumo	18.6mL	24.5mL	38.0mL
Codan	20mL	22.5mL	35.9mL

Time to alarm from occlusion

The occlusion times to alarm for the T34™ syringe pump are in accordance to the table below.
All the tests were performed using a CME extension set, 100-172S and a BD Plastipak syringes filled with water.

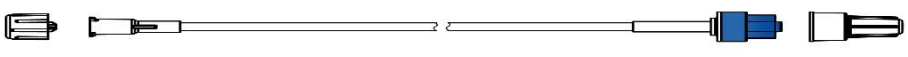
Time to alarm from occlusion					
Manufacturer	**Size**	**Rate**	**300mmHg**	**600mmHg**	**900mmHg**
BD Plastipak	5ml	1ml/h	11'	11'50"	14'30"
		100ml/h	7"	10"	10"
	10ml	1ml/h	17'30"	20'25"	31'30"
		100ml/h	8"	11"	13"
	20ml	1ml/h	29'30"	42'30"	58'45"
		100ml/h	19"	20"	23"
	50/60ml	1ml/h	46'	54'30"	117'
		100ml/h	28"	34"	36"

The tolerance for the BD Plastipak 50/60mll syringe is ±25% or ± 100mmHg
The tolerance of the BD Plastipak 5ml syringe is ±25% ±200mmHg

2.2 Administration sets

Introduction

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



Features and characteristics

Feature	Description
Materials	The administration 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 ambulatory configuration. Various lengths available.
Slide Clamp	Clamps: to prevent fluid flow to patient (optional on some sets).
Check valve (one-way valve) 	All CME Ltd. syringe extension sets contain a combination check valve to prevent uncontrolled flow of fluid either towards or from the patient. The syringe extension set with pressure activated anti-siphon/anti-reflux valve reduces the potential for gravity flow and backflow (backtracking). The pressure-activated anti-siphon valve requires pressure to open. The pump occlusion pressure setting may require adjustment to prevent occlusion alarms. The combination check valve enhances pump functioning by: ° Preventing siphoning (free-flow) in the event the set is detached from the pump or mechanical malfunction ° Preventing reflux (back-flow) in the event several infusion pumps are connected simultaneously to the same patient.
Luer Lock end connector 	The administration set is designed to be connected to Luer Lock syringes. Luer Lock syringe allows a needle to be twisted onto the tip and then locked in place. This provides a secure connection and prevents accidental removal.
Color-coded sets	Color coded sets are available as a visual aid to assist users in identifying a drug delivery route: o Clear sets may be used for any drug delivery route o Blue sets normally indicate intravenous drug delivery route o Yellow sets indicate epidural or intrathecal drug delivery route

WARNING: Ensure the administration set is NOT connected to the patient during priming.

WARNING: A kinked/occluded infusion line may impair the operation and accuracy of the pump. Before operation, verify that the infusion line is not kinked or occluded.

NOTE: Manufacturing data for set durability and accuracy of proprietary sets is up to 72 hours. Follow local guidelines for set use.

Advisory warnings and notes for syringes and administration sets:

WARNING: Never prime or purge a set with the extension set attached to the patient.

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

WARNING: 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.

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

WARNING: Use good aseptic technique when filling the syringe and priming the administration set. Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components and do not re-use singe use sets.

WARNING: Syringes and administration 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

Battery types and use

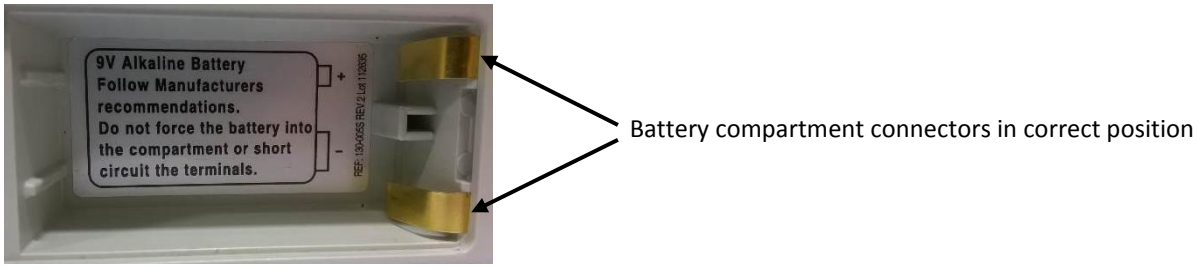
Always use a 9-volt alkaline disposable battery. CME Ltd. recommends to always use a battery carrying the international marking code 6LR61.

WARNING: 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.
Batteries marked 6LP3 are not recommended for use with the T34™ syringe pump.
6LP3 batteries can cause issues with the operation of the syringe driver, as the physical construction, and internal resistance of this type of battery, are different to the 6LR61 battery. Issues arising from use of the 6LP3 battery can include End Battery messages during Pre-Load, volume test fails, pressure test/calibration issues and reduced amount of infusions from a battery.

WARNING: There is some variation in size between different brands of batteries. Never try to force a battery into the battery compartment as this may damage the battery contacts. Incorrectly aligning the battery contacts will not cause any harm to the battery or the pump. Remove the battery and re-align the contacts.

Battery dimensions and battery fitting

Disposable battery dimensions can vary between different brands of batteries (either larger or smaller than the standard size).
Some brands of battery will not fit into the battery compartment area as the dimensions are too large and other battery brands may be smaller and appear loose in the battery area, which can result in movement within the battery housing with possible loss of connection/power.
If a battery is too large to fit, use a different battery brand.
If a battery within the T34™ housing appears loose careful adjustment of the battery connections may be needed to move them back to the correct position.
Return the pump to your service department for adjustment of the connections.



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
- Frequency of LED green light flashing
- Battery chemical and constructive compositions

The 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 YES to confirm or the battery power if fully depleted.

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

Indications to change a battery

Average battery life is approximately three to five days. Based on five days of normal pump use, for a battery with 100% power, battery power consumption would average 20% per day.
Guidance for battery changing may vary for different areas according to local policy and where the pump is to be used and who is managing the pump (healthcare professional or patient as end user).

If the 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.
If the 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 a 24-hour infusion, ensure that there is a minimum percentage available at the start of the infusion.

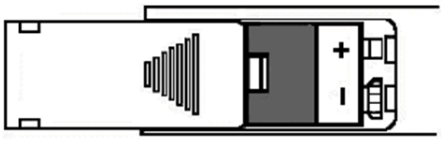
Battery fitting and removal

Inserting and removing a battery
The battery should fit securely to prevent loss of battery to pump electrode contact.

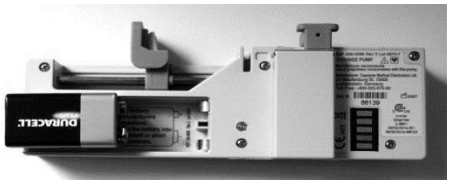
WARNING: DO NOT use scissors or metal objects to remove a battery.

To insert the battery into the pump:

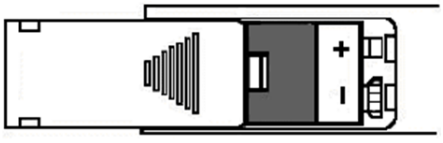
1. Slide the compartment cover off at the back of the pump.



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



3. Slide the cover back on.



To remove the battery from the pump:

a. Slide the compartment cover off at the back of the pump.
b. Remove the battery
c. Slide the cover back on.

2.4 Lockbox

Uses and features

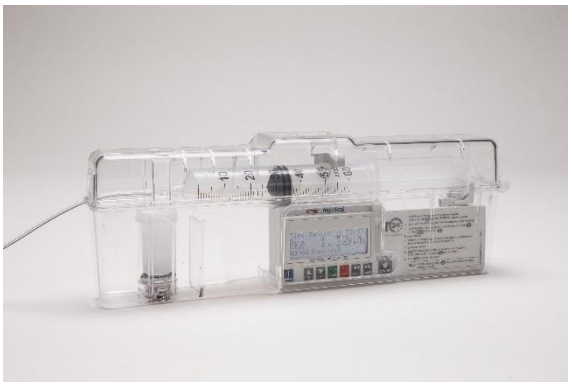
Lockboxes are designed to help protect the syringe from displacement and/or tampering.

Lock boxes are made from Polycarbonate due to its high impact, temperature resistance and optical properties, durability tests confirm that the overall design and construction of the T34™ syringe pump lock box ensures that they are fit for their intended purpose of protecting the T34™ syringe pump from damage caused through normal daily use and drops within the accepted normal range of one meter.

Types and sizes

Lockbox for commonly used syringes up to 30mL

Lockbox for commonly used syringes up to 50/60mL



- Lockboxes are available in clear polycarbonate and with a yellow transparent tinge.
- A clear lockbox can be used with any drug delivery route
- A yellow tinged lockbox denotes epidural or intrathecal drug delivery route

NOTE: lockboxes are designed for the use with CME Ltd. administration sets. If using an alternate brand of administration set with a commonly used 30mL syringe the set design may prevent the lockbox from fully closing and locking.

Refer to your local sales representative or CME Ltd. website for information on lockbox types, codes and costs.

Using the lockbox

When ready, place the pump into the lockbox +/- carry pouch:

1) Open the lockbox using the standard key that operates all T34™ lockboxes.
2) Place the pump into the lockbox so that the LCD display and keypad line up with the cut out opening.
3) Close the lockbox, guiding the administration set out of the slot at the side of the top section of the box.
4) Place the lockbox (or syringe pump if the security of the lockbox is not required for your practice) into the carry pouch and secure to the patient.

2.5 Carry Pouches

Pouch use and types

Disposable (single patient use) and re-useable (washable) pouches are available.

Refer to your local sales representative or CME Ltd. website for information on types, codes and costs.
Refer to Section 7 for re-usable pouch cleaning instructions.

Use of pouches for protection of pumps during transportation

WARNING: The T34™ syringe pump must always be used in a CME Ltd pouch or similar receptacle if used in direct sunlight. If the pump is exposed to direct sunlight, it may affect functionality.

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

When using the CME Ltd re-useable (washable) pouch, it is possible to access the screen and keypad of the device during infusion by lifting the velcro flap of the pouch whilst the pump remains in the pouch.
When using either a CME Ltd re-useable (washable) or disposable (single patient use) pouch it is possible to remove the forward part of the device during infusion from the pouch to inspect the syringe without removing the rear section of the device. CME Ltd pouches can be carried on the shoulder or around the waist for convenience.

SECTION 3: PUMP FEATURES AND DESCRIPTION

3.1 Overview

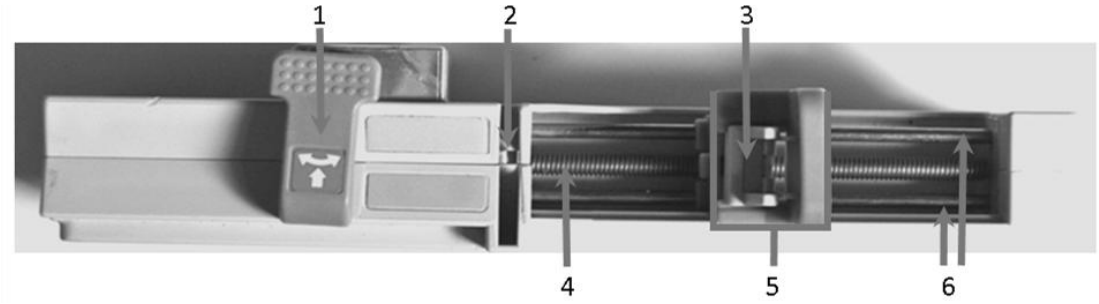
The T34™ syringe pump is a small, lightweight, robust, battery powered infusion pump. It is equally suitable for adults or paediatric use. The T34™ syringe pump may be used for a variety of clinical applications to deliver indicated medications via common infusion routes, including intravenous and subcutaneous.

Safety features

- Accommodates a range of commonly used syringe brand and sizes
- Three-point syringe detection system
- Access code protected areas for pump configuration
- Lockable infusion program
- Capable of small mL/hour rate delivery
- Post Occlusion Bolus Reduction System
- Configurable occlusion pressure setting
- LCD display screen with backlight
- Green LED indicator light to indicate if infusion is in progress
- Comprehensive range of alerts and alarms
- Keypad lock
- Event Log
- Lockable lockbox

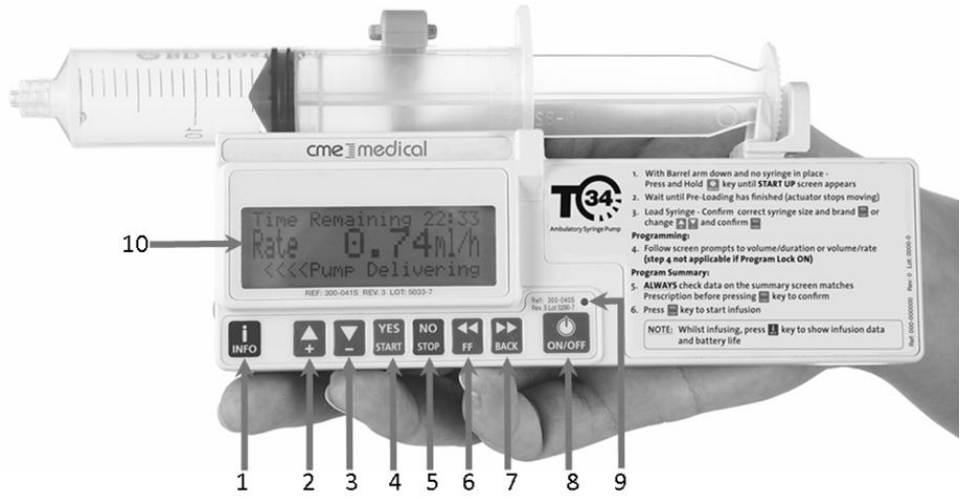
3.2 Pump description

Top of pump: syringe fitting



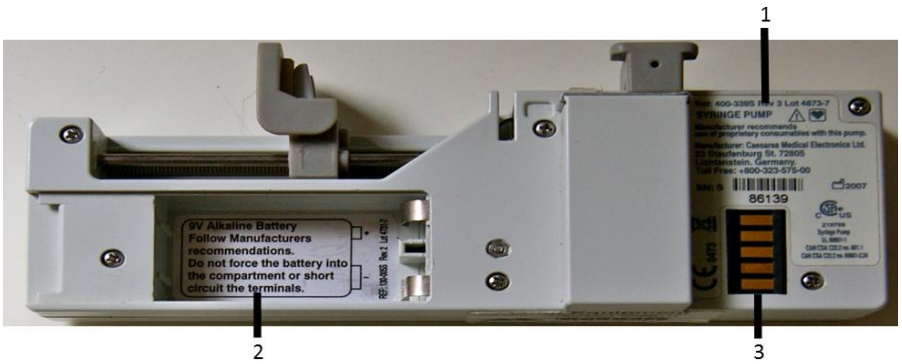
No.	Area	Function
1.	Barrel clamp arm sensor	Detects syringe barrel loading and secures syringe in place
2.	Collar sensor	Detects correct loading of the syringe collar
3.	Plunger sensor	Detects correct loading of the syringe plunger
4.	Lead screw	Moves actuator
5.	Actuator	Drives the syringe plunger 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 key	a) repeated presses during infusion will display infusion summary and battery level b) when pump paused, accesses the main (Info) menu c) activates/deactivates keypad lock
2.	UP arrow key	a) scrolls between options b) increases infusion parameters during programming/titration
3.	DOWN arrow key	a) scrolls between options b) decreases infusion parameters during programming/titration
4.	YES/START key	a) Confirms selection b) Starts infusion
5.	NO/STOP key	a) stops infusion b) takes user back a step during programming
6.	FF (Forward key	a) moves actuator forward when no syringe in place and the barrel clamp arm is down b) accesses purge function (if enabled)
7.	BACK (Reverse) key	Moves actuator backward when no syringe is in place and barrel clamp arm is down
8.	ON/OFF key	Powers the pump on and off
9.	LED light	A green indicator lights: (a) during system self-test (b) intermittently to indicate infusion delivery A red indicator lights: (a) continuously to indicate an alarm state (b) when pump paused/on stand-by mode
10.	LCD display screen	Displays pump and infusion status, programming choices and instructions

Back of pump: battery area and pump markings



No.	Area	Function
1.	Pump information and symbols	Labelling (including universal symbols) identify a device, its manufacturer, and communicates information on safety, use and performance.
2.	Battery fitting area	Includes instructions for inserting the battery into the correct position.
3.	Docking station communication connector	When the pump is placed into a docking station, provides connection to PC/ BodyComm™ Communication Software

3.5 Event Log

What is the 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 pump stores the last 512 in memory. For event s over 512, the pump deletes the oldest event in the log each time a new event occurs.
For example, after some time, the first event to appear when you enter the events history may be number 754. This means there have been 754 events in this pumps life and events 242-754 are stored in this history.
The pump deletes the oldest event in the log each time a new event occurs.
Events recorded include hourly self-testing when an infusion is running and certain key presses.
When the pump is infusing, the pump will record pump status every hour irrespective of any key presses.
The event log can be viewed via the pump or BodyComm™ Communication Software and a print out of events can be obtained using BodyComm™ Communication Software.

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.

Press the INFO key:

Info Menu Battery Level Select ↓/↑, Press YES	2. Use ↓/↑ keys to scroll to "Event Log"	Info Menu Event Log Select ↓/↑, Press YES	3. Press **YES**

The most recent event displays:

Event No: 1854 27.07.2011 16:01 Start Infusion Press INFO - Details	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 **INFO** to display detailed data for the event.*

When INFO is pressed:

VI 1.03ml VTBI 14.35ml Rate 0.64ml/h 30ml BD Plastipak	VI = Volume infused VTBI = Volume to be infused Rate = mL/hour rate 30mL BD Plastipak = Syringe brand and size confirmed
Travel 2.73mm/ml 1N (0mmHg) = 18mA 28N (540mmHg)=83mA Motor Current 0 mA Occlusion 720mmHg Battery 7.8V	Travel = Actuator travel distance (mm) to deliver 1mL (for syringe size/brand confirmed) 1N = Minimum actuator travel force (related to start up motor movement) 28 = 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 **NO**.*

The event information that displays when INFO is pressed will vary depending on the operational status of the pump for that event. Some events may only record one or two parameters, other events record numerous parameters.

NOTE: The pump does not automatically change for daylight saving, the date and time can be updated manually via the pump Change Set Up Menu or via the BodyComm™ Communication Software.

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.

3.6 Post Occlusion Bolus Reduction System (POBRS)

What is the Post Occlusion Bolus Reduction system?

During an occlusion, the pressure in the downstream section of the line and/or inside the syringe can increase above the occlusion pressure defined in pump settings. When the pump alarms the user must check the line and attempt to clear the occlusion. During an occlusion the pump's *Post Occlusion Bolus Reduction System* feature will reverse the operation of the motor and drive the actuator backwards otherwise the pressure build up could cause a surge of fluid into the patient' on release of the occlusion.

When the infusion is resumed, the user will notice that the volume to be infused (VTBI) increases and the volume infused (VI) decreases to indicate the pump back off feature and the infusion time remaining increases; this protects the mL/hour infusion rate.
Following activation of the POBRS and if the user presses "YES to Resume" the infusion VTBI increases and the VI decreases to indicate the pump back off feature.

Occlusion pressure

The occlusion pressure of a pump is the pressure in the system, registered at the pump, when the pump is still

operating but cannot sustain the flow rate. The resultant build-up of pressure sets off the occlusion alarm. (*Device Bulletin, 2010*).

Occlusion and response

An occlusion alarm can be activated by:

- A blockage in the delivery tubing - 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 extension line.

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 pump attempts to maintain sufficient pressure on the fluid to cause it to flow through all restrictions and overcome any additional resistance. Although fluid is incompressible, the administration set and other components of the system have some 'give' (compliance) and the tubing can expand under the increasing pressure. Other components of the system, such as the bung of the syringe, 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 pumping chamber increases from zero at the start of the infusion up to the alarm level. This is the most likely situation, as leaving clamps closed is the most usual cause of occlusions.

If the occlusion occurs after the pump has stabilised at its set flow rate, the alarm time will not be unusually long as the pressure in the pumping chamber increases from the already high running pressure up to the alarm level. For example, a time to alarm with an infusion rate of 1mL/h is 16 minutes 7 seconds *(PASA, 2006) Generally, shorter time to occlusion alarm occur with high flow rates, small syringes and good quality syringes.*

3. 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 fluid in the tubing can result in a bolus being delivered to the patient.

SECTION 4: MODES OF OPERATION

4.1 Modes of operation

Introduction

This section provides describes the common infusion mode of operation in which the T34 can be configured to operate. The pump can be configured for a continuous infusion with either duration or mL/hour as the primary setting.

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 pump will calculate the mL/hour rate.

Rate infusion (mL/hour)

The primary setting is mL/hour rate (rate over time infusion) which can be configured with a locked or changeable mL/hour infusion rate. Once the mL/hour rate is confirmed, the 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/hour rate
- Rate mode (Lock OFF) - adjustable mL/hour rate

Each of these modes can have additional functions enabled or disabled, to suit local requirements.
The pump default mode of operation is Lock On 24-hour duration.

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

Lock on mode (fixed duration)

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

$$\frac{\text{Syringe volume}}{\text{Fixed duration}} = \text{mL/hour infusion rate}$$

- 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 pump will deliver the syringe volume over the confirmed default duration or the duration inputted and confirmed by the user during programming, the pump then calculates the mL/hr infusion rate:

$$\frac{\text{Syringe volume}}{\text{Default or duration entered}} = \text{mL/hour infusion rate}$$

- With Program Lock Off, rate change (titration) during infusion can be enabled if required. There is no availability 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

Lock On
(Fixed Duration)

20ml BD Plastipak Select ↑/↓, Press YES
Volume 12.0ml Duration 24:00 Rate 0.50ml/h Confirm, Press YES
Start Infusion?

Lock off Mode
(Adjustable) Duration)

20ml BD Plastipak Select ↑/↓, Press YES
Occlusion xxx mmHg Max Rate 5ml/h Program Lock OFF Battery Status xx%
20ml BD Plastipak Volume 12 ml Change↑/↓, Press YES
20ml BD Plastipak Duration 24:00 Change↑/↓, Press YES
20ml BD Plastipak Rate 0.5 ml/h Confirm, Press YES
Volume 12.0ml Duration 24:00 Rate 0.50ml/h Confirm, Press YES
Start Infusion?

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 administration set. Your local policy will state which method to use.

Rate mode (lock on) - fixed mL/hour rate

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

$$\frac{\text{Syringe volume}}{\text{Fixed mL/hour rate}} = \text{Duration}$$

- 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

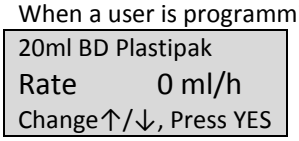
The pump will deliver the syringe volume over the mL/hour rate inputted and confirmed by the user during programming the pump calculates the infusion delivery duration:

$$\frac{\text{Syringe volume}}{\text{Confirmed mL/hour rate}} = \text{Duration}$$

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

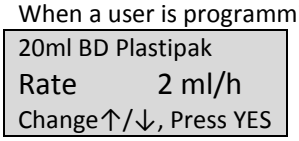
Rate mode programming screens

a) If the pump is configured with Rate Setting disabled, the default is 0mL/hour.
When a user is programming an infusion, the screen will display:



This example shows the default rate is 0mL/hour, the user enters the rate required.

b) If the pump is configured with Rate Setting enabled, the programmed rate becomes the default.
When a user is programming an infusion, the screen will display:



This example shows the default rate is 2mL/hour, 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 via BodyComm™ communications software and pump

A limited number of settings can be configured via the pump in Change Set Up, Rate Setting and Technician menus and for safety reasons, these areas are access code protected.
Full pump configuration can only be carried out via the BodyComm™ communication docking station and PC software.
Pumps must be configured correctly for their required application, this includes selecting the appropriate mode of operation, the required additional functions (e.g. purge, rate titration and KVO) for the intended application. However, the pump is configured, the user must ensure that the pump is configured correctly for the therapy category it is to be used for.

BodyComm™ Communication Software

BodyComm™ Communication Software is a PC based software package which enables the technical engineer to program pumps via a PC and pump docking station. The software allows pump set up and syringe data to be loaded to files (macros) and replay these files on to subsequent pumps. BodyComm™ also enables the user to download, save and print the events log. Use of this program can aid the investigation of clinical incidents and help ensure that all pumps are configured the same way, without error.

NOTE: For a list of settings, defaults and ranges when configuring a pump via the BodyComm™ Communications Software, please refer to BodyComm™ Communications Software user instructions.

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

- The pump is configured and appropriate for the therapy group as defined by the Medicines and Healthcare Regulation Authority (MHRA).
- 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/hour infusion.
- Optional features and functions that may be required are configured (e.g. Purge, KVO, titration, pump maximum mL/hour 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 pump for a specific clinical application.
No access code is required to turn the pump on and run an infusion, in normal clinical use the 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 pump INFO menu. The Technician menu code is only provided to fully trained, (by CME Ltd.) and authorised electrical biomedical engineering personnel.

WARNING: 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 only give code access to the 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 manual.

5.3 Pump INFO and configuration menus

INFO menu

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

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

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

INFO menu description

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

Change set up menu

Configurable parameters in the Change Set Up menu

Parameter	Default	Range	Description
Exit			Exit the Change Set Up menu.
Set Time and Date	Current date/time	Month/year Minute/hour	Sets a date and time stamp for the event log. *This does not automatically change for daylight saving.*
FF Key Operation	5mm	0.1-100mm	Limits the forward movement of the actuator when the FF key is pressed with no syringe in place and barrel clamp arm down.
Backlight Duration	5 seconds	On - Off (0-254 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 INFO key is pressed during an infusion.
Operation LED	32 seconds	Disable/2/4/ 8/16/32/64 seconds	Limits the frequency of green LED intermittent flashing during an infusion. NOTE: Red LED warning light is unaffected.
Titration Option	Disabled	Enabled/ Disabled	Enables rate change during infusion. Maximum rate is the pump max. mL/h rate. Minimum is 0.05mL/hour. Can only be enabled if Program lock is Off.
Default Duration	24:00 hours	00:00 (OFF) 99:00 hours	With a default duration set, the pump runs as a volume over time infusion. With default duration set to 0:00 hour, the pump runs as an mLs/hour infusion.
Occlusion Pressure	540mmHg	100-1500 mmHg	Sets the pressure level at which the occlusion alarm will activate.
KVO Rate Operation	0mL/hour	0 (OFF)-2.0mL/h	Activates Keep Vein Open infusion at end program.
Program Lock	ON	OFF/ON	With lock on, prevents alteration of default duration or mL/hour rate.

Rate setting menu

Configurable parameters in the Rate Setting area.

Parameter	Default	Range	Description
Rate Setting	0mL	0 mL/hr – Pump max mL/hr rate	Locks the mL/hr rate each time a new program is commenced in Rate Setting Mode. (If required, pump maximum rate is changed via Technician menu).

5.4 Pump Configurable settings for modes of operation

Configuration settings for lock on and lock off (duration) modes		
Mode → Parameter↓	**Lock On** (Fixed duration)	**Lock Off** (Adjustable duration)
Titration Option	Disabled	Enable if rate change during infusion required
Default Duration	e.g. 24:00 hours	e.g. 24:00 hours
Program Lock	On	Off
Rate Setting	0mL	0mL
Occlusion Pressure	Set the pressure for the drug delivery route e.g. subcutaneous, IV	
KVO	Set KVO mL/hour if required.	
Max. Rate	Change if required. Pump default 5 mL/hour.	
Purge	Set purge volume if required. Pump default 0mL.	

Configuration settings for rate (mL/hour) modes		
Mode → Parameter↓	**Rate Mode (Lock ON)** (Fixed mL/hour rate)	**Rate Mode (Lock OFF)** (Adjustable mL/hour rate)
Titration Option	Disabled	Enable if rate change during infusion required
Default Duration	00:00 hours	00:00 hours
Program Lock	On	Off
Rate Setting	1mL	E.g. 2mL/hour
Occlusion Pressure	Set the pressure for the drug delivery route e.g. subcutaneous, IV	
KVO	Set KVO mL/hour if required. Pump default 0mL.	
Max. Rate	Change if required. Pump default 5 mL/hour.	
Purge	Set purge volume if required. Pump default 0mL.	

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/hour rate and purge volume are configured via the pump Technician Menu or BodyComm™ Communications Software. If these settings need to be changed, you must consult technical staff.

NOTE: The pump uses an indirect method of pressure detection. The standard T34™ syringe pump occlusion pressure setting for subcutaneous route is 720mmHg and for Intravenous (IV) route is 540mmHg.

5.5 Optional configurable settings

KVO (keep vein open) operation

The T34 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 pump applies the KVO rate set until the syringe is empty. KVO can be configured in the pump Change Set Up Menu or via the BodyComm™ Communication Software.

KVO 0.2ml

After three/four beeps the End Program alarm stops and the pump switches to the configured KVO infusion rate. Every three/four minutes three/ four beeps will be heard to confirm the pump is still infusing.

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.

- This facility is available (if enabled) once only, prior to commencing an infusion.
- The purge facility is disabled by default (0.0mL) and the maximum deliverable is 2.0 mL.
- The purge function can be configured via the pump Technician menu or the BodyComm™ Communication Software.
- The purge function can be used with any mode of operation.

Purge sequence (all modes of operation)

1. Press the FF key when the infusion/program summary displays (Lock On Mode) or when the volume change screen displays (Lock Off and Rate Modes).

Purge? Disconnect patient Press YES to Confirm	2. Ensure the administration set is disconnected to the patient, confirm by pressing **YES**
Purge, Hold FF Key Purge 0.00ml	3. Press and hold the **FF** key until the slack is removed or purge volume is delivered (a purge volume will be configured, e.g. O.2mL)
Purge Completed	4. Wait for the next screen to display
20ml BD Plastipak Select ↑/↓, Press YES	5. If the syringe size/brand displayed matches the one used, confirm by pressing **YES** (Use +/- keys to select the matching syringe if necessary)
Press YES to Resume, NO for New Syringe	6. Two options are given, to either resume the current program or to start a new program, and the subsequent display screens will depend on the option selected

If the user presses YES:

- The duration of delivery decreases to account for the purge volume
- The purge volume will display on the volume infused (VI) infusion summary

NOTE: When purge is used with each syringe change and "YES to Resume" is selected each time causes the infusion duration at the end of the purge sequence each the time the healthcare professional needs to attend to change a syringe will be earlier each time.

If the user presses NO:

- The pump calculates a new program or the user must enter parameters for a new program

- As the purge volume has been accounted for before programming, the purge volume will not display on the volume infused (VI) infusion summary

NOTE: If purge is not enabled until the program summary screen, the user re-confirms syringe size/brand, then the "Press YES to Resume, No for New Syringe" screen displays.

- If YES is pressed the purge volume is accounted for and visible on the VTBI/VI screen, in addition, the infusion time remaining is reduced to reflect the volume used to purge.
- If NO is pressed the purge volume is not visible on the VTBI/VI screen and the infusion time remaining is the default duration.
- By pressing "YES to Resume" over several syringes/days, the time the healthcare professional needs to attend to change a syringe will be earlier each time.

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/hour rate limit will be the pump maximum rate which is configured via the pump Technician menu or via BodyComm™ Communication Software. The minimum rate is a standard 0.05mL/hour. 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/hour)
- Rate Setting Mode (mL/hour, Lock Off)

Rate change <u>cannot</u> be enabled in Lock On mode of operation.

To titrate the mL/hour rate during infusion

1. Deactivate keypad lock

Time Remaining 12:00 Rate 1.0 ml/h <<<< Pump Delivering
20ml BD Plastipak Rate 2 ml/h Change ↑/↓, Press YES
Time Remaining 06:00 Rate 2.0 ml/h <<<< Pump Delivering

2. With infusion is running, press ↑ *or* ↓ key to change the rate.
3. Enter infusion rate required using ↑ *or* ↓ key, confirm by pressing **YES**.
4. Check that the rate change completed and is correct (Note change to time remaining)
5. Activate keypad lock

5.6 Practise 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. Do not change any parameters unless you clearly understand the significance of the parameter and the effect the change will have on the operation and functionality of the pump.
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 **ON/OFF** key. Wait until Pre-Loading completes and screen prompt displays:

Load Syringe 	2. Press the I**NFO** key	Info Menu Battery Level Select ↑↓, Press YES	3. Scroll ↓ to "Change Set Up"
Info Menu Change Set Up Select ↑↓, Press YES	4. Press **YES**	Enter Set Up Code 0 Change ↑↓, Press YES	5. Enter access code, press **YES**

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

Change Set Up Exit Select ↑↓, Press YES	6. Scroll ↓ to "Set Time and Date"	Change Set Up Set Time & Date Select ↑↓, Press YES	Press **YES**
04.02.2009 16:15:00 Date 04 Change ↑↓, Press YES	7. Change date	04.02.2009 16:15:00 Date 10 Change ↑↓, Press YES	Press **YES**
10.02.2009 16:15:00 Month 02 Change ↑↓, Press YES	8. Change month	10.02.2009 16:15:00 Month 12 Change ↑↓, Press YES	Press **YES**
10.12.2009 16:15:00 Year 2009 Change ↑↓, Press YES	9. Change year	10.12.2009 16:15:00 Year 2011 Change ↑↓, Press YES	Press **YES**
10.12.2011 16:15:10 Hour 16 Change ↑↓, Press YES	10. Change hour	10.12.2011 16:15:00 Hour 12 Change ↑↓, Press YES	Press **YES**
10.12.2011 12:15:00 Mins 15 Change ↑↓, Press YES	11. Change minutes	10.12.2011 12:15:00 Mins 30 Change ↑↓, Press YES	Press **YES**
Change Set Up Exit Select ↑↓, Press YES	12. Press **YES**	Load Syringe 	The "Load Syringe" screen prompt now displays

13. Check changes by powering off and on, (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 **ON/OFF** key. Wait until Pre-Loading completes and screen prompt displays:

Load Syringe 	2. Press the I**NFO** key	Info Menu Battery Level Select ↑↓, Press YES	3. Scroll ↓ to "Change Set Up"
Info Menu Change Set Up Select ↑↓, Press YES	4. Press **YES**	Enter Set Up Code 0 Change ↑↓, Press YES	5. Enter access code, press **YES**

When the ↑ arrow is pressed and held down the pump will count up in single digits to ten, then in tens to one hundred and then in hundreds 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 YES to confirm.

Change Set Up Exit Select ↑↓, Press YES	6. Scroll ↓ to "Program Lock"	Change Set Up Program Lock Select ↑↓, Press YES	Press **YES**

Program Lock ON Change ↑↓, Press YES	7. Change to “OFF”	Program Lock OFF Change↑↓, Press YES	Press **YES**
Change Set Up Program Lock Select ↑↓, Press YES	8. Scroll ↓ until “Exit” displays	Change Set Up Exit Select ↑↓, Press YES	Press **YES**
Load Syringe 	9. The “Load Syringe” screen prompt now displays		

10. Check changes by powering off and on, (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 2mL/hr rate. *Change Default Duration to 0 hours in Change Set-Up Menu and enter 2 mL/hour in Rate Setting Menu.*

1. To power on, press **ON/OFF** key. Wait until Pre-Loading completes and screen prompt displays:

Load Syringe 	2. Press the I**NFO** key	Info Menu Battery Level Select ↑↓, Press YES	3. Scroll ↓ to “Change Set Up”
Info Menu Change Set Up Select ↑↓, Press YES	4. Press **YES**	Enter Set Up Code 0 Change ↑↓, Press YES	5. Enter access code, press **YES**

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

Change Set Up Exit Select ↑↓, Press YES	6. Scroll ↓ to “Default Duration”	Change Set Up Default Duration Select ↑↓, Press YES	Press **YES**
Default Duration 24:00 Change ↑↓, Press YES	7. Change to 00:00	Default Duration 00:00 Change↑↓, Press YES	Press **YES**
Change Set Up Default Duration Select ↑↓, Press YES	8. Scroll ↓ until “Exit” displays	Change Set Up Exit Select ↑↓, Press YES	Press **YES**
Load Syringe 	9. Press the I**NFO** key	Info Menu Battery Level Select ↑↓, Press YES	10. Scroll ↓ to “Rate Setting”
Info Menu Rate Setting Select ↑↓, Press YES	11. Press **YES**	Enter Rate Code 0 Change ↑↓, Press YES	12. Enter access code, press **YES**
Rate setting 0ml/h Change ↑↓, Press YES	13. Change to 2mL/hour	Rate setting 2ml/h Change ↑↓, Press YES	Press **YES**
Load Syringe 	14. The “Load Syringe” screen prompt displays		

15. 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 describes user actions detailed information for starting a new infusion.

The sequence to starting an infusion in this section is using the Prime and Load method of administration set priming, which is suitable the low-priming volume of all CME syringe administration sets.

NOTE: An alternate sequence that may be used (Load and Prime) is priming the set after programming the pump, this method is for sets which require a large priming volume. The decision for which method to use should be judged on administration set availability, local circumstances and policy. Consideration must be given to clinical risk, ease of use for the device user and consistency in start-up procedure for all wards/departments and clinical areas.

Summary of the user stages required to start a new infusion

Stages	Lock on mode	Lock off mode	Rate mode
A. Preparing syringe and prime the set	✓	✓	✓
B. Checking the pump	✓	✓	✓
C. Inserting the battery	✓	✓	✓
D. Powering on and observing Pre-Loading	✓	✓	✓
E. Checking the battery level (via the Info menu)	✓	✓	✓
F. Syringe loading, detection and confirmation	✓	✓	✓
G. Entering/confirming the program	The number of pump screens that display will vary, depending on the mode of operation and any additional functions enabled or disabled within individual pump configuration.		
H. Starting the infusion	✓	✓	✓

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.

WARNING: 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.

To manually prime the administration set

Preparing the syringe and administration set:
Select the correct syringe administration set, and remove from packaging
Attach the extension set to prepared Luer lock syringe, maintaining sterility
Remove cap from end of extension set
Gently push syringe plunger forward until air is expressed from the set
Cap the end of the extension set

NOTE: For instructions on priming cannula, refer to cannula manufacturer instructions.

B. Check the pump

Ensure that the device 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 pump and/or accessories should include checking that the:

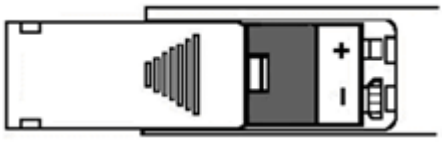
Pump is undamaged
Lockbox is locked and intact (if in use)

C. Insert the battery

NOTE: The battery needs to fit snugly to prevent loss of battery/pump electrode contact. When the pump is new, it may be difficult to remove the battery until the metal electrodes loosen slightly with use and over time.

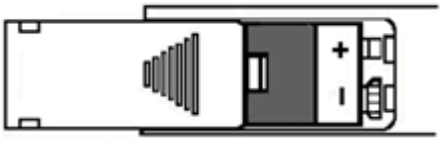
To insert the battery into the pump

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



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

3. Slide the cover back on.



D. Powering on and Pre-Loading

WARNING: do not insert foreign objects around or near the actuator during automatic actuator movement (Pre-Loading) or when manually adjusting the actuator.

Powering on

With no syringe is in place and barrel clamp arm down, press the ON/OFF key until the screen illuminates and the first screen displays:
When the pump is powered on, Pre-Loading commences.

T34
Version NCATxxxx
ID: *(Syringe Pump)*

Pre-Loading

Pre-Loading is a simultaneous sequence of screen information displaying and automatic actuator movement, during Pre-loading:
The 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 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 and should not require adjustment for a new program/syringe.
Pre-Loading only takes place when no syringe is in place and the barrel clamp arm is in the down position.
If the pump is powered on with no syringe in place but with the barrel clamp arm raised, Pre-Loading does not take place.

WARNING: The actuator will only move automatically or manually by using the FF/Back 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 device 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 FF/Back keys.

During Pre-Loading the following screens display in sequence:

T34 Version NCATxxxx ID: *(Syringe Pump)*

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

The default identification name (ID) is "Syringe Pump"; this can be configured via BodyComm™ to e.g. asset number or user site, up to a maximum of 17 digits.

Pre-Loading Use NO to Interrupt

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

If the user pressed NO, the actuator stops moving and the "Load Syringe" screen will display.

Pump default settings

Occlusion xxx	mmHg
Max Rate	5ml/h
Program Lock	ON

Line 1 - Occlusion pressure setting
Line 2 – Pump maximum mL/hour Rate that can be set
Line 3 - Program lock status

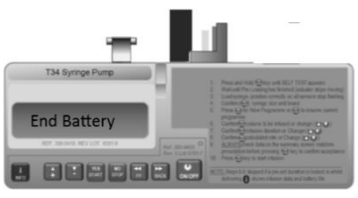
* During actuator movement this value fluctuates, do not rely on this figure as the true battery percentage.

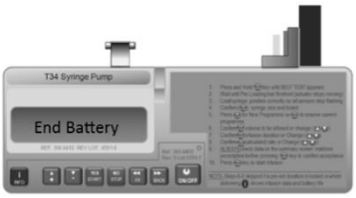
Load Syringe 

On completion of Pre-Loading the screen displays.
This screen displays and flashes until a syringe is detected in all three syringe sensors.

Procedure for releasing a trapped, foreign object from 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.





The screen prompts and advice for each alert and alarm is different, *therefore, ignore screen prompts as the prompt that may display is in relation to alarm activation and NOT the trapped object.*

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)

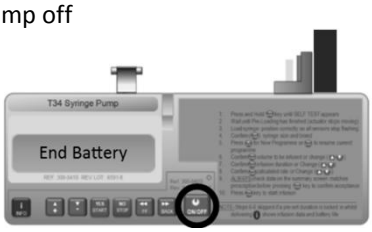
1. Power the pump off
2. With the pump positioned with front of pump facing.
3. To move the actuator towards the barrel clamp arm, place finger on guide screw and roll finger towards the pump screen/keypad (🡻).
4. To move the actuator towards the front of the pump, place finger on guide screw and roll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

Back of pump (battery compartment area)

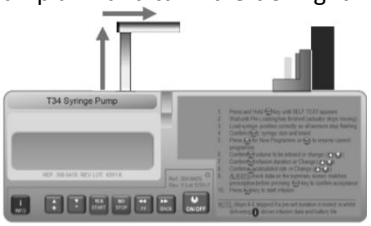
Front of pump (screen and keypad area).

Option 2 (adjustment of actuator using FF/Back keys)

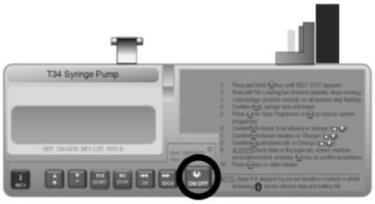
1. Power the pump off



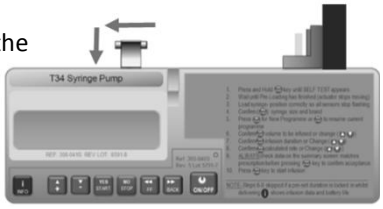
2. Raise the barrel clamp arm and turn it left or right to keep it in the raised position



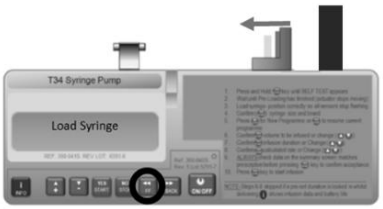
3. Power on



4. Turn and lower the barrel clamp arm



5. Use the FF (or Back key) key to release the object

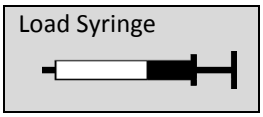


Event log interpretation of alarms

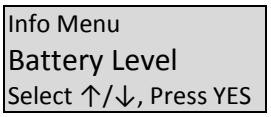
Interpretation of the pump event log can assist in identifying the effects on the pump with an object being trapped in front of, or behind the actuator. Recorded events will reflect the alarm that was activated at the time. If a low or end battery alarm is activated, you may see that the battery voltage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

E. Check the battery level

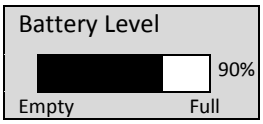
Check the battery level via the Info menu
The LED light will be display red (no infusion running)



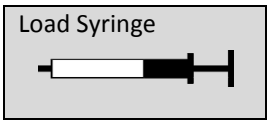
1. Press **INFO** key



2. Press **YES**



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



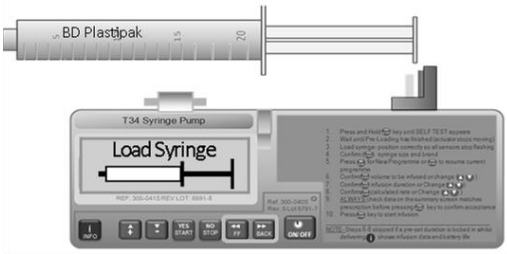
F. Syringe loading, detection and confirmation

Manual adjustment of the actuator

1. Ensure the barrel clamp arm is down.

2. Place the prepared syringe above the pump to visually align the syringe collar to the collar sensor.

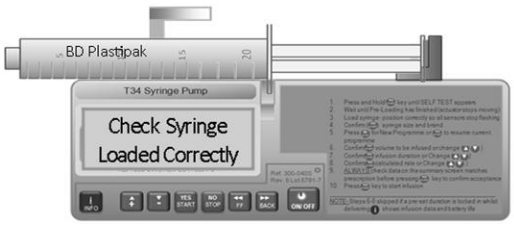
3. Use the **FF/Back** keys (if required), to move the actuator to the correct position for placing the syringe collar and plunger into the matching pump sensor areas.



Syringe loading

1. Lift the barrel clamp arm fully and turn the arm 90° (either way).

2. Place the syringe collar vertically into the pump collar slot and the syringe plunger into the pump plunger slot, (the syringe should click into position).



3. Turn and lower the barrel clamp arm onto the syringe.
As you correctly seat each point of the syringe, the flashing indicator for that sensor becomes solid on the screen display, when all three sensors detect, a syringe size and brand will display.

Syringe detection and confirmation

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

1. Check that the syringe brand and size inserted into the pump matches the syringe brand and size displaying, if they match confirm by pressing **YES**.

<u>Incorrect syringe size/brand detected</u>
Pump identifies a syringe brand which is different from the one being inserted, this can be caused by:

The syringe is not correctly fitted into the 3 sensor areas and the syringe detected has dimensions within (+/-) 1mm of a 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 brands of similar dimensions using the ↑/↓arrow keys.
When the correct syringe displays, press YES/START 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 into any or all the sensors.
The syringe brand/size being fitted may not be configured to the 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 is affected.
Re collar sensor: ensure the collar of the syringe is facing downwards into the slot as the sensor is positioned at the bottom of the slot.

Either use a compatible syringe brand or arrange for the new type of syringe brand to be configured into the pump by authorised personnel.

NOTE: Enabling/disabling of syringe brands is carried out via the BodyComm™ communications docking station and PC software. Any new brands of syringes that may become available in the future can be measured and configured into the pump.

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

WARNING: If the *Volume to be Infused* displayed on the 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 pump and, with the barrel clamp arm down, turn the 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 pump from use and return to an authorized service center for inspection, testing and calibration.

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

G. Entering/confirming the program

When programming the pump for a mode of operation, specific screens and user interactions will depend on the 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/hour rate
Rate mode (Lock OFF) - adjustable mL/hour rate

Lock On mode – fixed duration

Following syringe confirmation, the program summary displays:

Volume 12 ml Duration 24:00 Rate 0.5 ml/h Confirm, Press YES	Review the infusion/program summery to check that the parameters displayed match the prescription: visibly check the volume/duration/rate, to confirm infusion, press **YES**.

(The mL/hour rate has been calculated from the syringe volume and fixed duration)

Lock Off mode – adjustable duration

Following syringe confirmation, the program sequence commences:

Occlusion xxx mmHg Max Rate 5ml/h Program Lock OFF Battery Status xx%	Review pump configuration settings and wait for next screen prompt.
20ml BD Plastipak Volume 12 ml Change↑/↓, Press YES	Visibly check if the volume in the syringe matches the volume displayed. Change if necessary, confirm by pressing **YES.**
20ml BD Plastipak Duration 2400 Rate 0.5 ml/h Change↑/↓, Press YES	Change duration if necessary, by using +/- keys, confirm by pressing **YES**
Duration Changed, Check Rate	If the default duration is changed this screen displays for a few seconds
20ml BD Plastipak Rate 1.0 ml/h Confirm, Press YES	The rate displays (calculated from the syringe volume divided by the duration confirmed), check and confirm by pressing **YES**
Volume 12 ml Duration 12:00 Rate 1.0 ml/h Confirm, Press YES	Review the infusion/program summery to check that the parameters displayed match the prescription: visibly check the volume/duration/rate, to confirm infusion, press **YES**.

(The mL/hour rate has been calculated from the syringe volume and confirmed duration).

Rate mode (Lock ON) - fixed mL/hour rate

Following syringe confirmation, the program sequence commences:

Occlusion xxx mmHg Max Rate 5ml/h Program Lock ON Battery Status xx%	Review pump configuration settings and wait for next screen prompt.
Volume 12 ml Duration 24:00 Rate 0.5 ml/h Confirm, Press YES	Review the infusion/program summery to check that the parameters displayed match the prescription: visibly check the volume/duration/rate, to confirm infusion, press **YES**.

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

Rate mode (Lock OFF) - adjustable mL/hour rate

Following syringe confirmation, the program sequence commences:

Occlusion xxx mmHg Max Rate 5ml/h Program Lock OFF Battery Status xx%	Review pump configuration settings and wait for next screen prompt.
20ml BD Plastipak Volume 12 ml Change↑/↓, Press YES	Visibly check if the volume in the syringe matches the volume displayed. Change if necessary, confirm by pressing **YES.**
20ml BD Plastipak Rate 0.0 ml/h Change↑/↓, Press YES	***If rate setting disabled, the default of 0mL/hour will display*** Enter the infusion rate required, confirm by pressing **YES.**
20ml BD Plastipak Rate 2.0 ml/h Change↑/↓, Press YES	***If rate setting enabled, the configured mL/hour value will display*** Change or confirm the infusion rate, confirm by pressing **YES.**
Volume 12 ml Duration 6:00 Rate 2.0 ml/h Confirm, Press YES	Review the infusion/program summery to check that the parameters displayed match the prescription: visibly check the volume/duration/rate, to confirm infusion, press **YES**.

(The duration has been calculated from the syringe volume and confirmed mL/hour rate).

H. Start infusion (all modes)

Connect to patient

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

Start Infusion?	To commence the infusion, press **YES/START**

Check and confirm infusion is running

Visually check that the infusion running screen is visible and the green LED light flashes intermittently.
When the pump is operating, note that the bottom line alternates between the syringe brand and size confirmed and "Pump Delivering" (with moving chevrons):

Time Remaining 24:00 Rate 0.50 ml/h <<<< Pump Delivering	← The last line alternates →	Time Remaining 24:00 Rate 0.50 ml/h 20ml BD Plastipak

SECTION 7: MONITORING AND MANAGING INFUSIONS

7.1. Pump and infusion safety checks

Ensure that the device 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 pump, accessories and the progress of the infusion.

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

For signs of physical damage to the pump and lockbox
Pump is positioned correctly
Lockbox is locked and lines are positioned safely

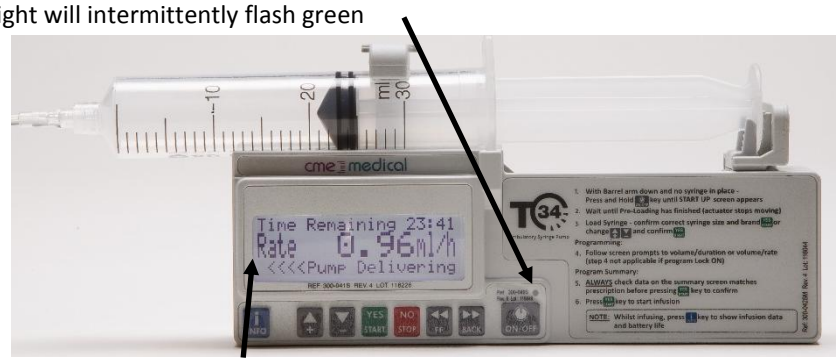
Pump positioning

It is good practise to minimised disturbance to the pumps and to maintain the pump at the same level throughout an infusion as far as possible. Optimal operation occurs with positive pressure infusion devices are positioned at the same level as the infusion site. It is good practise to adopt this advice where possible.

WARNING: 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

a) The pump LED light will intermittently flash green



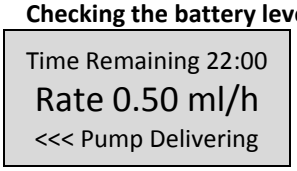
b) The LCD screen will display information:
Line 1 - displays infusion time remaining
Line 2 - displays the mL/hour infusion rate
Line 3 - alternates between the syringe size and brand confirmed by the user during set up and "<<<< Pump Delivering"

Regular monitoring should include checking:

- Battery level
- Syringe volume history
- Keypad lock is on (if in use)

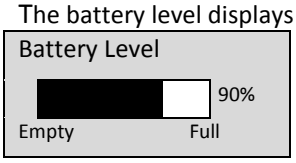
NOTE: Follow local guidance for a full list of infusion monitoring checks.

Checking the battery level during infusion (LED light is green)



Press **INFO** key twice.

The battery level displays as a percentage (%):



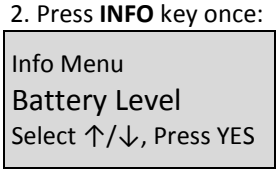
Wait a few seconds for the screen to default back to infusion running screen again or press the INFO key again, to display infusion running screen.

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

Checking the battery level with infusion paused (LED light is red)

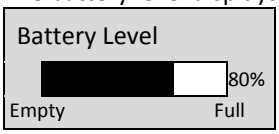
1. Stop infusion

2. Press **INFO** key once:



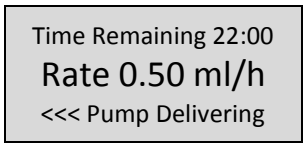
Press **YES**

The battery level displays as a percentage (%)

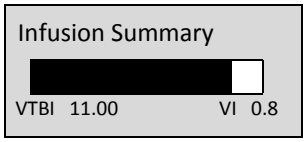


Wait a few seconds for the screen to the default screen or press the NO key to reverse out of the screen.

To check the volume history during infusion



Press **INFO** key twice



The syringe volume to be infused (VTBI) and volume infused (VI) display.
(The total of the two values equal the starting volume).

NOTE: After pressing the INFO key either a third press or waiting a few seconds returns the display to the base display screen. Excessive key presses or usage of the INFO 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 un-trained personnel tampering with the pump.

The STOP and START 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 pump is stopped/paused for longer than 2 minutes, the "Pump Paused Too Long" alarm will active to alert the user to the pump status. In this instance, the Event Log records these events.

When the pump is used with the keypad lock activated:

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

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

Note the following principles with an active keypad lock:

- If the power supply is interrupted during an infusion and the user powers the pump on again (with syringe in place): if the "Press YES to Resume, NO for New Syringe" screen displays, the infusion can be resumed but "NO" option is inactive. This is to prevent accidentally programming for a new infusion.
- The use of the FF/Back keys for manual actuator adjustment is not accessible (when no syringe in place and barrel clamp arm is down).

- The syringe brand and size that displays cannot be changed using the ↑ and ↓ arrow keys as this would as this would delete the current program.
- The purpose of Pre-Loading, (automatic actuator movement) is to delete the current program in the 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 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 YES to Resume, NO for New Syringe" screen displays, the infusion can be resumed but "NO" option is inactive.

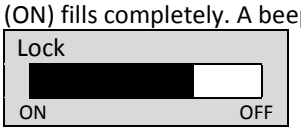
NOTE: It is recommended that the keypad lock is used if rate change (titration) is enabled. This gives additional protection against unintentional rate change during infusion.

NOTE: If power supply is interrupted during an infusion and the keypad lock is active, on resumption of power an infusion can be resumed.

Applying and removing the keypad lock

To activate the keypad lock

With the pump infusing, press and hold the INFO key down until the black graphic moving from left (OFF) to right (ON) fills completely. A beep is heard, confirming that the lock has been activated.



To deactivate the keypad lock
Press and hold the INFO key down until the black graphic, moving right (ON) to left (OFF) fills completely. A beep is heard, confirming that the lock has been deactivated.

7.3 Program protection and “Resume”

Program protection

There is only the current “program” available in the pump memory at any one time and it is possible to resume a program in certain circumstances. Pre-Loading (automatic actuator movement) will clear a program from the pump memory. Power interruption or failure does not clear a program.
Programming protection and ability to “Resume” applies specifically to the mL/hour rate.

NOTE: For detailed information on Pre Loading, refer to Section 6, D2 "Pre-Loading".

Key press options of “Resume” and “New Syringe”

A program (infusion) may be interrupted, for example, by alarm activation (e.g. syringe displacement or occlusion) or the pump is powered off for any reason and powered on with a syringe in place. Following an interruption to the program and during the start-up sequence, the user will be prompted to re-confirm the correct syringe brand and size:

20ml BD Plastipak Select ↑/↓, Press YES

Check that the syringe brand and size displayed matches the one placed into the pump. If they match, confirm by pressing **YES**.

Re syringe fitting and confirmation:

- When it is user`s intention to resume an infusion, if a different syringe brand/size from the original program is confirmed, the current program will be deleted, therefore the “Yes to Resume, No for New Syringe” screen will not display.
- If an incorrect syringe brand displays and the correct syringe does not appear in the menu, lift the barrel clamp are and re-seat the syringe so that the correct syringe displays.
- If a different syringe brand and size displays which differs from the syringe being used, scroll through the syringe options to find the correct syringe, when the correct syringe displays, confirm and the “Yes to Resume, No for New Syringe” screen will display.
- If the screen prompt “Press YES to Resume, NO for New Syringe” does not display following syringe confirmation, there is no current program available.

Press YES to Resume NO for New Syringe

The user has the option to either Press YES or NO:

- Pressing **YES** retains the current program (mL/hour rate is protected)
- Pressing **NO** deletes the current program. A new program is then calculated or entered (depending on mode of operation).

NOTE: When the screen prompt “Press YES to Resume, NO for New Syringe” displays, before pressing keys, be sure you select the right option. When NO is pressed, the current program is immediately deleted and cannot be retrieved.

The important feature to remember is that “Resume” protects the infusion rate for the current program, so:

- *If the syringe volume is increased and the infusion is resumed, the duration of delivery will increase*
- *If the syringe volume is decreased and the infusion is resumed, the duration of delivery will decrease*

NOTE: Follow local policy/procedure for the appropriate option to press when this screen displays following purge.

7.4 Stopping/pausing the infusion and powering off

To stop the infusion (pump paused)

1. If the user presses NO during an infusion the pump is paused (stopped) for two minutes, the LED light changes from green to red and the screen message displays:

Pump Stopped Press YES to Resume	Either press YES to restart the infusion or No to continue pause state.

2. If the paused state continues with no key presses, after two minutes the pump will alarm and the screen message displays:

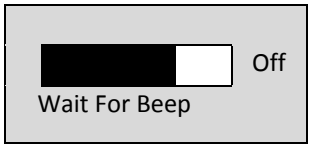
Pump Paused Too Long	Either press YES to restart the infusion or No to continue pause state.

Powering off

If the pump is no longer required:

1. Remove keypad lock if necessary and stop/pause the infusion if running.

2. Press and hold down the ON/OFF key until the graphic (moving from left to right) fills completely black, a beep is heard and the display screen power is removed.



3. Disconnect the syringe and administration set from patient access device.
4. Remove syringe from the pump and place the barrel clamp arm down.
5. Remove battery if the pump is no longer required.

7.5 Alerts, alarms and troubleshooting

Alerts

The pump will activate an alert for:

- Low Battery
- Program Nearly Complete

When the alert activates:

1) The infusion continues
2) Three beeps are heard approximately every three/four minutes
3) A screen message alternates with the infusion running screen until the end alarm activates

- A Program Nearly Complete alert activates approximately 15 minutes prior to an alarm state.
- A low Battery alert activates approximately 30 minutes prior to an alarm state.

Alarms

The pump will activate an alarm for:

- Syringe Empty
- End Battery
- Syringe displaced
- Occlusion/Empty Syringe
- Pump paused too long
- Occlusion/Check line
- System (technical) error

When the alarm activates:

1. The infusion stops.
2. The LED indicator light turns from green to red.
3. The alarm sound continuously until either the pump is paused or the problem is rectified.
4. A screen message indicates the alarm cause.

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 STOP, START and INFO keys are accessible.	Disengage keypad lock if further access required.
Press YES to Resume, NO for New Syringe	The current program has been interrupted and two options are available for programming.	Press YES resumes the current program. Press NO to delete the current program (to allow a new program to be set up).
Pump Stopped Press YES to Resume	The infusion has been stopped.	Press YES to Resume the infusion or press NO 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 pump has been stopped/paused for more than 2 minutes without any key presses.	Either press YES to resume the infusion, press NO 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 line, occluded o kinked. Actuator has reached the minimum travel position.	Release the clamp, flush/replace the access device or clear the occlusion.
System Error. Press & Hold INFO for Details. If problem persists send pump for service. ERROR, Startup MotMov Fail, 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 INFO to obtain error message. Record error code and summary of fault and return pump to designated service centre.

Technical problem/error and failure identification.

- The 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 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 Changing syringes/administration 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 infusion 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 YES to confirm the end of the infusion
    b. If the Program Nearly Completed alert has activated, press the INFO key to access volume history and record the volume infused (VI), then press STOP 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
6. Power on, observe Pre-Loading and wait for the screen display “Load Syringe”
7. Check battery level
8. Load the new syringe into the pump, check syringe brand/size is correct and to confirm press YES
9. Enter/check new program, if correct, press YES
10. The screen will display "Start infusion?" Connect set to syringe and when ready to do so, press YES
11. Check that the infusion is running

Checklist for priming a new administration 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 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 pump and use the FF key to resize the syringe to the actuator
7. Raise the barrel clamp arm
8. Load the new syringe into the pump, check syringe brand/size is correct and to confirm press YES
9. When the screen prompt "Press YES to Resume, No for New Syringe" displays, press YES to resume
10. Check the program summary screen, if correct, press YES
11. The screen will display 'Start infusion? Connect set to cannula and when ready to do so, press YES
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 YES to confirm the end of the infusion
    b. If the Program Nearly Completed alert has activated, press the INFO key to access volume history and record the V,I then press STOP 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 pump
6. Dispose of the syringe and line according to local policy
7. Clean and store the pump as per local policy

7.7 Servicing and maintenance

Servicing and maintenance

The T34™ syringe pump requires annual maintenance and calibration. CME recommends that calibration of the T34™ within technician's mode should be carried out with a metal cased battery.

The pump must only be serviced or repaired by one of the following:

- CME Medical or its approved service representative
- Qualified biomedical technicians trained and certified by CME Medical

In between maintenance the pump requires cleaning only between patients (or as necessary). It is recommended that the performance of the pump is checked periodically.

WARNING: If the pump does not perform as expected, if it is dropped, gets wet or is damaged in any way, then remove it from use immediately. Mark it clearly as quarantined and preferably take it out of the working area so that it cannot be accidentally used again, Return the pump for inspection to your authorised service centre.

WARNING: Adjustments, maintenance, or repair made by un-certified service personnel may impair the operation of the pump and/or the accuracy of the infusion. Make sure any adjustments, maintenance, or repair of the device is carried out by authorised and skilled personnel.

WARNING: Unauthorised modifications or the use of any spare parts, other than those supplied by the manufacturer or their distributor, will void any warranty.

WARNING: The T34™ syringe pump should be operated within a temperature range of +15°C (+59°F) to +45°C (+113°F). Operation at temperatures outside this range may affect accuracy.

Pump cleaning

Before connecting the pump to a patient, and periodically during use, clean the unit using a lint-free cloth lightly dampened with warm water and a mild detergent, disinfectant or a bleach solution up to concentration of 10%. Once a month (or as required) clean the main pump screw thread and guiding rods with a small dry brush to remove debris or other particles.
To clean and disinfect the pump and, follow your organisation`s policies and procedures as well as the following recommendations from the manufacturer.

WARNING: Always turn the syringe pump off and remove the battery before cleaning.

WARNING: Do not clean the syringe pump with chemicals such as Xylene, Acetone or similar solvents. These chemicals can cause damage to components and labels.

WARNING: Do not soak or immerse any part of the T34™ syringe pump in water or any other solution, immersing the pump in liquid could cause damage to components.

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.

WARNING: If other substances are used which are different to those recommended, this may impact on the materials used in the lockbox construction.

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.

Pump storage

If the 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.

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.