

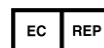


# **T34L<sup>TM</sup>**

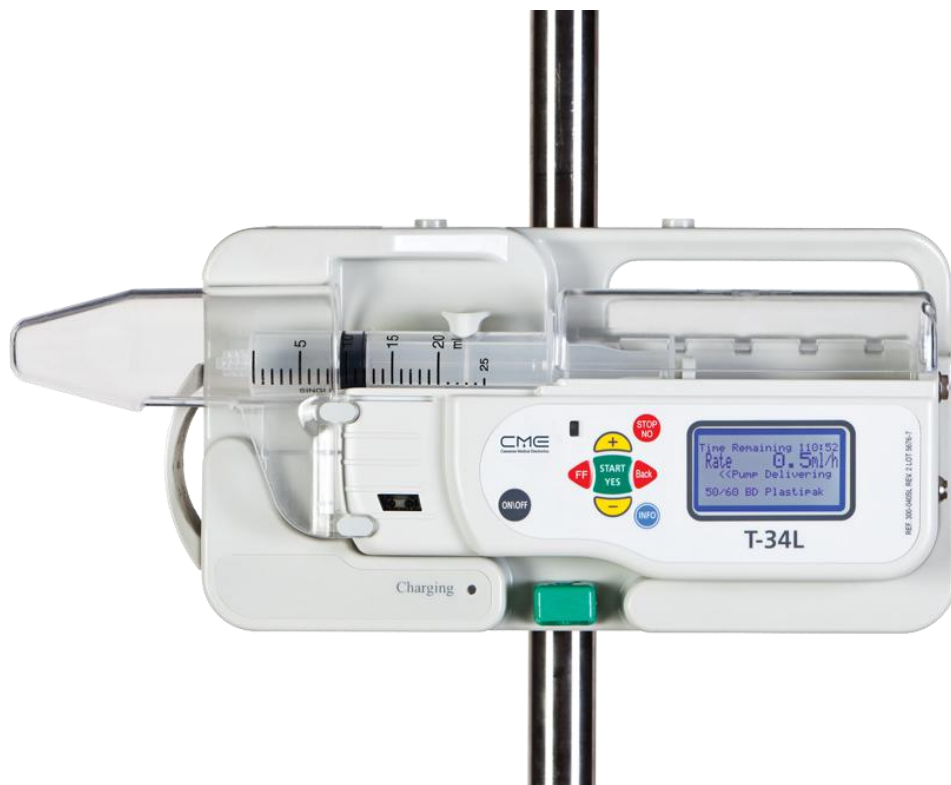
## **Syringe Pump Operator Manual**



**Caesarea Medical Electronics Ltd.**  
16 Shacham street, North Industrial  
Park Caesarea  
P.O.Box 4294, Caesarea 38900, Israel  
Tel: +972-46271737  
[www.cme-infusion.com](http://www.cme-infusion.com)



**MedNet GmbH.**  
Borkstrasse 10  
48163 Muenster  
Germany  
T: +49 251 32266 0



☞ **NOTE:** *Caesarea Medical Electronics Ltd. (CME) strongly recommends that this manual is read by every user of the T34L™ syringe pump and that they comprehensively understand its contents before operating the device. It is also recommended that before being allowed to use the device all personnel should receive training from either Caesarea Medical Electronics Ltd. (CME) or those trained by Caesarea Medical Electronics Ltd. (CME) to deliver training on this device. Competency of all attendees should be assessed with both the trainee and assessor signing to confirm their readiness to operate the device in the clinical setting*

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# 1 – Introduction

*T34L™* is a small, lightweight, robust, battery or mains powered, both hospital and ambulatory syringe pump designed to deliver the contents of most commonly used 2 to 60ml syringes over a specified duration or at a given rate in milliliters per hour (ml/h). A screw drives the pump actuator and syringe plunger forward at a controlled rate. This rate is adjustable from 0.1 to 650 ml/h; in increments of 0.1 ml/h up to 100 ml and 1 ml from 100 to 650 ml/h.

The size and weight of the *T34L™* makes it ideal for ambulatory use in either a hospital or homecare/out-patient setting. It is equally suitable for adults or for pediatric use.

The syringe pump can be easily concealed beneath clothing in a pouch fitted at either the chest (inside a jacket) or on the waist. A compact lockbox is available to protect against damage to or tampering with the pump or displacement of the syringe.

*T34L™* offers 3 point syringe detection enabling the pump to identify all commonly used (or programmed) syringe brands & size. This feature minimizes the risk of user programming errors. The sensors also activate an alarm if the syringe is removed or partially displaced during infusion.

The pump may be used to deliver via any common infusion routes including central, peripheral venous, epidural, intra-arterial or subcutaneous providing the medicines being administered are licensed for such use.



**Warning:** Do not operate the *T34L™* until you have read and understood the contents of this user manual paying attention to Warnings, Cautions & Notes as described below.

This manual will ensure the user will:

1. Be able to identify the key features of the *T34L™* and understand their function
2. Be able to correctly load a syringe into the *T34L™*
3. Be able to program the *T34L™* to deliver the contents of the syringe
4. Be able to access and interpret patient history and event log data
5. Be able to troubleshoot and resolve alarm conditions

In the user manual you will find important information marked as followed:



**Warning:** Indicates the information is a warning. Warnings advise you of circumstances that could result in INJURY OR DEATH to the patient/operator.



**Caution:** Indicates that the information is a caution. Cautions advise you of circumstances that could result in DAMAGE to the device.



**Warning:** Indicates that the information is additional important information or a tip that will help you recover from an error or point you to related information.



**Warning:** *T34L™* is a medical device designed for the safe, accurate delivery of appropriate infusion regimes and should only be operated by, or under the supervision of, a medical professional. Incorrect or inappropriate use could lead to serious injury or death.

## 2 – Modes of Operation

The T34L™ Syringe Pump has three modes of operation. In summary these are:

- 1) VOLUME OVER TIME (Program Lock OFF) – Pump will deliver the volume confirmed over the default duration or a new duration confirmed by the user.

THIS MODE IS IDEAL WHERE - it is common to use the same delivery regime (duration) but some flexibility may occasionally be required.

- Although the pump calculates volume in the syringe the user can set a lower VTBI (e.g. if KVO is required) during infusion set up.
- Pump is configured with a Default Duration (e.g. 24 hours) to guide the user to make the appropriate selection during set up but the user can change the duration. The next time a new program is set the default is restored.
- OPTIONS - Titration can be enabled allowing the user to set upper and lower infusion rate limits during set up to allow titration of the infusion rate without stopping the Pump.

- 2) VOLUME OVER TIME (Program Lock ON - DEFAULT) – Pump will deliver the full contents of the syringe fitted over the Default Duration set on the pump.

THIS MODE IS IDEAL WHERE – the entire contents of a syringe are always required to be delivered over the same duration (e.g. 24 hours). The duration is locked so the user CANNOT change it. This prevents programming errors and makes setting up an infusion very simple.

- User CANNOT change either the VTBI or the Default Duration time
- Pump calculates the volume, applies the pre-set duration and calculates the appropriate rate for the infusion.
- User only checks and confirms infusion summary screen (showing duration, rate and volume) matches the prescription before Starting the infusion
- User access code required to change any of the pumps settings
- Titration is NOT possible in Program Lock ON mode

- 3) RATE PER HOUR MODE – Default Duration is set to Zero under the Change Set Up menu (access code required).

THIS MODE IS IDEAL WHERE – different infusion rates are used each time and the users are familiar and comfortable with making the calculation of infusion rates themselves.

- Pump calculates the volume in the syringe and then the user sets the rate in ml/hr (default is ALWAYS zero if New Program confirmed so user has to scroll to select the infusion rate or infusion cannot be started)
- Titration can be enabled in Rate per Hour mode. See "Rate Titration" feature in Change Set Up Menu (code required).

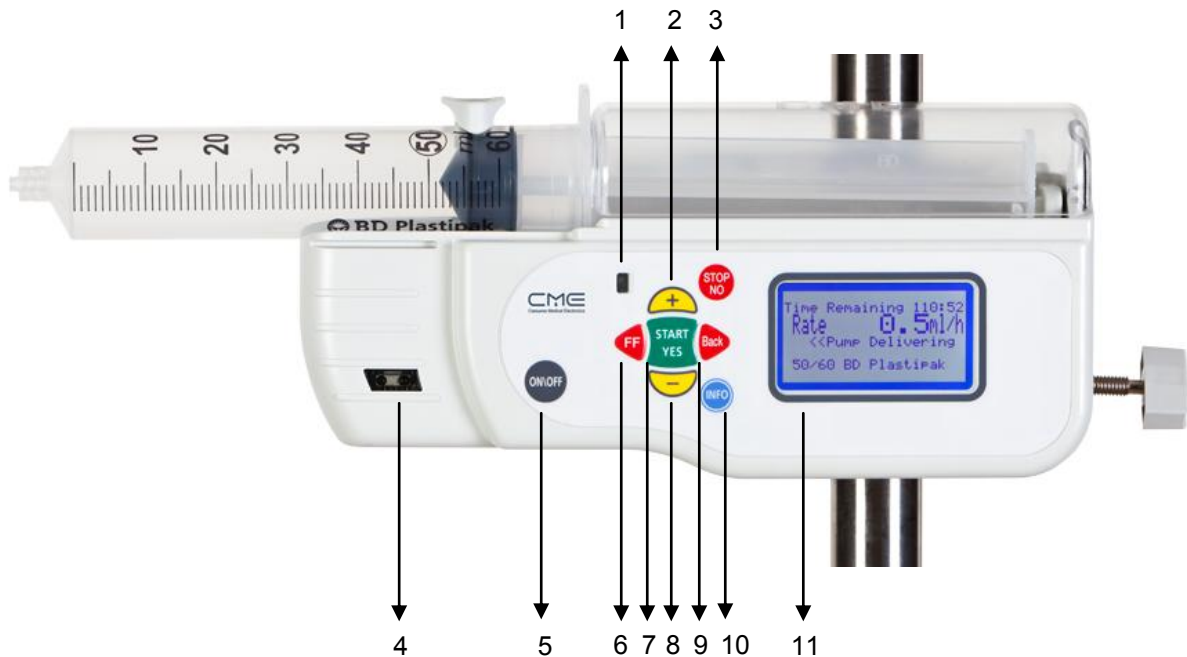


**Warning:** make sure you fully understand all of the possible modes especially the one your pump is configured to before operating the T34L™.



**NOTE:** your T34L™ can be configured to one of the above modes (as appropriate to your clinic/setting) during installation by either CME or your service centre. Take time to consider which mode is best for your practice.

## 3 – Keypad Description and Functions



No.	Function	Description
1.	Operation LED	<b>Green Indicator</b> Lights during system Self-Test An intermittent green light indicates infusion delivery <b>Red Indicator</b> Indicates an alarm state with a continuous red light Lights when the pump is in a stand-by mode during programming
2.	Plus key	Scrolls between options
3.	NO/STOP key	a. Takes user back a step b. stops pump
4.	Infra Red sensor	
5.	ON/OFF key	Switches the pump on and off
6.	Forward key	
7.	YES/START key	Confirms choices
8.	Minus key	scrolls between options
9.	Backward key	
10.	Info key	a. shows technical data and Battery status b. Long press will Lock/Unlock Keypad
11.	Pump display	Backlight can be enabled when any key pressed

## 4 – Symbols, Warnings and Cautions

### System Symbols

The following symbols are used on the *T34L™* 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.



Caution



Refer to operating instructions



CE mark indicates conformance to Medical Device Directive 93/42/EEC.



Do not dispose of in municipal waste. Symbol indicates separate collection for electronic equipment. (WEEE Directive 2002/96/EEC). **NOTE:** Does not apply to the battery.



Do not dispose of battery in municipal waste. Symbol indicates separate collection for battery is required.



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



Type CF applied part.



Date of Manufacture

**SN**

Serial Number



Expiry Date (consumables)

**LOT**

Lot Number (consumables)



Sterilized with Ethylene Oxide

## Terms Used In Manual



**Warning:** Indicates that the information is a warning. Warnings advise you of circumstances that could result in injury or death to the patient or operator. Read and understand this manual and all warnings completely before operating the T34L™ syringe system.



**Caution:** Indicates that the information is a caution. Cautions advise you of circumstances that could result in damage to the device. Read and understand this manual and all cautions completely before operating the T34L™ syringe system.



**NOTE:** Indicates that the information that follows is additional important information or a tip that will help you operating the T34L™ syringe system.

## Intended Use

The T34L™ Syringe Driver is designed for infusion of medications or fluids requiring continuous or intermittent delivery at precisely controlled infusion rate through all clinically acceptable routes of administration including intravenous, percutaneous, intra-arterial, epidural, enteral, in close proximity to nerves, and into intraoperative site (soft tissue/body cavity/surgical wound site). The system is intended for patients who require nutritive fluids, chemotherapeutic agents and general fluid therapy in hospital and home care environments.

## 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

## Warnings

To avoid the possibility of injury or death, please note the following advice before using the T34L™ Syringe Pump:



**Warning:** CME syringe pumps should not be used for infusion of medications whose stoppage or interruption could cause serious injury or death.



**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.



**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:** Ensure there is no air present in the syringe and also completely prime the administration set before loading the syringe into the pump to prevent the risk of infusing air into the patient (air embolism).



**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 authorized skilled technicians



certified by CME service centre.



**Warning:** The T34L™ syringe pump system should be operated within a temperature range of 5°C to 40°C and in humidity in range of 5% to 90%. Operation at temperatures and/or humidity outside this range may affect accuracy.



**Warning:** Unsafe operation may result from using improper accessories. Use only accessories and options designed for this system supplied by CME.



**Warning:** Disposables must be compatible with the medicine delivered. Please check with the manufacturer of the administration set before use.



**Warning:** Dropping the Syringe Pump could cause damage to components. If the pump is dropped, return the pump for inspection by qualified service personnel.



**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 single use sets.



**Warning:** Do not operate the pump near high-energy radio-frequency emitting equipment, such as electro-surgical cauterizing equipment as this may result in false alarm signals or error messages being displayed.



**Warning:** The maximum volume that may be infused under SINGLE FAULT CONDITION is 0.15 ml (depending on syringe size in use).



**Warning:** The equipment is not suitable for use in the presence of flammable mixtures.



**Warning:** The T34L™ 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.

## Cautions

To avoid possible damage to the equipment, observe the following:



**Caution:** Xylene, Acetone or similar solvents could damage components. Do not clean the pump with these chemicals. Clean solution spills immediately using a damp, not wet, cloth or sponge and a mild detergent or 10% bleach solution. Wipe dry.



**Caution:** Immersing the T34L™ Syringe pump in liquid could cause damage to components. Do not immerse the pump into any type of liquid.



**Caution:** Battery damage could occur at ambient temperatures >50°C (122°F).

# 5 – Installation and Set Up

## Unpacking

1. Remove the *T34L™* Syringe Pump & accessories from the packaging and inspect for damage during shipment or storage.



**Warning:** Do not use *T34L™* if there are any obvious signs of damage. Return for inspection by authorized service personnel.

2. Make sure you have the following items:

- *T34L™* Syringe Pump
- Operation Manual
- Carry Pouch (Optional)
- Lockbox (Optional)
- External Charger
- Pole mounting unit (Optional)

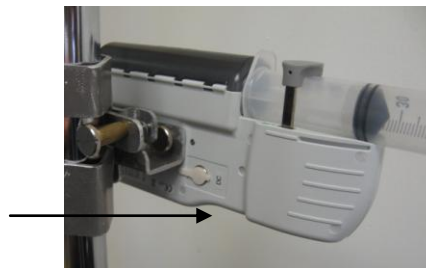
If any items are missing or damaged, contact your supplies department to order replacement.

## Power Supply and Charging the Pump

The *T34L™* pump includes a Li-Polymer battery which enables operation when the patient is ambulatory, being moved, or even during electrical power failures. Fully charged, the battery provides 15-17 hours of operation at an infusion rate of 125 ml/h.

### Wall Charger

To charge the battery, connect the charger plug to mains power supply and to the pump DC connector on the rear of the pump. Note that the DC connector must be inserted directly in the correct way.



**NOTE:** After the “End Battery” signal has been activated or following long periods of storage, wait 2 minutes after the pump has been connected to an AC power supply before operating.



**Caution:** Leaving the battery in an uncharged state for a long period of time may damage the battery.



**Caution:** do not twist the DC connector while disconnecting from the rear of the pump.



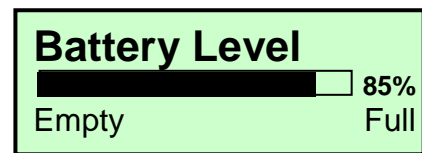
**NOTE:** Whenever possible, use the pump connected to an AC power supply. This preserves the battery power supply for emergency use or for situations where the AC power is not available.

- ☞ NOTE: Replace the battery once every two years in certified service centers.
- ☞ NOTE: Charge the unit with dedicated T34L™ charger only.

## Battery Test

When setting up the pump on a patient **always check** that there is enough battery charge remaining to cover the infusion duration. To do so follow one of the procedures below:

- Check the Start Up Screen, displayed on power up, indicating % battery life remaining
- Press INFO key when the pump is stopped and select Battery Level, press YES to view battery meter
- During infusion press the INFO key twice to check Battery Level, in all cases verify sufficient battery charge is available to complete the current program. If not, charge the battery.
- Sufficient battery charge may vary depending on your setting, infusion rate, number of times the information options/screen backlight are used.

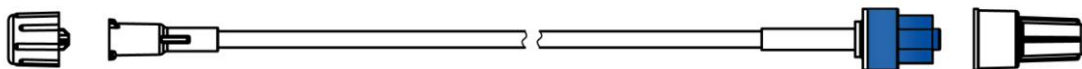


## 6 - Administration Sets

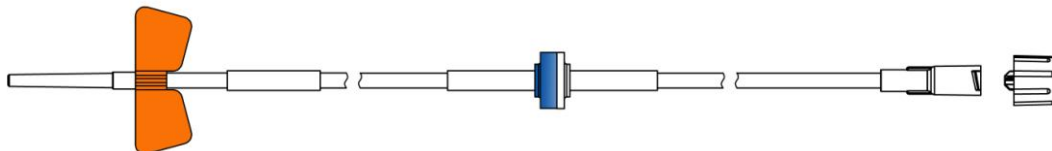
The *T34L™* Syringe Pump System can be operated with any extension set with a luer connection however, for system optimization, accuracy & performance, CME recommends the use of CME proprietary sets.

Proprietary sets available from CME include:

### 150cm IV infusion set with check valve



### 100cm Sub-cut set with needle



**Warning:** Replace the administration set at least every 24 hours (or in accordance with local guidelines) to reduce the possibility of bacteria formation/infection.



**Warning:** Visually inspect packaging and contents before each use. Do not use consumables if the packaging is in any way damaged as sterility may have been compromised.



**Warning:** Air embolism during an IV infusion can cause death or serious injury to the patient. Do not connect a patient to the *T34L™* Syringe Pump until all air has been cleared from the fluid path & syringe. Carefully read the instruction for loading. Puncturing set components could result in air embolism.



**Warning:** Drugs must not be administered to the epidural space unless indicated for this purpose and administered in accordance with the drug manufacturers package insert. Epidural administration of drugs other than those indicated for epidural use could result in serious injury or death to the patient.



**Warning:** Disposables must be compatible with the medicine delivered. Please check with the manufacturer of the administration set before use.




**Caution:** 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 minimize leaks, disconnection and component damage.

# 7 – Access Codes & Keypad Lock

## User Access Codes

The T34L™ employs three levels of user access protection to prevent unauthorized changes to the set up or configuration. Although no access code is required to turn the pump on and run an infusion certain settings and features may have been configured and locked as appropriate to the clinical application the Pump is being used for in your practice.

 **NOTE:** No access codes are contained in this manual. Please refer to senior clinical or technical staff for these codes ONLY if you have been trained and authorized to use them.



**Warning:** Do not attempt to access Code Protected areas if you are not trained or authorized to do so. If authorized do not share the Codes with un-authorized personnel.

Placing these settings in a secure area of the pumps menus also simplifies operation of the pump as everyday users are not required to repeatedly confirm or change common set up parameters whilst setting up a simple infusion regime.

'Change Set Up' mode (see later section) contains configurable settings and features and is protected by a user code from un-authorized access.

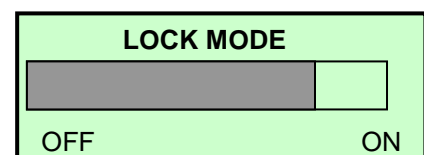
'Technicians Menu', used for service and/or repair of the Pump, is also protected by a special access procedure and different user code from that for 'Change Set Up'.


In normal use the nurse will not see these fields or be prompted for the technician codes.

## Keypad Lock


As well as the ability to lock or limit certain infusion parameters or pump settings, T34L™ allows users to lock the operation of the keypad if concerned about patients, relatives or un-trained personnel tampering with the pump. To active the Keypad Lock: -

- With the pump infusing, press and hold the INFO key until a chart is displayed showing a bar moving from left (OFF) to right (ON).
- Hold the key until the bar has moved completely across the screen and a beep is heard to confirm the lock has been activated.
- To turn the lock off repeat this procedure. The bar will now move from right (ON) to left (OFF) and a beep will be heard to confirm de-activation.



 **NOTE:** for safety reasons the keypad lock does not affect the operation of the START or STOP keys as users or patients unaware of how to deactivate the lock may need to STOP an infusion in an emergency and/or re-start the infusion (e.g. after clearing an alarm).

# 8 – Infusion Set Up & Programming

 **NOTE:** all three operating modes are covered below. Note instructions as to how programming differs in each mode and how to tell what mode the pump is configured in.

## Alarms Verification

Audible and visual alarm should be checked according to the following procedure: “switch on” the pump. Wait more than 2 minutes with no action. Audible alarm and visual message “Pump paused too long” should be activated.

## Syringe Selection

The T34L™ is programmed to recognize most commonly used syringe brands from 2 to 60 ml. Luer lock syringes **MUST** be used to ensure secure connection of the administration set.

## Priming the Administration Set

1. After filling the syringe attach the administration set, prime manually and apply the clamp.



**Warning:** Never connect to the patient before loading the syringe into the pump.

## Pre-Loading & Syringe Placement

2. Before turning the pump on ensure the syringe is not fitted and the barrel clamp arm is down


## Power Up

3. Press ON/OFF key to power the pump up. Screen displayed during pump Self Test shows (1) Pump model name, (2) Software version & (3) Pump ID (default ‘Syringe Pump’ but can be configured to local ID requirements e.g. asset no. or user site through BodyComm™ PC software).
4. The display will indicate PRE-LOADING and the actuator will start to move. Wait until it stops moving and the LOAD SYRINGE flashing screen appears
5. During pre-loading a setting summary screen is displayed showing key locked parameters that may be appropriate to/restrict the programming of the pump.

<b>T34L</b>
Version LCATXXXXX ID: HOSPITAL NAME

<b>Pre-Loading</b>
Use NO to Interrupt .....

Occlusion	540mmHg
Max. Rate	5ml/h
Program Lock	ON
Battery Status	98%

 **NOTE:** During Pre-Loading the actuator returns to the start position of the last infusion programmed. If the user regularly uses the same syringe brand, size and fills to the same volume the actuator will return to the correct position each time & not require adjustment.

- If the actuator is not in the required position to accommodate the syringe leave the barrel clamp arm down and use the FF or BACK keys to move the actuator to the required position (hold the syringe above the device to gauge the correct location). Forward movement of the actuator is limited for safety reasons so repeated presses of the FF key may be required. Backwards movement is not restricted).



**Caution:** The actuator can only be moved as described above. Do not use force to try to move the actuator manually as this could damage the device and/or affect calibration.

- Note that the syringe graphic on the Load Syringe screen flashes in three places, lift the barrel clamp arm and load the syringe into the Pump. First position the flange/collar and plunger simultaneously. As you correctly seat each point of the syringe note that the flashing indicator for that sensor becomes solid on the display
- Note that the syringe graphic on the Load Syringe screen flashes in three places, lift the barrel clamp arm and load the syringe into the Pump. First position the flange/collar and plunger simultaneously. As you correctly seat each point of the syringe note that the flashing indicator for that sensor becomes solid on the display.
- Finally lower the barrel clamp arm to sit on top of the syringe barrel. If the syringe is correctly loaded the graphic (right) will become solid (no flashing components) and the pump will display the Size and Brand of the syringe detected.



**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 leading to the pump running at an inappropriate speed for the syringe loaded.

## Syringe Detection & Confirmation

- Check the LCD display to ensure that the Pump has correctly identified the syringe size and brand.

**10ml BD Plastipak**  
Select ↑↓ Press YES

☞ **NOTE:** If the syringe brand displayed is not correct use the UP or DOWN arrow keys to scroll between brands of similar dimensions. This will only happen if the syringe selected has dimensions within +/-1mm of another commonly used brand that has not been disabled.

- Press YES/START key to confirm the displayed syringe brand is correct
- If the pump was stopped and turned off before the last program reached “End Program” the Resume prompt screen will appear (e.g. if, during an infusion, the pump was powered off). Press NO to continue programming the new regime.

**Press YES to Resume**  
**NO for New Program**

☞ **NOTE PURGE OPTION:** In order to eliminate/reduce slack (visible spaces at the syringe collar & plunger loading points) and ensure a faster start up time (time to reach the programmed infusion rate), the user can purge the system (once only) up to a volume limit configured under Change Set Up (max 0.5 ml). To use this option after syringe confirmation:

- Press FF key.
- Ensure the patient is NOT connected to the set & Press Yes to confirm.
- Press and Hold the FF key until the slack is removed and/or purge is completed
- Press STOP to return to programming screens when purge is completed.

PROGRAMMING MAY NOW TAKE TWO DIFFERENT PATHS DEPENDING ON WHETHER THE PUMP HAS BEEN CONFIGURED WITH PROGRAM LOCK ON OR OFF. PROCEED AS FOLLOWS DEPENDING ON THE SCREEN DISPLAYED

10ml BD Plastipak  
**Volume 12 ml**  
 Change ↑↓ Press YES

PROCEED TO STEP 12  
 PROGRAM LOCK IS OFF

Volume 12.0ml  
 Duration 24:00  
 Rate 0.50ml/h  
 Confirm, Press YES

PROCEED TO STEP 18  
 PROGRAM LOCK IS ON

## Setting Infusion Parameters

- Once the syringe brand & size are confirmed the pump calculates and displays the deliverable volume in the syringe.
- The user can use the arrow keys to adjust the Volume to Be Infused (VTBI) e.g. to allow a residual volume for KVO (Keep Vein Open) if required.

10ml BD Plastipak  
**Volume 12 ml**  
 Change ↑↓ Press YES



**Warning:** If the volume displayed after loading the syringe is significantly different than the volume visually confirmed on the syringe scale, remove the syringe, turn off the pump, remove the pump from use and return to an authorized service centre for inspection, testing and recalibration.

- Press YES/START key to confirm VTBI
- VOLUME OVER TIME MODE ONLY.** The LCD display prompts the user to set the infusion Duration. Press YES to confirm the Default Duration or use the ↑↓ arrow keys to change the duration then press YES.

10ml BD Plastipak  
**Duration 24:00**  
 Change ↑↓ Press YES

☞ **NOTE:** Every pump has a Default Duration set in the access code protected Change Set Up menu. For example, senior clinical personnel may have set a 24:00 hour default duration. If so the Duration screen will always default to this duration when New Program is selected.

☞ **NOTE:** In **RATE PER HOUR MODE** the Duration screen does not appear. Instead the pump skips straight to the RATE screen (left), showing a rate of 0ml/h and asking the user to set the rate using the ↑↓ arrow keys. In this mode the user sets the rate required in ml/h instead of the pump calculating the rate based on pre-set or selected duration). Use the ↑↓ keys to set the rate & press YES.

10ml BD Plastipak  
**Rate 0ml/h**  
 Change ↑↓ Press YES

## Setting the Infusion Rate

- The Pump calculates and displays the rate (in milliliters per hour) required to deliver the VTBI over the infusion duration confirmed.
- Press YES to confirm the calculated rate.

10ml BD Plastipak  
**Rate 0.5 ml/h**  
 Confirm, Press YES



- ☞ **NOTE:** In **VOLUME OVER TIME** configuration (UNLOCKED) the user can only set the rate by selecting the required duration. If a change of rate is required, press NO to back up to the duration screen and amend duration as required. Upon confirmation of duration change, the pump alerts the user (right) to check the new rate which is then displayed.

**Duration Changed  
Please Check rate**

- ☞ **NOTE:** In **VOLUME OVER TIME** Senior clinical personnel or technicians may have set a MAXIMUM RATE LIMIT to prevent T34L™ being programmed at rates above a fixed limit in line with the application the pump is regularly used for. Pump will not allow the user to scroll to a duration that requires a rate above this limit to deliver the contents of the syringe over that time.

19. The Summary Screen displays the Volume (To Be Infused), Duration and Infusion rate.

Volume 12 ml  
Duration 24:00  
Rate 0.5 ml/h  
Confirm, Press YES



**Warning:** Always take time to check the contents of the summary screen match the prescription before starting infusion.

20. Press YES/START to confirm acceptance of the pre-set (if Program Lock ON) or programmed (if LOCK OFF) infusion parameters.

21. Pump prompts START INFUSION? Check administration set is attached to patient access device and the clamp is released. Press YES/START to commence infusion

**Start Infusion?**

22. Whilst infusing the display shows Infusion Time Remaining (top line), Infusion Rate (main/central line) and the bottom line will alternate between Syringe Size & Brand and a delivery animation to indicate the pump is running (in case the LED indicator on the keypad has been disabled to conserve battery life (see Change Set Up).

Time Remaining 23:58  
**Rate 0.5ml/hr**  
10ml BD Plastipak

Time Remaining 23:57  
**Rate 0.5ml/hr**  
<<<<< Pump Delivering

## 9 – Accessories

Optional accessories for the T34L™:

- Carry pouch for pump (up to 50/60ml syringe)
- Pole mounting unit

### Carry Pouch

After the syringe has been loaded the T34L™ can be placed into the carry pouch to protect the Pump, syringe & contents from damage or syringe displacement. The pouch can be carried on the shoulders or over the waists.

### Use of pouches for protection of pumps during transportation

**WARNING:** The T34L™ 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.

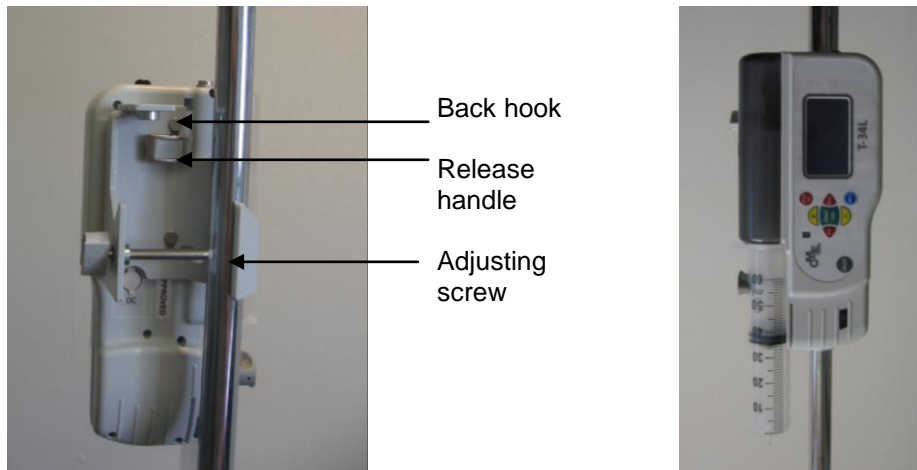
When using the CME Ltd re-useable (washable) pouch, it is possible to access the screen and keypad of the device during infusion by lifting the Velcro flap of the pouch whilst the pump remains in the pouch. When using either a CME Ltd re-useable (washable) or disposable (single patient use) pouch it 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.



## Pole Mounting Unit

The T34L™ is pole mountable, vertically or horizontally. Connect the pole mounting unit to the pole using the adjusting screw, and just click in the T34L™ back hooks onto the pole mounting unit.

Mounting device for two syringe pumps is also available.

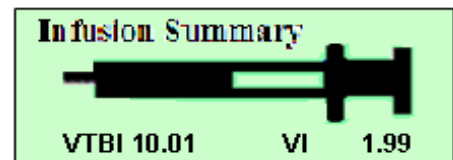


# 10 – Recommended Checks during Infusion

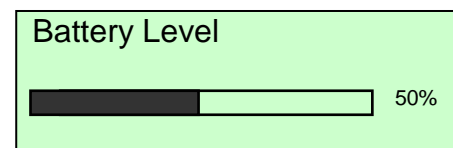
It is recommended that procedures are established for regular checks on the progress of the infusion. Patients, relatives as well as medical staff, should be made aware of a few simple checks that can be made. These are to confirm the following: -

- CHECK THE LCD DISPLAY to confirm the pump is still running at the same infusion rate as originally set (unless the Titration option has been enabled and the user/patient has been authorized to adjust the rate within the programmed limits)
- CHECK THE GREEN LED IS FLASHING AND/OR “<<<<<Pump Delivering” animation appears intermittently on the bottom line of the LCD display (green delivery LED can be disabled or the interval lengthened to preserve battery life)
- CHECK FOR SIGNS OF PHYSICAL DAMAGE to the Pump or accessories.
- PRESS THE INFO KEY to check:

**SINGLE PRESS** - Volume to be Infused (VTBI) & Volume Infused (VI). Syringe graphic shows VTBI & VI in graphical form



**DOUBLE PRESS** for Battery life remaining shown as a percentage and in graph form.



☞ **NOTE:** After pressing the INFO key either a third press or waiting a few seconds returns the display to the main infusion display screen. Excessive key presses or usage of the INFO feature will reduce battery life. Use only as required to optimize battery performance.

## Event Log (History)

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. To view the event log: -

1. Press STOP to temporarily interrupt the infusion
2. Press the INFO key and scroll to 'Event Log'. Press YES to confirm selection.
3. Screen now shows the most current event, alarm, date, time, etc. Use the Up & Down arrow keys to scroll through events to find the event of interest (e.g. an alarm or programming change).
4. Pressing INFO when on any chosen event to display further data regarding this event. The user can scroll through the information using the UP and DOWN arrow keys to check how the pump was set up, whether keypad lock was ON and the pressure settings and other technical data at the time of the event.

Event No.:	2635
04.03.2005	17:08
Switched ON	
Press INFO - Details	

VI	0.1ml
VTBI	14.2ml
Rate	0.6ml/h
20 ml BD Plastipak	
Travel	3.61 mm/ml

☞ **NOTE:** Each event is assigned a number and the pump stores the last 512 in memory. The event log “loops” adding the newest and deleting the oldest event.

# 11 – Advanced Functions

## KVO (Keep Vein Open) Operation

can be configured to deliver a KVO infusion to commence at END PROGRAM keep the patients IV access device patent until the clinician can attend. With KVO enabled T34L™ applies the KVO rate set under Change Set Up until the Syringe is empty.

- After four beeps the End Program alarm stops and the pump switches to the configured KVO infusion rate
- Every four minutes four beeps will be heard to confirm the pump is still running/infusing.
- Press NO to Stop the pump and set a new program, if there is still sufficient volume in the syringe, if not change syringe

**KVO**  
**0.5ml/h**

## Infusion Rate Titration

Infusion rate titration can be enabled so that the patient/caregiver or clinician can adjust the rate during infusion within pre-set maximum (max.) and minimum (min.) limits. This option can be Enabled by users with access code rights in Change Set Up. If enabled, the pump requires the user, after confirming the infusion rate calculated during programming, to set a maximal & minimal rate. To titrate the rate up or down during infusion follow these steps:

- Use the UP or DOWN arrows on the keypad to adjust the rate to the desired new setting as displayed on the main LCD screen
- Press YES (within a few seconds of making the change) to confirm the new rate
- Pump sounds a beep to confirm the change and the screen will display the new rate

**Max. Titration Limit**  
**3.5ml/h**  
Select ↑↓ Press YES

☞ **NOTE:** Titration requires Two separate, distinct actions (rate selection with arrow keys followed by YES key press to confirm and apply the new rate) to protect against accidental rate titration if the keys are nudged or tampered with during infusion.

☞ **NOTE:** In order to limit the maximum titration limit configurable by users without access code rights it is possible to set a Maximum Rate limit from the Technician menu. For example senior clinicians could decide to limit the maximum possible rate programmable on the pump to 3ml/hr for both rate and titration limit to prevent accidental over infusions.

# 12 – Alarm Conditions and Troubleshooting

## Alarm Conditions

When the Pump detects a problem, four things occur:

- The infusion stops (unless the event is an Alert\*, see table below).
- An audible alarm is activated.
- A message appears on the display (example right) screen indicating the cause of the alarm, and:
- The LED indicator turns red.

**End Program**  
 Press YES to Confirm

Alarm/Alert*	Possible cause	Action
Occlusion/Syringe Empty Check Line & Syringe Press YES to Confirm	Patient access device blocked Clamp on the infusion line Tubing occluded (kinked or trapped) Pump has reached the minimum travel position	Flush or replace access device Release the clamp Clear the occlusion Turn pump off
Syringe Displaced Check Syringe Press YES to confirm	One or more of the syringe detection sensors is not detecting up the syringe	Check the syringe and re-seat as necessary
Pump Paused Too Long	Pump has been left in STOP mode with no keypad presses detected for 2 minutes	Start the infusion, continue programming or turn the pump off if not needed.
Near End*	15 minutes from End of Infusion	Prepare to change syringe or turn pump off
End Program Press YES to Confirm	Infusion is complete	Pump will either default to KVO program if set (wait for nurse to attend) or, if not, turn the pump off.
Low Battery*	Battery is almost depleted	Prepare to charge battery
End Battery	Battery is depleted	Charge battery



**NOTE:** Occlusion alarm will be operated after 5 hours on minimum rate of 0.05 ml/hr, after one minute on rate of 10 ml/hr and after less than 5 seconds on maximum rate of 1500 ml/hr (using one meter tubing inner diameter 0.5 mm).

## Troubleshooting



**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 altogether, so that it cannot be accidentally used again, until it has been returned for inspection by qualified service personnel.

<b>Fault</b>	<b>Possible cause</b>	<b>Action</b>
The Pump will not start	Battery is depleted/very low	Charge battery
	Pump is faulty	Service required
The infusion is going too quickly/has ended early or too slowly/ volume remaining in syringe at end of infusion.	Incorrect rate set	Check displayed rate against prescription, change if necessary.
	Wrong syringe brand confirmed during set up	Re-train user to prevent repeat of this event
	Pump faulty or incorrectly calibrated.	Service/calibration required
The Pump has stopped before emptying the syringe	Exhausted	Charge battery, turn pump on, confirm syringe size and brand, select resume to continue infusion.
	Blocked/trapped infusion set	Clear the occlusion

# 13 - Change Set Up



**Warning:** The following instructions will affect the operation/functionality of the T34L™ for all infusions. Set up parameters should only be changed by clinical or technical staff with user code access rights only. If you are unsure about your authority to change these settings please consult your clinical lead personnel or the local biomedical engineering staff.

- When the pump is in program mode, or stopped during infusion, pressing the INFO button will take you to the main menu.
- Select Change Set Up from the menu using the UP / DOWN arrows and press YES
- Pump will prompt for User Code (not given in this manual, please consult senior clinical personnel or biomedical engineers), use the UP arrow to scroll code in. When the UP arrow is 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 the key again, UP or DOWN arrow depending on digit displayed on the screen, to select the final, correct code. Press YES to submit code.



**Warning:** Do not change any parameters unless you clearly understand the significance of that parameter and the effect your change will have on the operation and/or functionality of the pump.

- If correct code has been inputted and confirmed, the Set Up menu will be displayed.

Parameter	Application	Range
<b>Set Time &amp; Date</b>	Ensures all events in log are correctly date and time stamped (ensure local update for DST)	
<b>FF Key Operation</b>	Limits the forward movement of actuator caused by pressing the FF key during syringe loading	0.1 – 100mm
<b>Backlight Duration</b>	Limits backlight duration to preserve battery life	0 – 60 secs.
<b>Info Duration</b>	Sets time info screens are displayed	1 – 20 secs.
<b>Operation LED</b>	Turns off the green operation LED to preserve battery life. Red warning LED still operates	0 (Disabled) – 64 seconds
<b>Titration Option</b>	enables setting a titration limit ( $\leq$ max.rate)	Enable/Disable
<b>Default Duration</b>	When entering a new program pump resets to this default (setting to zero skips duration step during programming). When Program Lock is ON (see below) default duration cannot be set to zero.	00:00 (OFF) to 99:59 hours
<b>Occlusion Pressure</b>	Sets pressure level at which occlusion alarm will activate	100–1500mmHg, 10mm increment
<b>KVO Operation Rate</b>	Activates Keep Vein Open infusion at End Program	0 (KVO OFF) – 2.0ml/h
<b>Program Lock</b>	Prevents alteration of default duration and infusion rate during set up (with Program Lock ON Default Duration cannot be set to zero)	ON/OFF



# 14 – Specifications

Type:	Syringe pump with motor driven linear actuator, pulsed motion (60 pulses per mm)
Flow Rate:	0.1 - 650 ml/h
Actuator travel:	c.106 mm available
Syringe sizes:	2 ml to 60 ml (most commonly used manufacturers, see Default Syringe section for more details)
Accuracy:	± 5 % system accuracy
Occlusion pressure:	100-1500mmHg configurable (10mmHG increments). Max. Actuator force 50N (5 Kgf).
Battery:	Rechargeable Li-Ion 1800 mAh
Battery Operation:	c. 15 hours at 125ml/hr rate
Indicators:	Graphic Display 128 x 64 pixels with back light (8 keys) & dual color operation LED
<b>Alarms:</b>	When a problem is detected, the <i>T34L<sup>IM</sup></i> displays the following alarm messages, sounds an audible alarm and the red LED lights: <ul style="list-style-type: none"> <li>• Syringe not Recognized</li> <li>• Occlusion</li> <li>• End Program</li> <li>• Near End/Nearly Complete</li> <li>• End Syringe Travel</li> <li>• Low Battery</li> <li>• End Battery</li> <li>• Pump Paused</li> <li>• Lock Mode</li> <li>• Syringe Displaced</li> <li>• Check Syringe Placement</li> </ul>
<i>T34L<sup>IM</sup></i> Dimensions:	205X98X45 mm
Classification	Type CF Equipment
Housing:	ABS (fire retardant)
Weight	411 gr. with battery
Electrical Safety	Complies with: <b>EN 60601-1</b> (Medical Electrical Equipment Safety), <b>IEC 60601-2-24</b> (Infusion pumps and controllers), <b>IEC 62304</b> (Medical device software – Software life cycle processes)
Standards	Manufacture in accordance to <b>ISO 9001:2008</b> and <b>ISO 13485:2003</b> . <b>CE marked</b> (In accordance with the Medical Devices Directive 93/42/EEC)
EMC	IEC 60601-1-2 (EMC)
Environmental Specifications	Non Operating Conditions (Transportation and Storage): - <ul style="list-style-type: none"> <li>• Temperature: -25oC to 50 oC (-13 oF to + 122 oF)</li> <li>• Humidity: 5 % to 100% R.H., non-condensing</li> <li>• Air pressure: 48kPa to 110kPa</li> </ul> <p>Operating Conditions: The system may not meet all performance specifications if operated outside of the following conditions: -</p> <ul style="list-style-type: none"> <li>• Temperature: +15oC to +45 oC (+59 oF to + 113 oF)</li> <li>• Humidity: 5 % to 90% R.H. at +40 oC, non-condensing</li> <li>• Air pressure: 70kPa to 110kPa</li> </ul>

# 15 – Service and Maintenance

*T34L™* Syringe Pump requires annual maintenance and calibration. In between maintenance the Pump requires only battery charging and cleaning between patients (or as necessary). It is recommended that the performance of the Pump is checked periodically.



**Warning:** If the Pump is damaged in anyway return to an authorized service centre.

## 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 10% bleach solution.

**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.**



**Warning:** Always turn the syringe Pump off before cleaning.



**Caution:** Do not clean the *T34L™* syringe pump with chemicals such as Xylene, Acetone or similar solvents. These chemicals can cause damage to components and labels. Use a lint-free cloth dampened with warm water and mild detergent or 10% bleach solution.



**Caution:** Do not soak or immerse any part of the *T34L™* in water or any other solution.

## Storage

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

## Service

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

- CME or its approved service representative,
- Qualified biomedical technicians trained and certified.



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



**NOTE: DISPOSAL/DECOMMISSIONING** - when the time comes to dispose of the pump, accessories or packaging do so in the best way to minimize any negative impact on the environment. You may be able to use special recycling or disposal schemes. To find out about these contact your local waste disposal service. Existing national or local regulations concerning waste disposal must take precedence over the above advice.

# 16 – Default Syringes

## Default Syringe Brands Configured for Use with T34L™

- Braun Omnifix 2, 5, 10, 20, 30 & 50ml
- BD Plastipak 3, 5, 10, 20, 30ml & 50ml
- Monoject 6, 12, 20, 35 & 50ml
- Codan/Once 2.5, 5, 10, 20 & 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 centers or biomedical engineers. Please consult a biomed engineer or your local T34L™ distributor should this need arise.

## Time to Alarm from Occlusion

The Time to Alarm from Occlusion for the T34L 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 50/60ml syringe is  $\pm 25\%$  or  $\pm 100\text{mmHg}$

The tolerance of the BD Plastipak 5ml syringe is  $\pm 25\%$   $\pm 200\text{mmHg}$

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# LIMITED WARRANTY

The T34L™ 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 above-mentioned 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.

Mr. Zvi Barak  
Managing Director  
Caesarea Medical Electronics Ltd. (CME)