

T34L

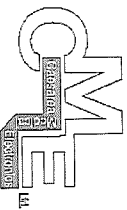
Syringe Pump Instruction Manual

IMPORTANT NOTICE: Caesarea Medical Electronics 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. or those trained by Caesarea Medical Electronics Ltd. 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.



0473

Ref.: 100-090SLU May 2008



*Org code 99
Technician code 123*

Table of Contents

A - Introduction.....	4
What is the T34L?.....	4
Indications for Use.....	5
Contraindications.....	5
Pump Lockout Protection Features.....	5
B - Warnings.....	6
C - Precautions.....	8
D - Modes of Operation.....	9
E - Feature Recognition.....	10
F - Symbols on pump, consumables & accessories.....	11
G - Installation and Inspection.....	11
H - Administration Sets.....	12
I - Recommended batteries, fitting & testing.....	13
J - Access Codes & Keypad Lock.....	14
K - Infusion set up & programming.....	15
Syringe Selection.....	15
Priming the administration set.....	15
Pre-Loading & Syringe Placement.....	15
Power Up.....	15
Syringe Detection & Confirmation.....	16
Setting Infusion Parameters.....	17
Setting the Infusion Rate.....	17
L - Using Accessories with T34L Syringe Pump.....	19
M - Recommended Checks during infusion.....	20
Event Log.....	20
N - Advanced Functions of Caesarea Medical Electronics Ltd. T34L Pump.....	21
KVO (Keep Vein Open) Operation.....	21
Infusion Rate Titration.....	21
O - Alarm Conditions.....	22
P - Troubleshooting.....	23
Q - Change Set Up.....	24

R – Caesarea Medical Electronics Ltd. T34L Syringe Pump Specifications	25
S – Service and Maintenance	26
Cleaning	26
Storage	26
Service.....	26
T – Patient Training – Using the T34L.....	27
U - LIMITED WARRANTY	28
V – Default Syringes	29
W – Detailed Index	29

A - Introduction

NOTE: 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
6. Train patients and/or patient's caregiver in the use of the T34L

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.

NOTE: 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.

What is the T34L?

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/hr). A screw drives the pump actuator and syringe plunger forward at a controlled rate. This rate is adjustable from 0.1 to 1000 ml/h in increments of 0.1 ml/h up to 100 ml and 1 ml from 100 to 1000 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.

NOTE: 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, and (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: The user that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Indications for Use

The T34L SYRINGE DRIVER 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, intra-arterial, epidural, enteral, in close proximity to nerves, and into an intraoperative site (soft tissue/body cavity/surgical wound site). The system is intended for patients who require maintenance medications, analgesics, PCA therapy, parenteral and enteral nutrition fluids, chemotherapeutic agents and general fluids therapy in hospital and homecare environments.

NOTE: T34L is a medical device designed for the safe, accurate delivery of appropriate infusion regimens 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.

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.

Pump Lockout Protection Features

The T34L has several lockout features that ensure that unintended programming and key presses do not occur.

- The T34L syringe is contained within a locked box. Only the healthcare provider is able to open the box.
- After the healthcare provider programs the T34L for infusion, they will lock the program with a special code. The T34L infusion program cannot be changed unless the healthcare provider re-enters the code and changes the program.
- The keypad has a locking feature that prevents unintentional power off of the unit. This lock is available to the patient.

Service screens and troubleshooting are protected with a technician's code. These codes are only available to personnel trained in servicing the T34L.

B – Warnings

To reduce potential risks to patients and healthcare providers.

- ⚠ The T34L is a medical device designed for the safe, accurate delivery of appropriate infusion regimens and should only be operated by, or under the supervision of, a medical/healthcare professional.
- ⚠ For pumps used in a home setting, once the prescription has been programmed into the pump, lock the system to ensure that the program cannot be changed by the patient.
- ⚠ The equipment is not suitable for use in the presence of flammable anesthetic gas /oxygen/nitrous oxide mixture. Do not use the system in environments where these agents are present.
- ⚠ Do not use the T34L pump in the presence of high-intensity magnetic fields (e.g., MRI scanners). Exposure to strong magnetic fields may impair the operation of the pump and/or the accuracy of the infusion.
- ⚠ Never take a syringe that is not empty off the pump if it is still connected to the patient. Before removing the syringe, the infusion line must be disconnected or clamped to prevent free flow. Depending on the medication and route of administration, free flow into the patient may cause serious injury or death.
- ⚠ Before connecting to the patient, purge all air from the syringe and the administration set. Depending on the route of administration and the volume of air, air emboli infused into the patient may cause serious injury or death.
- ⚠ Patients using the T34L Syringe Pump on their own, or individuals responsible for helping a patient using the pump, must be instructed in its proper use.
- ⚠ Adjustments, maintenance, or repair made by un-certified service personnel may impair the operation of the T34L System and/or the accuracy of the infusion. Make sure any adjustments, maintenance, or repair of the device is carried out by authorized skilled technicians trained by the T34L distributor.
- ⚠ Dropping the Syringe Pump could cause damage to components. If the pump is dropped, return the pump for inspection by qualified service personnel.
- ⚠ Use good aseptic technique when filling the syringe and priming the infusion 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 IV sets.
- ⚠ Immersing the T34L Syringe pump in liquid could cause damage to components. Do not immerse the pump into any type of liquid.

- ⚠ Federal [USA] Law restricts this device to sale by, or on the order of, a physician.
- ⚠ The maximum volume that may be infused under SINGLE FAULT CONDITION is 0.15 ml (depending on syringe size in use).
- ⚠ Voltage present on internal components may cause severe shock or death upon contact. Disconnect the Charger from the mains, prior to opening the casing. Only trained service personnel should open the pump cover.
- ⚠ Blown fuses could cause a fire hazard. Replace blown fuses on the Charger only with fuses of the same type and rating (see fuse values on the Charger PCB).
- ⚠ The T34L should be operated within a temperature range of 15°C (59°F) to 45°C (113°F) and up to 85% humidity. Operating the pump at temperatures and/or humidity other than within that range may affect accuracy.
- ⚠ Battery charging is enabled as long as the charger cord is connected to the mains and the pump is connected to the charger. Switching the pump off does not disconnect it from the mains. To disconnect from mains, remove the charger cord from mains. To disconnect pump from mains, disconnect it from the charger.

C – Precautions

- Information to ensure safe and effective use.
- ⇒ Before use, the user must become thoroughly familiar with the operating instructions contained in the T34L user manual.
- ⇒ The provider is responsible for ensuring that the T34L pump and medications are used according to the physician's infusion therapy prescription.
- ⇒ The provider is responsible for educating the patient in proper use of the pump.
- ⇒ Do not allow water or other fluids to get inside the pump or the lockbox. Fluids getting into the pump may damage it. If the pump gets wet, stop the pump and initiate service of the pump.
- ⇒ A security code must be keyed in to access the lock-level 2 programming functions. This code is designed to allow access to the provider only. To prevent a patient from tampering with programmed settings, this security code should not be given to the patient.
- ⇒ As with any infusion, the disposables used with the T34L pump must be compatible with the medication being delivered. Check with the manufacturer of the disposables before use. Consult the drug manufacturer's insert for precautions, guidelines, and instructions for preparing and using the medication.
- ⇒ Do not drop the pump, strike it against hard objects or otherwise subject it to extreme physical stress. This could damage the pump, which may impair the operation of the pump and/or the accuracy of the infusion. If the pump is dropped, return the pump for inspection by qualified service personnel.
- ⇒ Unsafe operation may result from using improper accessories. Use only accessories and options designed for this system and supplied by the T34L distributor.
- ⇒ 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.
- ⇒ Make sure any adjustments, maintenance or repair of the device are carried out by authorized service technicians certified by the T34L distributor. Adjustments, maintenance or repair made by un-qualified service personnel may impair the operation of the pump and/or the accuracy of the infusion.
- ⇒ Battery damage could occur at ambient temperatures >55°C (131°F).
- ⇒ The pump housing is not hermetically sealed – immersing the pump in liquid could cause damage internal components. Do not immerse the pump into any type of liquid.
- ⇒ If fluid is spilled on the pump, clean and dry it immediately. A damp cloth should be used for cleaning and a mild detergent may be used if needed. Xylene, acetone or similar solvents could damage the pump – do not clean the pump with harsh chemicals.