Supporting Information

Essential reading for those formulating a Purchasing for Safety Initiative for safer ambulatory syringe drivers
On 16 December 2010 the National Patient Safety Agency published a Rapid Response Report requiring all NHS organisations to develop a Purchasing for Safety Initiative with regards to the ambulatory syringe drivers that are extensively used in palliative care and other specialist applications (NPSA RRR019, 2010).

CME Medical understands the challenge that Trusts and their care teams face in the transition from long-established equipment to a new ambulatory syringe driver.

The CME T34™ features all of the additional safety requirements set out by NPSA, and complies with all safety standards in place at the time of the Rapid Response Report.

Our team has already helped around 50% of UK Trusts to make this transition since the launch of T34™ in 2006. We are the only team in the UK with extensive experience of helping palliative care teams make the safe and successful transition described by NPSA, and the T34™ is the only product widely proven to be intuitive enough to ensure clinical teams adapt quickly and safely to the benefits of the latest technology.

Furthermore, you have my assurance, as Managing Director of CME Medical, that appropriate resources and support will be available to your teams to ensure that you can take the steps required to reduce the risks during the transition period.

Our experience to date has shown that a collaborative approach to the implementation of new infusion technology guarantees a safe and successful implementation.

As Rapid Response Reports require Trust Chief Executives to nominate an executive director to oversee action taken to address the issues raised, CME’s executive team are available on request to liaise with Trust executives if required.

Should any member of your implementation team wish to discuss how CME can help you respond to the Rapid Response Report, please call our team on 0844 9744090.

Stephen Thorpe
Managing Director
CME Medical UK Ltd
Purchasing for Safety initiative

The CME T34™ meets all of the key requirements for new technology set out in the Rapid Response Report, namely:

- Rate setting in millilitres (mL) per hour
- Mechanisms to stop infusion if the syringe is not properly and securely fitted
- Alarms that activate if the syringe is removed during infusion
- Lock-box covers and/or lock-out controlled by password
- Provision of internal log memory to record all pump events (NPSA, 2010)

Furthermore, the CME T34™ could have addressed all of the reported issues that resulted in 8 fatal and 167 non-fatal incidents with syringe drivers that occurred during this timeframe, as described in the table below.

<table>
<thead>
<tr>
<th>Type of error reported to NRLS</th>
<th># of Events</th>
<th>Is the issue addressed by CME T34™?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect rate setting</td>
<td>53</td>
<td>Addressed. T34™ calculates the rate for the user based on locally applied settings</td>
</tr>
<tr>
<td>Unexplained fast infusion</td>
<td>42</td>
<td>Probably a result of incorrect rate setting (see above)</td>
</tr>
<tr>
<td>Confusion between mm/hr device &amp; mm/24hr device</td>
<td>14</td>
<td>Addressed. There is only one device type to prevent confusion</td>
</tr>
<tr>
<td>Syringe incorrectly inserted</td>
<td>11</td>
<td>Addressed. T34™ has three-point syringe detection and alerts/advice for users</td>
</tr>
<tr>
<td>Syringe dislodged</td>
<td>9</td>
<td>See above. Infusion will stop and pump will alarm</td>
</tr>
<tr>
<td>Unexplained slow infusion</td>
<td>8</td>
<td>Probably a result of incorrect rate setting (see above)</td>
</tr>
<tr>
<td>Driver set up incorrectly</td>
<td>8</td>
<td>Screen messages and alerts during set up should prevent common set-up errors</td>
</tr>
<tr>
<td>Tampering by patient</td>
<td>7</td>
<td>Addressed. T34™ features program code protection, keypad locks and a lockbox</td>
</tr>
<tr>
<td>Confusion over mm and ml</td>
<td>7</td>
<td>Addressed. T34™ runs only in mL/hr, most commonly used unit for fluid delivery</td>
</tr>
<tr>
<td>Unexplained failure to deliver infusion</td>
<td>5</td>
<td>Addressed. T34™ features history &amp; event logs to detail any alarms/alerts</td>
</tr>
<tr>
<td>Other</td>
<td>11</td>
<td>T34™ has addressed all concerns raised by users and MHRA with regards to older technology</td>
</tr>
</tbody>
</table>

Total 175

Source for types of error reported to NRLS and number of events: NPSA, 1287A. 2010:5
Product information

The T34™ Ambulatory Syringe Pump offers the features and functionality of a much larger pump in a small, battery-powered device. Safe, simple and reliable, the T34™ can deliver infusions for a wide range of clinical applications, enabling small volumes to be administered with high levels of accuracy. Suitable for subcutaneous, intravenous, epidural, and intra-arterial administration, it is ideal for use where fixed or variable infusions of medications are required in hospitals, hospices, nursing homes and in the community.

At CME Medical we believe that simplicity of operation can enhance the safety of a product; we have therefore made programming the T34™ so straightforward that full set-up instructions fit on a small label on the front of the device.

Once the user has correctly seated the syringe and confirmed the syringe brand and size (sensors automatically detect all commonly used syringe brands and sizes from 2ml to 50ml), the pump calculates the volume in the syringe, eliminating the need to measure the length of the syringe content. The pump then uses the pre-set default duration and syringe dimension data stored in its memory to calculate the infusion rate specific to the volume identified. The user is not required to perform any calculations, significantly reducing the risk of programming errors.

The T34™ has alerts for low battery and near end of infusion. It also monitors for alarm conditions during the infusion, such as occlusion, syringe displacement (an on-screen indicator shows which part of the syringe is displaced), system malfunction, end battery and end of infusion. Users are made aware of alarm states both visually and audibly, by LCD screen messages, a red LED on the keypad, and by an alarm sound.

Current infusion history can be accessed during infusion via the INFO key on the keypad. A 512-event (date- and time-stamped) log is available that can be viewed from the pump info menu or downloaded to a PC for analysis.* The event log records, for example, infusion history, user interactions, alarm states and pump hourly self testing.

* Optional hardware and software is required for download to PC. See Page 15 for further information.
NHS buyers guide

In December 2008, the Centre for Evidence-based Purchasing (then part of the NHS Purchasing and Supply Authority) published an ambulatory syringe driver buyers guide. This market review was compiled by the Bath Institute of Medical Engineering and compared ambulatory syringe drivers available in the UK market. The review discusses the technical, operational, economic and purchasing issues that potential buyers should consider and also includes the results from a panel assessment of usability and a user survey.

INDEPENDENT USABILITY ASSESSMENT

The usability assessments were carried out by a team of trained evaluators and palliative care specialists, working in both hospital and community settings. The participants were asked to carry out pre-defined tasks with each syringe driver, based on typical procedures, and then to individually complete a usability questionnaire.

In the panel assessment of usability the T34™ achieved the highest score of all the drivers assessed for setting up the pump, setting up the infusion and monitoring. For overall usability the T34™ received the highest award of all of the drivers assessed, of 4 out of 5 stars.

The T34™ was identified in the report as fully complying with International Standard IEC 60601-2-24, Particular Requirements for the Safety of Infusion Pumps and Controllers, which was developed to ensure the safety of infusion pumps.

<table>
<thead>
<tr>
<th>T34 user assessment results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>User survey results</strong></td>
</tr>
<tr>
<td>Support from manufacturer</td>
</tr>
<tr>
<td>Ease of cleaning</td>
</tr>
<tr>
<td>Meeting user needs</td>
</tr>
<tr>
<td><strong>Panel assessment of usability</strong></td>
</tr>
<tr>
<td>User instruction</td>
</tr>
<tr>
<td>Setting up the pump</td>
</tr>
<tr>
<td>Setting up the infusion</td>
</tr>
<tr>
<td>Monitoring</td>
</tr>
<tr>
<td>Safety</td>
</tr>
<tr>
<td>Overall usability for palliative care applications</td>
</tr>
</tbody>
</table>

★ = Very poor ★★ = less than acceptable ★★★ = acceptable ★★★★ = good ★★★★★ = very good

Source: Buyers Guide Ambulatory Syringe Drivers (CEPo8046)
Clinical training

TRAINING PROVISION
by CME Medical Clinical Support Team

Successful change in any hospital, large or small, is wholly dependent on the collaboration between your organisation and the CME Medical Clinical Support team. During the pre-conversion stage, a product and training needs analysis will be conducted by the Clinical Support Specialist assigned to your project, to identify any clinical practice and local policy issues associated with conversion and to design a training programme that is individual to local needs, fit for purpose and achieves training objectives.

Pre-implementation meetings with the hospital conversion team allow all key stakeholders to participate in the planning process to ensure successful transition. A Training Manager Resource file is provided which contains all of the information, forms and resources required for a successful device transition.
Clinical training

TRAINING METHODS

CME Medical has developed a range of face-to-face and e-learning competency-based educational training programmes based on current and established principles of teaching/training standards and methods.

All training delivered by CME Medical complies with national standards for medical device training (MHRA Device Bulletin: Infusion System. DB2003 (02) v2.0 November 2010).

Training modules include:

- Professional User Workshop
- Device Expert (super user) Workshop
- Advanced User Workshop*
- Device User Workshop*
- Device Awareness sessions

* Device User and Advanced User training workshops are RCN-accredited.
Clinical training

TRAINING AND PUMP CONVERSION PROCESS FLOW CHART

- Initial contact with Training Manager
  - The Clinical Support Specialist will carry out:
    - Training needs analysis
    - Clinical analysis of infusion therapy products and practices
    - Arrange professional user training for key stakeholders (if required)

- Pre-implementation meetings with conversion team*
  - Discuss, plan and agree:
    - Results of TNA and clinical analysis of infusion therapy products and practices
    - Pump management: lines/lockbox/pouches use
    - Writing of local policy on pump use
    - Pump configuration (+/- access codes)
    - Pump service and maintenance requirements
    - Training methods and dates
    - Confirmation and signing of training contract
  *Conversion team may include medical devices educator, equipment library, clinical engineering, pharmacy, medical and nursing staff, learning and development colleagues

- Training and device conversion
  - Train staff over the agreed time period
  - Clinical Support Specialist will support device experts prior to and during pump conversion
  - Revise planning if challenges or issues arise

- Evaluation post-conversion
  - Was the device conversion successful?
  - Has the quality of training and learning been evaluated?
  - Have any process improvements been identified?
    - Post-conversion follow-up visit within three months
    - Annual super user training required

Training and device conversion evaluation post-conversion
Technical support services

Your technical support needs are our priority. As an ISO 13485 certified support facility, we can offer you high quality technical support and training, with services developed by our customers for our customers.

You and your team will benefit from market leading technical training and support services. We will work with you to ensure you receive the best possible service package for your needs.

EQUIPMENT REPAIR AND SERVICING

Our team of highly skilled engineers will support you by ensuring competitive turnaround times. Prompt order fulfilment for spare parts is guaranteed by our significant stock holding capability.

SERVICE CONTRACTS

When entering into a service contract with CME Medical, a partnership is formed to ensure your requirements are identified and addressed from the outset.

If you require any additional information regarding the services CME Medical offers, please do not hesitate to contact the Technical Services team on 01253 220135 or email service@cmemedical.co.uk.
Technical training

Your own biomedical engineer has an important role in supporting and maintaining the T34™ syringe pump. CME Medical provides technical training courses designed to give your engineer the knowledge and skills to effectively support our range of infusion devices.

BIOMEDICAL ENGINEER TRAINING

Assisted (First-Line) Service Technical Training

This instructional demonstration shows the biomed engineer how to perform acceptance and functional testing. It provides sufficient instruction to enable your organisation to take out an Assisted Level service contract, covering:

- Clinical and user operations
- Equipment specification
- Functional test procedures
- The use of BodyComm software and docking station (optional), to enable you to download the event log and upload settings and protocols.

Comprehensive (Second-Line) Service Training

This one-day training course is designed to impart all of the knowledge and expertise necessary to enable the engineer to provide first- and second-line technical support.

The training deals with the following areas:

- Clinical and user operations
- Equipment specification
- Functional test procedures
- Tools and test equipment requirements
- Accessing and navigating the Technician’s Menu
- Planned preventative maintenance procedures
- Fault diagnosis – system error coding
- Disassembling and reassembling the pumps
- Calibration routines
- The use of BodyComm software and docking station (optional), to enable you to download the event log and upload settings and protocols.

At the end of the training course each engineer will be forwarded a certificate of attendance.
BodyComm software and docking station

BodyComm is a PC-based software package that enables the engineer to programme the T34™ Ambulatory Syringe Pump via an RS232 communication docking station. The software allows you to save the set-up and syringe data and relay these files to subsequent pumps. BodyComm also enables you to download, save and print the events log.

Use of the software and docking station can aid the investigation of clinical incidents and can help ensure that all pumps are configured the same way without error. They are not, however, essential for the repair of the T34™.
Quality assurance

QUALITY MANAGEMENT SYSTEMS


It is our policy to provide infusion pumps, consumables, accessories and the associated servicing and training that continually meet or exceed our customers' needs and expectations with respect to quality, safety and reliability.

Our Quality Management System is supported by documentation, procedures and records to ensure that customers receive products and services at the highest level of quality.

CUSTOMER CARE

We operate a proactive customer care system by encouraging comments, both positive and negative, from our customers via our feedback system, thus ensuring that we maintain and improve satisfaction for all our customers.

Our robust customer complaints procedure ensures that all complaints are handled in a timely manner. It is our objective to close out complaints within a six-week period.

The procedure ensures the following:

• All complaints are acknowledged on receipt
• Any patient incident is determined and the risk assessed

• A full investigation is conducted to determine the root cause of the incident
• Short-term and long-term corrective action is implemented to prevent a recurrence
• The customer is informed of the outcome.

We co-operate with all regulatory authorities, where applicable, to make certain that any incidents are resolved effectively, thus ensuring the continued safety of all our products.

To assist us with an effective complaint investigation we ask that our customers:

• Report all incidents pertaining to our devices as soon as possible after occurrence
• Provide us with the details of any patient incident/injury
• Give full details of the incident, including product code, lot/serial number, medication in use/procedure taking place at the time of the incident
• Return the product or part in question if possible. For pump complaints, the administration set in use at the time of the incident should also be returned. Please note that contaminated products must not be returned.
Frequently asked questions

**Q** Are there any infusions for which the T34™ is not suitable?

As it was designed predominantly for ambulatory use, the T34™ is a battery-operated device, and unlike some mains-operated infusion pumps does not contain a back-up power supply. In line with MHRA guidelines, no battery-operated device should be used to deliver medications or infusions that are considered to be life-sustaining without a suitable back-up being in place. The decision whether or not to use a battery-operated device ultimately rests with the physician, who should consider the risks and benefits of its use in each case before proceeding.

**Q** How long do the disposable batteries last?

The average battery life lasts through 7 full infusions. Actual battery life is dependent on what is being infused and for how long. Excessive key presses can also cause faster battery depletion.

**Q** Can the T34 use rechargeable batteries?

Yes. The life expectancy of rechargeable batteries varies from brand to brand and diminishes with use, so we recommend that a disposable 9V Duracell battery is retained as a secondary power source, in the event of premature power loss.

**Q** What are the benefits of using a lockbox?

The lockbox can help prevent interference with the syringe or accidental displacement, and provides the pump with some protection against wear and tear, including offering limited protection against impact (such as being dropped).

**Q** Can the keypad be locked to prevent tampering or inadvertent key press?

Yes. A specific technique is required to lock and unlock the keypad. With the keypad locked and an infusion running the user can monitor the infusion but cannot access the menus, change settings or power off the pump.

**Q** How long is the warranty on the T34™ and when does it commence?

The T34™ Ambulatory Syringe Pump is supplied with a 24-month warranty. The warranty period starts from the purchase date, as indicated on the invoice.

**Q** What happens if I don’t take out a service contract and the pump needs servicing or repairing?

Our Service Centre offers a return-to-base option at a fixed cost. This is inclusive of labour and any parts that may be required for the service or repair. If the pump is under contract but the fault is judged to be the result of accidental or malicious damage, our Service Centre staff will evaluate the damage and send you a quotation for the repair.

**Q** What are my post-warranty service contract options?

CME Medical offers a range of service contract options, as detailed on page 13 of this guide.
# T34 specification

<table>
<thead>
<tr>
<th>Type</th>
<th>Syringe pump with motor driven linear actuator, pulsed motion (540 pulses per mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow rate</td>
<td>0.05–10ml/h in 0.01ml increments, 10 to 650ml/h in 1 ml increments</td>
</tr>
<tr>
<td>Actuator travel</td>
<td>c.67 mm available</td>
</tr>
<tr>
<td>Syringe sizes</td>
<td>2 ml to 50 ml (manufacturers most commonly available)</td>
</tr>
<tr>
<td>Accuracy</td>
<td>± 5 % system accuracy (pump and set combined)</td>
</tr>
<tr>
<td>Occlusion pressure</td>
<td>100–1500mmHg configurable (10mmHg increments). Max. actuator force 50N (5 Kgf)</td>
</tr>
<tr>
<td>Battery</td>
<td>9V alkaline, IEC 6LR61 type</td>
</tr>
<tr>
<td>Battery operation</td>
<td>Approximately 7 full infusions</td>
</tr>
<tr>
<td>Indicators</td>
<td>4 Line LCD display (122 x 32 pixels), Dual colour operation LED</td>
</tr>
<tr>
<td>Alarms</td>
<td>When a problem is detected, the T34 displays the following alarm messages, sounds an audible alarm and the red LED lights: Occlusion or syringe empty, Pump paused too long, End program, Syringe displaced, End battery, Syringe empty</td>
</tr>
<tr>
<td>T34 dimensions</td>
<td>169 x 53 x 23mm</td>
</tr>
<tr>
<td>Classification</td>
<td>Type CF Equipment, degree of protection against electrical shock, Class II equipment, IPX3 protection against ingress of water</td>
</tr>
</tbody>
</table>

| Housing | ABS (fire retardant) |
| Weight | 210g without battery, 274g with battery |
| Electrical safety | Complies with EN 60601-1 (Medical Electrical Equipment Safety), IEC 60601-2-24 (Infusion pumps and controllers), IEC 60601-1-4 (Programmable Electrical Medical System) |
| EMC | CME Medical T34™ Ambulatory Syringe Pump is designed to be in compliance with EN60601-1 (safety) and IEC 60601-2-24 (EMC) |
| Environmental specifications | Non-operating conditions (transportation and storage): Temperature: –25°C to +55°C (–13°F to +131°F) Humidity: 5 % to 100 % RH, 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: 0°C to +45°C (32°F to +113°F) Humidity: 20% to 85 % RH at +40°C, non-condensing Air pressure: 70kPa to 110kPa |

Source: CME UK T34™ Ops Manual Rev 1.4
Pricing structure

To ensure transparency across all accounts, we have established the following discount structure. Prices apply to individual order volumes only, and cannot be applied retrospectively on cumulative order quantities.

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>T34™ Ambulatory Syringe Pump</td>
</tr>
<tr>
<td>Clear Pump Lockbox*</td>
</tr>
<tr>
<td>Yellow Pump Lockbox*</td>
</tr>
<tr>
<td>*Lockbox supplied with two keys</td>
</tr>
<tr>
<td>Small Carry Pouch (pump only)</td>
</tr>
<tr>
<td>Standard Carry Pouch (pump and lockbox)</td>
</tr>
<tr>
<td>Disposable Carry Pouch (pump and lockbox)</td>
</tr>
<tr>
<td>Spare Lockbox Key</td>
</tr>
</tbody>
</table>

For current price information, please contact our customer services team:

01253 206630
salesorders@cmemedical.co.uk
## Pricing structure

### ADMINISTRATION SETS

<table>
<thead>
<tr>
<th>Product code</th>
<th>Colour</th>
<th>Syringe connection</th>
<th>Patient connection</th>
<th>Length</th>
<th>Priming volume</th>
<th>Additional features</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>100-172S</td>
<td>Clear</td>
<td>Female luer lock</td>
<td>Male luer lock</td>
<td>100cm</td>
<td>0.5ml</td>
<td>Anti-siphon valve and clamp</td>
<td>Price on request</td>
</tr>
<tr>
<td>100-170S</td>
<td>Clear</td>
<td>Female luer lock</td>
<td>25g butterfly needle</td>
<td>100cm</td>
<td>0.5ml</td>
<td>Anti-siphon valve and clamp</td>
<td>Price on request</td>
</tr>
<tr>
<td>100-172SB</td>
<td>Blue</td>
<td>Female luer lock</td>
<td>Male luer lock</td>
<td>200cm</td>
<td>0.7ml</td>
<td>Anti-siphon valve and clamp</td>
<td>Price on request</td>
</tr>
<tr>
<td>100-172SE</td>
<td>Yellow</td>
<td>Female luer lock</td>
<td>Male luer lock</td>
<td>100cm</td>
<td>0.5ml</td>
<td>Anti-siphon valve and clamp</td>
<td>Price on request</td>
</tr>
<tr>
<td>100-172SC</td>
<td>Blue</td>
<td>Female luer lock</td>
<td>Male luer lock</td>
<td>100cm</td>
<td>1.0ml</td>
<td>Anti-siphon valve and clamp</td>
<td>Price on request</td>
</tr>
<tr>
<td>100-171S</td>
<td>Clear</td>
<td>Female luer lock</td>
<td>Male luer lock</td>
<td>100cm</td>
<td>0.5ml</td>
<td></td>
<td>Price on request</td>
</tr>
</tbody>
</table>

All sets are latex-free and use anti-kink tubing. Length and priming volume are approximate.

All prices are exclusive of VAT. Costs correct at time of printing.
Account and ordering information

PURCHASING DIRECT

CME Medical is able to accept orders by post, fax and e-mail. Orders should be placed via official purchase orders from your organisation.

Orders are accepted subject to our Terms and Conditions of Sale as printed on the reverse of our invoice (available to view on request).

If you already have an account set up with us our standard payment terms of 30 days from date of invoice will apply. Requests for credit accounts should be referred to our Finance Department. Approval for NHS Trusts is guaranteed; however, private organisations may need to provide information to enable us to set up and approve the account before dispatch. All non-NHS customers are required to pay on a proforma basis for their first order.

CME Medical also accepts payment by credit and debit cards.

Should your organisation be exempt from VAT on your purchased goods you will need to supply us with a completed VAT exemption certificate at the time of order.

PURCHASING VIA THE NHS SUPPLY ROUTES

T34™ and other CME infusion products have been awarded positions on the following National Framework agreements, which may be referenced or quoted when compiling a business case or justifying a purchase.

NHS Supply Chain
Framework for the Supply of Infusion Pumps
2009/s183-263581
Framework for Infusion Supplies
233080-2010
Framework for Administration Sets
264243-2011
www.supplychain.nhs.uk

National Services Scotland
NP146/10 Infusion devices and related consumables
Mark.nicol@nhs.net
Contact details

CME Medical operates out of purpose-built premises. Our address is:

Kincraig Business Park
Kincraig Road
Blackpool
Lancashire
FY2 0PJ

Telephone: +44 (0)1253 894646
Fax: + 44 (0)1253 896648
Email: info@cmemedical.co.uk
References


