Health Guidance

CME T34 Ambulatory syringe pump
Used in the provision of adult palliative and end of life care

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The contents should not be regarded as a statement of The Care Inspectorate policy, nor relied upon as a comprehensive statement of best practice, but as common sense guidance on issues of topical interest based upon authoritative statements of best practice in the field, at the time of preparation, and which may be of assistance to Care Inspectorate staff when reviewing practices and policies.

This guidance may be of interest to others who have an interest in the use of T34 ambulatory syringe pump.
CME T34 Ambulatory syringe pump

Care Inspectorate staff may come across this medical device, that is, the CME T34 ambulatory syringe pump, in care homes, care at home services and hospitals due to the size and portable nature of this device.

Outcome of Health Guidance
To ensure people in the services we regulate are cared for in a safe environment by staff who know how to use medical equipment safely.

This guidance provides information on systems that must be in place in registered care services to ensure that the CME T34 ambulatory syringe pump (previously has been referred to as the McKinley T34 syringe pump) is used safely. Staff in services must be sure that they can demonstrate competent person-centred, safe and effective healthcare.

To support best practice in the hospital, hospice and community setting throughout Scotland there is a national policy and guidelines on this device. These can be found at NHS Education for Scotland (NES) at the Pharmacy section for further reference (March 2011)¹
http://www.nes.scot.nhs.uk/media/347814/mckinley_20t34_20syringe_20pump_20guidelines_20final.pdf

What is Palliative Care?
Palliative care is a proactive approach involving a multi-professional team. As well as controlling pain and other distressing symptoms, it applies a holistic approach to meeting the physical, practical, functional, social, emotional and spiritual needs of patients and carers facing progressive illness and bereavement.

Although historically associated with the later stages of cancer, it is now established that palliative care should also be a routine part of care for those living with and dying from a wide variety of non-malignant conditions, such as dementia, heart failure, Huntington's disease, motor neurone disease, multiple sclerosis, muscular dystrophy, Parkinson's disease, renal failure and respiratory failure among others.

Palliative care can be provided at any stage following diagnosis of a life-limiting illness or condition, and not solely in the last few days, weeks or months of life. A palliative care approach should be used as appropriate alongside active disease management from an early stage in the disease process (Scottish Partnership for Palliative Care, 2014)².
Introduction
An important element of palliative care is concerned with controlling pain and other symptoms for an individual person. When a person is unable to swallow oral medicines to relieve symptoms, for example, pain relieving medicine (analgesia) or anti sickness medicine (anti emetic) other alternative ways of administering medicine may have to be considered.

One method is by administering medicine by a continuous subcutaneous infusion (CSCI) via a syringe pump which avoids the need for repeated injections which can be painful and unacceptable.

The medical infusion device that this guidance refers to is the CME (McKinley) T34 syringe pump which was launched in the United Kingdom in 2005.

What is the CME T34 Syringe Pump?
The CME T34 syringe pump is a small, lightweight, battery powered, ambulatory syringe pump which has a Liquid Crystal Display (LCD) screen.

The pump can detect the size of the syringe, and calculates the appropriate rate. It also has a rapid occlusion alarm and a message appears on the display screen indicating the cause of the alarm.

Summary of what can be displayed:

- deliverable volume
- rate in milliliters per/hour (ml/hr)
- duration of infusion
- syringe size
- cause of the alarm and alerts
- error messages
- context-sensitive instructions

The standard delivery period for a continuous subcutaneous infusion in palliative care is 24 hours.
Advantages
- Acceptability and reliability
- Reduced need for injections
- Maintenance of a person’s mobility
- Constant therapeutic drug levels over a 24 hour period
- Only requires being re-filled every 24 hours

Disadvantages
- Potential source of infection
- Skin site reactions
- In emaciated people or those on long term infusions, skin site availability may become an issue
- Need for daily visit in the community
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Policy and procedure:
To inform and guide staff the service must have a policy and procedures on the use of the CME T34 syringe pump.

Manufacturer’s guidance:
The service should have the manufacturer’s instruction manual on the use of the CME T34 syringe pump available for staff, service users and their relatives.

Education and training:
Before use staff must have received education and training on the setting up and management of these devices. Professionals in health and social care are personally accountable when they use devices and have a personal responsibility and accountability to ensure they receive education and training in the safe use and observation of any medical device they need to use. (MHRA)


The provider and manager of care services, such as, care homes and care at home services should ensure that education and training takes place and maintains a record of staff that is trained and competent to use such devices.

“The Healthcare organisation should ensure that continuous professional development and training activities include the safe use of medical devices during staff appraisal”. (Medicines and Healthcare products Regulatory Agency (MHRA) Managing Medical Devices 2014)


Registered nurses must be registered with the Nursing & Midwifery Council (NMC). At supervised practice a nurse can discuss continuing education, training and supervised practice to keep up to date.

Recording and documentation:
The service should have the following appropriate documentation to monitor the CME T34 Syringe Pump:

- a record of the type of device being used
- infusion sites, care of and site changes
- prescription chart for medicines
- records for recording and checking medicines for use in syringe pumps
- monitoring chart (to record checks whilst syringe pump in use)
- assessment tool for pain and / or symptom control

Registered nurses must comply with the most recent guidance published by the Nursing and Midwifery Council (MWC) about records and record keeping.
Access to specialist advice:
Often medical devices such as syringe pumps are not used on a regular basis in services such as care homes. It is very important that care services have access to specialist advice and support when required. From, for example, members of the primary healthcare team, such as, district nurses, general practitioners, or from staff based in hospices or specialist palliative care units in general hospitals.

Services should have access to advice on medicines used in the CME T34 syringe pump, for example, on drug choice and dose. Sources of advice may be from the service users GP, specialist palliative care pharmacists, hospital palliative care pharmacists or local hospice staff. Advice may also be found in the services local NHS palliative care guidelines.

The service should be aware that staff / practitioners should be seeking advice for drugs and combinations with which they are not familiar.6

Guidelines about syringe pump:
The services should have access to their local NHS guidelines on the CME T34 Syringe Pump.

Informed consent:
The individual / service user should give informed consent. Where this is not possible the Adults with Incapacity Act (Scotland), should be referred to7.

Service user information:
Service user information should be available, for example, if the service user goes home with the device at a weekend, or on pass, they should be given verbal and written information on the use of the syringe pump device and who to contact in an out of hours and emergency situation.

Safety and risk assessment:
The service should assess if they require using accessories that protect the syringe pump from accidental knocks and tampering, such as, the optional lockbox or carry pouch.

Safe storage:
The service should have proper safe storage facilities for this device.

Syringe pump maintenance:
If the service provider owns the device, systems must be in place to have the T34 syringe pump serviced regularly, at least annually whether used or not. The service should be made at a medical physics department by authorised personnel.

Syringe pumps should be sent for maintenance checks immediately if they have been dropped, suffered fluid ingress, for example, fluid split over the device or device accidently dropped in a bath or if there is any doubt as to their functional operation whilst in use.
Cleaning and decontamination:
Cleaning should be carried out as recommended by the manufacturer. Access to infection prevention and control personnel should be available if required.

Adverse Incidents and Hazard Warning Notifications:
Role of the Medicines and Healthcare products Regulatory Agency (MHRA)

- MHRA has responsibility for ensuring that medicines and medical devices are effective and acceptably safer. MHRA asks healthcare workers, carers, patients, and members of the public to report adverse incidents involving medical devices. When a medical device is suspected or known to be faulty, MHRA will work with manufacturers and distributors on the most appropriate and timely action to take⁴.

- The service should be aware of how to report adverse events or incidents to the Regulating Medicines and Medical Devices (MHRA) if there is an incident involving a device. http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Devices/

- The service should receive or have access to safety warning notices and medical device alerts. It is important that relevant notices are acted and reported upon.

Out of hours arrangements:
Out of hour’s arrangements for staff should be in place, for example, if the device was to stop in an out of hour’s situation contact details of who to contact should be available to support staff.
References

1. NHS Education for Scotland Guidelines for the McKinley T34 at Pharmacy (2011)
   http://www.nes.scot.nhs.uk/media/347814/mckinley_20t34_20syringe_20pump_20guidelines_20final.pdf

2. Scottish Partnership for Palliative Care (2014) online definition What is palliative care?
   http://www.palliativecarescotland.org.uk/content/what_is_palliative_care/

3. Medicines and Healthcare products Regulatory Agency (MHRA) Devices in Practice (June 2014) Checklists for using medical devices
   www.mhra.gov.uk/home/groups/dts-bs/documents/publication/con007424.pdf

   www.mhra.gov.uk/home/groups/dts-s/documents/publication/con2025143.pdf


7. Adults With Incapacity Act (Scotland) Act 2000
Further reading

CME T34 Syringe pump brochure can be accessed at:
http://cmemedical.co.uk/products/t34-ambulatory-syringe-pump/index.asp

Regulating Medicines and Medical Devices: What you need to know, this brochure can be accessed at: www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con2031677.pdf

MHRA for care homes

Report medical device adverse incidents at www.mhra.gov.uk

Health Facilities Scotland Incident Reporting and Investigation Centre (IRIC)
http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric

McKinley T34 Guidelines are available from Health Boards areas:
http://www.palliativecareguidelines.scot.nhs.uk/subcutaneous_medication/

Local palliative care guideline information:
www.palliativecareguidelines.scot.nhs.uk

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