Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/038 Issued: 29 October 2019 at 14:00

Syringe driver pumps: T34™ 3rd edition models only – stop using the pump until updated instructions for use and BodyComm™ V3.0 software are released

Summary

Manufactured by CME (a BD company) – the intended operation of these pumps cannot be verified due to errors in the instructions for use (IFUs) and the incompatibility with older versions of BodyComm software (88-102).

Action

- Identify whether you have any 3rd edition T34 syringe driver pumps (see device details section).
- Identify patients currently receiving treatment supported by these pumps.
- Identify all relevant healthcare professionals involved with care delivery using these pumps and advise them to discontinue using the device when clinically appropriate.
- BD/CME will contact you directly regarding the BodyComm V3.0 software and when the updated version of the IFUs are available.
- Once you receive the updated IFUs, make sure users are aware of the revised intended use of the pump and other performance specification changes from the previous, 2nd edition, T34 syringe driver pump. BD/CME offers training if required.
- Pumps can be returned to service once the updated IFUs have been received and there is a system in place for the configuration of 3rd edition T34 pumps to only be used with V3.0 BodyComm software. Note: previous versions of the BodyComm software (88-102) are not compatible with 3rd edition T34 pumps (see device details section).
- 2nd edition T34 syringe driver pumps are not affected by this notice so can be used as long as corrective actions detailed in MDA/2016/002, MDA/2019/013 and MDA/2019/030 have been undertaken (see problem section).
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Action by
All technical staff responsible for servicing these devices and healthcare staff who use these pumps.

Deadlines for actions
Actions underway: 05 November 2019
Actions complete: 19 November 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

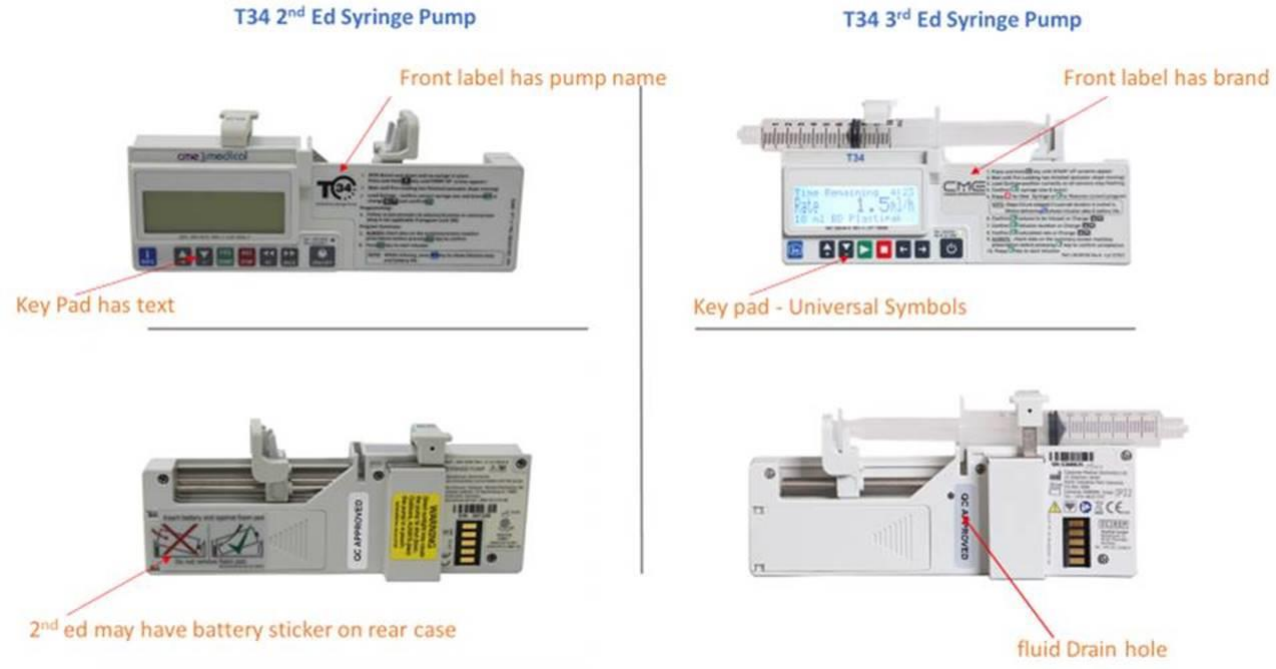
Device details

In April 2018 the manufacturer released an updated version of the T34 syringe driver pump, referred to as the 3rd edition.

The product identifier is 999-103EN

This was updated primarily to ensure compliance with version 3.1 of the medical electrical equipment and systems standard IEC 60601-1.

Images showing the difference between 2nd and 3rd edition pumps:



Problem / background

Following the release of the 3rd edition T34 pump, MHRA has received reports of problems associated with using it.
This involves, but is not limited to:

- errors and inconsistencies in the instructions for use
- incompatibility of the BodyCommTM 88-102 software with 3rd edition pumps
- changes to battery life
- use implications due to change in device interface

2nd edition T34 syringe driver pumps (the previous version) are still affected by separate corrective actions addressing the following issues:

- sunlight protection (MDA/2016/002)
- battery connection issues (MDA/2019/013)
- fluid ingress checks (MDA/2019/030)

MHRA is working with the manufacturer on these issues.

Manufacturer contacts

Becton Dickinson UK Ltd.

Customer service line: 0800 917 8776 (press option 2, then option 4)

BDUKGCSAction@bd.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- Adult intensive care units
- Anaesthetic medical staff
- Biomedical engineering staff
- Community children's nurses
- Community hospitals
- Community nurses
- District nurses
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Hospital at home units
- IV nurse specialists
- Medical directors
- Medical libraries
- Medical oncologists
- Medical oncology, directors of
- Medical physics departments
- Neonatal nurse specialists
- Neonatology departments
- Oncology nurse specialists
- Paediatric nurse specialists
- Paediatric oncologists
- Palliative care teams
- Purchasing managers
- Radiation & medical oncology departments
- Supplies managers

NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- General practice managers
- General practice nurses
- General practitioners (for information only)

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Care management team managers
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Equipment stores
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number **MDA/2019/038** or **2019/009/027/401/009**.

Technical aspects

Roopa Prabhakar or Emma Rooke, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 255278 or 03000 255510

Email: Haz-Aic@gov.wales

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).