Medicines & Healthcare products Regulatory Agency

MHRA

Infusion pumps: T34 syringe drivers

In November 2020 the Medicines and Healthcare products Regulatory Agency issued a joint statement with the stakeholder group regarding T34 syringe drivers. This is a summary of actions related to T34 syringe driver issues, which mitigate residual risks with these devices. We provide an overview of the issue, an assessment of the risk and a proposed risk mitigation measure.

These devices are very widely used in the UK and there are very few alternative pumps that fulfil the same function and are suitable for use in hospital and community settings.

Battery issues

There were several issues identified related to the batteries used in T34 devices.

1 The problem:
Pumps stored without the main 9V battery for several days or weeks, were causing the internal battery of the pump to lose its charge.

The risk to patient safety:
Patient not receiving medication as intended.

Actions to fix the problem:
The manufacturer sent a Field Safety Notice (FSN) to inform healthcare professionals about this.

2 The problem:
Specific brands of 9V 6LR61 batteries were causing the pumps to shut down or alarm when they should not.

The risk to patient safety:
Patient not receiving medication as intended.

Actions to fix the problem:
The MHRA worked with BD to identify and validate suitable batteries. The manufacturer sent these recommendations to customers in an FSN. Current information on valid batteries can be found on BD's website.

3 The problem:
A very small difference in size (+/-2mm) of the batteries used in the pumps was causing connection problems.

The risk to patient safety:
Patient not receiving medication as intended.

Actions to fix the problem:
The MHRA worked with the manufacturer to identify a solution to prevent movement of the battery in its housing and published a safety communication.

4 The problem: Customers noticed that the battery life is shorter for 3rd edition T34 pumps compared with 2nd edition pumps.

The risk to patient safety:
Patient not receiving medication as intended.

Actions to fix the problem:
The manufacturer has started to roll out a software upgrade to increase the battery life of 3rd edition pumps.

Flow-related issues

The problem:
Some 2nd and 3rd edition pumps, manufactured before May 2020, would not give an alarm when they did not infuse medication. This was due to mechanical wear of the pump's 'lead screw'.

The risk to patient safety:
Patient not receiving medication as intended.

Actions to fix the problem:
BD/CME issued an FSN and the MHRA supported it with MDA/2020/007.

We are aware that this safety corrective action is not possible in the following T34 populations:

- Specific older 'legacy' 2nd edition pumps
- Specific older 3rd edition pumps with older software S0300XXXX to S00402877, manufactured from September 2018 to May 2020.

As it is not possible to undertake safety corrective actions on these pumps, BD will be exchanging this specific T34 pump population with BodyGuard-T pumps in 2021. Please refer to the BD customer letter or contact BD directly for further information.

Sunlight causing bolus infusion

The problem:
When exposed to direct sunlight, 2nd edition pumps may deliver an unintended bolus followed by the pump stopping.

The risk to patient safety:
Over-infusion of medication, or the patient not receiving treatment as intended.

Actions to fix the problem:

The manufacturer issued a field safety notice (FSN) telling customers to obtain pouches from BD/CME to protect the pump from direct sunlight. The MHRA published a safety message MDA/2016/002.

Fluid ingress

The problem:
Fluid getting into the pump because of specific cleaning and disinfection practices would stop the pump working properly.

The risk to patient safety:
Patient not receiving medication as intended.

Actions to fix the problem:
The manufacturer issued a field safety notice (FSN) with revised maintenance and cleaning instructions. The MHRA published a safety message MDA/2019/030.

Background and further information

T34 is a family of ambulatory syringe driver pumps predominantly used for pain relief in palliative care. The devices are manufactured by Caesarea Medical Electronics (CME), which is owned by Becton Dickinson (BD).

T34 pumps used in the UK are:

- 2nd edition – legacy McKinley T34 and standard 2nd edition
- 3rd edition – old software and new software; old design of lead screw and stainless steel lead screw
- Bodyguard-T – next generation model for T34 syringe drivers

The devices are used in a range of settings including hospitals, hospices and other community settings such as a patient's home.

The stakeholder group formed to look at T34 syringe drivers included representatives from the following organisations:

Medicines and Healthcare products Regulatory Agency (MHRA)
Association of Palliative Care
Healthcare Safety Investigation Branch (HSIB)
Hospice UK
Medical Device Safety Officer network
NHS England and NHS Improvement
NHS National Services Scotland
NHS Supply Chain
Northern Ireland Department of Health
Welsh Government

Conclusions

T34 syringe drivers can be used to deliver a range of medications to patients, as outlined in the manufacturer's instructions for use. The issues and risks identified to date may be mitigated by following the actions summarised above.

It is important to follow the instructions for use and carry out all regular checks and maintenance.

If an alternative device is being considered for purchase or deployment, we recommend referring to the MHRA publication Managing Medical Devices for further information and guidance.

The MHRA will continue to monitor these issues and consider any further information we receive. This will allow us to update our guidance where necessary.
Please contact the manufacturer for more details of the issues.

Report problems

Report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You can also report safety concerns relating to any supply disruption, training issues as well as concerns arising from the use of mixed fleets of models.

The Yellow Card Scheme is vital in helping the MHRA monitor the safety of all healthcare products in the UK to make sure they are acceptably safe for patients and those that use them.