Medicines & Healthcare products Regulatory Agency

MHRA

Medical Devices Safety Bulletin

Regular safety information for healthcare professionals

Issued: 05/11/2020 Ref: MDSB-20-02

Introduction

The Medicines and Healthcare products Regulatory Agency (MHRA) has responsibility for the safety of medicines and medical devices on the UK market.

This is a pilot for a regular bulletin from MHRA to inform health and care professionals in the UK of new or ongoing safety issues with medical devices. We are no longer issuing medical device alerts (MDA).

To help ensure the safety of patients, we recommend you read this bulletin and act on any aspects that affect your practice or the care you provide. You should also share the content of these safety messages with colleagues who you think need to know this information.

Some topics covered in this bulletin will also be disseminated through other mechanisms such as manufacturers' field safety notices (FSN).

We are collecting feedback and data on this new bulletin and will use it to evaluate and develop this communication tool.

MHRA also issues safety communications for medicines, including Drug Safety Update. Sign up to receive MHRA email alerts here.

In this issue

You said…. we did…

In feedback, you asked for information on specific devices.

In this edition, we bring you the latest news on battery replacements for the CME / Becton Dickinson (BD) T34 pumps.

The advice in this safety bulletin supersedes the Field Safety Notice issued by the manufacturer in September 2020, which included some restrictions regarding T34 use.

We need your feedback

Take this short online survey to tell us your thoughts on this new safety communication from MHRA

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health and Social Care.

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T34 infusion pumps

Actions

- put into use any pumps that were quarantined
- you can use the Duracell Plus battery – England NHS Supply Chain NPC code WPA244
  Scotland NDC code 253029
- read BD's latest safety information for customers
- continue to report any problems.

Background

The T34 is an ambulatory syringe pump primarily used for palliative care in the UK.

MHRA was made aware of an increased number of reports of battery complaints. As a result, MHRA worked with CME/BD to recommend the Duracell Plus battery as suitable for use within these pumps.

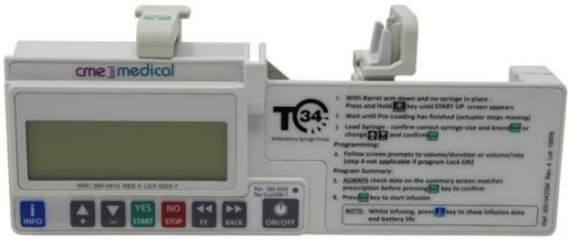
The new battery has successfully undergone extensive testing by both BD and a selection of customers.
MHRA has agreed to lift T34 restrictions and to allow CME/BD to re-start selling the pumps. CME/BD will contact customers regarding this.

MHRA continues to collaborate with external stakeholders and we have recently published a targeted letter to update customers.

Our stakeholders:
Association of Palliative Medicine
Healthcare Safety Investigation Branch (HSIB)
Hospice UK
NHS England and NHS Improvement
NHS National Services Scotland
NHS Supply Chain
Northern Ireland Department of Health
Welsh Government

There are 2 versions of pumps available:

2nd Edition sold until 2019



3rd Edition sold from July 2019 onwards

Other current T34 safety information:

Updated instructions for use and BodyComm V3.0 software
All T34 3rd Edition syringe pumps (FSN which supersedes MDA/2019/038)

Lead screw
All T34 and T34L (T60) syringe pumps – risk of under-infusion and no alarm (MDA/2020/007)

Fluid ingress
All T34 syringe pumps: Updated cleaning advice and maintenance requirements (MDA/2019/030)

Foam pad for battery
All T34 ambulatory syringe pumps battery connection issues (MDA/2019/013)

Sunlight causing bolus
T34 and T60: Protect pumps from sunlight and recall of extension sets (MDA/2016/002).

Field safety notices

A field safety notice (FSN) is an important communication about the safety of a medical device that a manufacturer, or their representative, sends to customers. For more information, see our flyer.

MHRA publishes these for information only. If you have affected devices, the manufacturer or distributor should send the FSN directly to your organisation.

If you are a Medical Devices Safety Officer (MDSO) you can ask manufacturers to add you to their FSN distribution lists.

Targeted letters

A targeted letter (TL) is a safety communication about a medical device, which we send only to the healthcare organisations that have the device.
We will also send TLs to professional bodies and other organisations to send it on to the relevant target audience.

You can access recent TLs here.

Reporting safety issues

The Yellow Card scheme is vital in helping the Medicines and Healthcare products Regulatory Agency (MHRA) monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and users.

Report a suspected problem or incident involving:

- side effect to a medicine, vaccine, herbal or homeopathic remedy
- a medical device including diagnostic tests, software and apps
- defective medicine (not of an acceptable quality)
- falsified or fake medicine or medical device
- side effect or safety concern with an e-cigarette

Report through the Yellow Card website or download the Yellow Card app (from iTunes for iOS devices or PlayStore for Android devices).

You can also report side effects for medicines through some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals.

There are different ways for healthcare professionals to report a problem with a medical device if you're in Scotland or Northern Ireland.

You can use our new dedicated COVID-19 reporting website to report any suspected side effects from medicines, future vaccines or medical devices relating to COVID-19 treatment.