HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

T34 Ambulatory Syringe Pumps

Priority 2 – Warning

HPRA Safety Notice: SN2020(03) **Issue Date: 12th March 2020**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
BD/CME	V42655

ISSUE

BD/CME has identified, through Post Market Surveillance feedback, that the syringe pump motor block mechanism may become affected over time by "wear / tear". This scenario causes under infusion situations without the pump alarm being generated.

Further information is provided in the accompanying follow up field safety notice (FSN).

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Refer to the accompanying FSN and follow the instructions provided by the manufacturer and the distributor.

2 Forward a copy of this Safety Notice and FSN to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred.

3	Acknowledge receipt of the FSN if you have not already done so.
4	Report any concerns/incidents involving these devices and/or this remediation activity to the manufacturer and the HPRA.

TARGET GROUPS	
All wards	Nursing Managers
Carers	Nursing staff
Clinical Directors	Oncology Nurse Specialists
Community care managers	Palliative Care Staff
Community nurses	Purchasing Managers
Hospices	Risk Managers
Hospital Managers / CEOs	Supplies Managers
Nursing Homes	

BACKGROUND

The manufacturer has advised that this issue can be observed when the actuator does not move as the lead screw is rotating, resulting in potentially no pressure on the syringe plunger to deliver syringe contents.

BD/CME has advised that the cause of this issue is the actuator nut being worn enough to stop or lose traction on the lead screw due to irregular surface of the lead screw. The "wear / tear" effect can be visually observed as the lead screw is progressively wearing the plastic actuator nut overtime, leaving white plastic debris along the lead screw.

BD/CME have revised the Directions for Use (DFU) to include specific instructions for users to check for plastic white debris on the lead screw during pump set up. The Technical Service Manual (TSM) instructions have also been updated to outline changes to the maintenance and repair processes to check for plastic white debris on the lead screw and to preventively change the lead screw and/or motor block assembly where necessary.

BD/CME advise that the pump has to be checked prior to each use for plastic white debris. Users responsible for pump set-up need to double check that the infusion rate and amount was as prescribed, due to the fact that the pumps will **not alarm** the user in case of under-infusion.

The HPRA is issuing this Safety Notice to raise awareness of this field safety corrective action in Ireland. Please refer to the accompanying FSN for further details.

HPRA advise users of the T34 pump to ensure they are up to date with all recommendations issued by BD/CME in relation to this device. Copies of HPRA Safety Notices 2016(05), 2016(41), 2018(09), 2018(31), 2018(34), 2019(07), 2019(29) and FSNs issued by the manufacturer are available on the HPRA website.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Caesarea Medical Electronics Ltd.
(now part of BD)
16 Shacham Street
Industrial Park Caesarea North
P.O.Box 3009
Caesarea 3088900, Israel

Telephone: +44 (0) 800 090 2460
(UK Number)
E-mail: BDUKFieldAction@bd.com
Website: www.cme-infusion.com

Enquiries to the **distributor** should be addressed to:

Rockford Healthcare Limited
3 The Westway Centre
Ballymount Avenue
Dublin 12

Telephone: +353-1-4509050
E-mail: fieldsafetyaction@rockford.ie
Website: www.rockford.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie