Caesarea Medical Electronics

Safety Information **Field Safety Notice** **Ref: FSN2015-002**

Product Details:

Product name: T34 Ambulatory Syringe Pump
Product Code: 100-100SM / 300-100S / 400-000S
Batch Numbers: Infusion pumps and housing manufactured 2013 onwards

Date: 12th October 2015
Type of Action: Safety Information

Attention: All T34 syringe pump customers who purchased devices or plastic housings for same from 2013 onwards.

Description of the problem:

CME Ltd have received a small number of reports of related syringe pump product (T60) stopping and activating an alarm condition while being transported during use in direct sunlight. To date no such reports have been received in relation to T34

The issue relates to a change in the pump housing material in June 2013. CME is continuing to investigate but we have decided to issue this FSN to reinforce the importance of following the instructions for use when using the T34 syringe pumps outdoors or in bright light (i.e. patient transportation or when patients are ambulatory).

CME recommends customers avoid using the pump in sunlight or, if it is necessary for the patient to go outdoors, protect the pump from exposure (for example by placing it in a pocket or a bag). This advice is in line with pharmaceutical manufacturer's advice to protect certain drugs commonly used in end of life care from sunlight during administration. CME syringe pump pouches are available from CME should patients regularly use the device outdoors. This pouch has the added benefits of protecting the syringe pumps from damage and provides straps for securement during transport.

T34 Washable Pouch

T34 Disposable Pouch

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RISK ASSESSMENT

PREVALENCE: c. 40,000 T34 pumps are used in the UK & Ireland. To date CME have received zero reports of T34 failures of this kind in clinical use. Since the T34 is predominantly used for pain & symptom management in end of life care, it is generally used in a patient's home or care facility. The likelihood of the device being exposed to sunlight is considered low, and should also be avoided due to the potential effect on medications commonly used in end of life care, potentially explaining the prevalence of zero clinical reports.

SEVERITY: Should the device alarm when exposed to sunlight the pump encoder fails leading to a single fault condition prior to the pump stopping. An unintended bolus will be delivered. The amount varies depending on syringe size and brand loaded into the pump but advice taken confirms this to be well within the safe parameters of a typical stat/bolus dose.
The pump stoppage could cause a delay to the patient's therapy however this is transient and easily resolved by placing the pump back in the pouch or removing from sunlight and restarting the pump.

PREVENTION: Use of the pump indoors or putting it into a pouch when outside will prevent the issue from occurring/re-occurring.

This issue may also affect Customers with pumps manufactured pre-June 2013 who have replaced either or both the front or rear pump housings.

ADVICE TO USERS:

The T34 is not recommended for the delivery of critical medications as clearly stated in the Operations Manual as follows: "Contraindication – infusion of critical medications whose stoppage or interruption could cause serious injury or death." CME has become aware that NPSA guidance published in 2010 required Trusts to produce a local list of "Critical" drugs. This advice required certain categories of drugs to be included whose omission or delay had been found and recorded by NRLS to result in serious harm or death. Analgesics were not stated as a critical category for inclusion however we are aware that some Trusts may have listed drugs used in end of life care on their local critical drugs list. To this end, when considering whether T34 is suitable for delivery of a particular therapy, physicians should revert to the manufacturers' definition of "critical" as clearly stated in the IFU for the pump and consider this alongside their local critical medications list and/or the advice of their pharmacy colleagues. Further communications may be issued when the medication side of things has been thoroughly reviewed.

We have tested the pump in the proprietary pouches available from CME and this prevents the issue. The issue would also be resolved by placing the pump & lockbox into a patient's own bag or concealing the device under clothing or in a pocket as many patients prefer.

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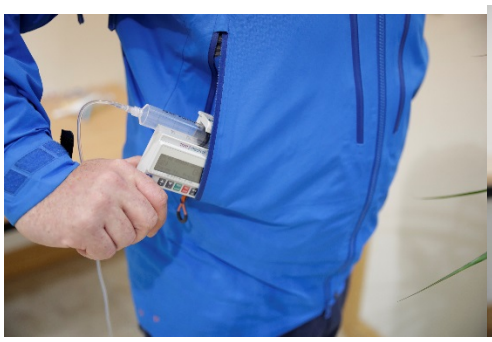
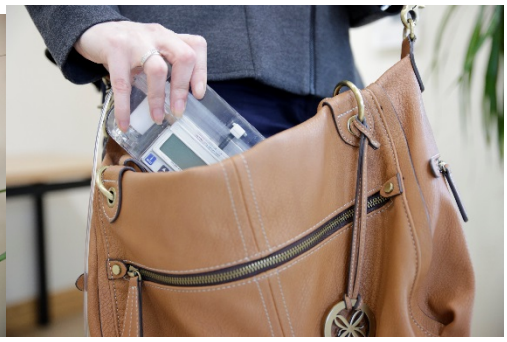
Users can check the pump manufacture date located on the rear housing label by the prefixed logo . If the device was manufactured in 2013 or later, users should note and follow the advice contained in this FSN which may also be considered good practice for use of the T34 generally.

We recommend that any pumps that may be exposed to sunlight during patient transportation should be kept in a dedicated CME syringe pump pouch, or the equivalent, when infusing. It is possible to access the screen and keypad of the device by lifting the Velcro flap of the washable pouch whilst the pump remains in the pouch. It is also possible to remove the forward part of the device from the pouch to inspect the syringe without removing the rear section of the device.





ACTION – Users should note the advice not to use the pumps in sunlight. Pouches are available from CME. CME will keep customers informed as to its investigations and whether any further action is deemed necessary.

Please contact our Quality Department to arrange shipment of pouches.
Email: QA@cmemedical.co.uk

Any questions relating to this notice should also be directed to the above email address or alternatively please call our customer support department on 01253 206700

Please complete the acknowledgement form provided with this FSN and return it to the address provided. Alternately, please scan and email back to the QA email address above.

The undersigned confirms that the relevant competent authorities have been advised of this safety notice.

Signed:

[redacted] ectronics Ltd.

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