



Caesarea Medical Electronics

Safety Information **Field Safety Notice**

Ref: FSN2016-004

Product Details:

Product name: CME Ambulatory Syringe pumps – T34, T60 and TPCA
Product Code: T34 - 100-100SM, T60 - 100-100PSLM, TPCA - 100-106PSLM, PMP00007
Batch Numbers: All pumps
Date: 23.10.2016
Type of Action: Safety Information

Attention: All T34, T60 and TPCA syringe pump customers

DETAILS:

Following the issuing of Field Safety Notices, FSN2015-002, FSN2015-003 & FSN2016-003 which notified customers of the effect of exposure to direct sunlight on the functionality of the above pumps (pumps manufactured since 2013), CME Limited has revised the operating manuals for the pumps.

The following warning has been added to the manuals:

The (pump type) syringe pump must always be used in a CME Ltd pouch, or similar receptacle, if used in direct sunlight. If the pump is exposed to direct sunlight, it may affect functionality.

ADVICE TO USERS:

Users are advised to adhere to the new warning in the manual for all of the above pumps.

Although the original issue only affected pumps manufactured since 2013, customers are advised to use all CME syringe pumps in a pouch if used in direct sunlight. This is considered to be best safety practice and eliminates the need for users to identify the age of the pump or whether the case has been replaced.

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ACTION – CME will provide labels identifying this new warning. Customers are asked to adhere the labels to the pump as a reminder to users.

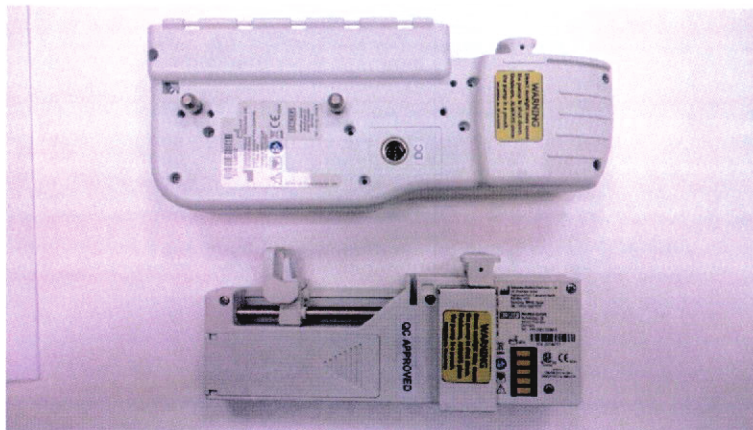
Please contact our Customer Support Department to arrange for labels to be delivered.
Telephone: 01253 206781
Email: FSN2016-004@cmemedical.co.uk

For customers who have purchased the pumps via Rockford Healthcare in Ireland, please contact service@rockford.ie to arrange for labels to be delivered.

Please supply the following information:

- Quantity of labels required
- Contact name and telephone number
- Delivery address

Please see below an example of where the labels could be attached.



Transmission of this Field Safety Notice:

This notice must be passed on to all those who need to be aware within your organisation or to any organisation where the affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.



Caesarea Medical Electronics

Contact reference person:


Clare Unsworth – QA Manager, CME Medical UK Limited

E-mail: QA@cmemedical.co.uk

The opening of this Field Safety Notice, from the link in the attached email, will be used as acknowledgement of receipt. If you have any questions, please contact the email above.

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

Signed:


Swi Barak
CEO
Caesarea Medical Electronics Ltd.

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