

## **CME McKinley UK Limited**

Kincraig Business Park, Kincraig Road Blackpool, Lancashire, FY2 0PJ

Telephone: 01253 894827 Facsimile: 01253 896648

www.cme-mckinley.co.uk info@cme-mckinley.co.uk

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## **Field Safety Notice**

Product Description: T34 Syringe Driver

Manufacturers Product Code: 100-100PSM

Serial numbers affected: Individual customers will receive an addendum detailing delivery dates and serial numbers of T34 pumps that may be affected.

CME Ltd has notified us that some/all of the pumps purchased by the Trust may be affected by a problem identified during the soldering phase of one of the PCB (printed circuit boards) manufacture. In some cases one component on the board may not have received sufficient quantity of solder paste during manufacture.

In some cases the components received sufficient solder to enable the pumps to function during the QC and 'burn in' checks in the factory but with the potential for the connection to be dislodged during transit to our facility or en route to the customer.

A number of customers who received the pumps subsequent to this then reported pumps failing during their internal commissioning checks and in some rare cases, in use.

**MANIFESTATION OF THE PROBLEM:** When the T34 is powered up the pump Self test procedure rotates the motor as part of the start up routine. <u>In all cases</u> the failure will manifests itself in a completely predictable manner with the error message 'Startup Mot Fail' or 'Mot Move Fail' as the affected component in question is the drive transistor to the motor.

**IMPORTANT NOTE:** CME Ltd regulatory affairs have performed a risk analysis and have deemed there is no risk to the patient or operator as a result of this fault and therefore a recall is not indicated.

**ACTION REQUIRED:** Check pump serial numbers against the addendum provided and contact CME McKinley to agree a scheduled inspection and, where necessary, re-work of pumps that may be affected. CME has a dedicated line for customer to report the fault, ask questions and to schedule the inspection of their units.

Each T34 pump on the list may be returned under warranty for a period of 12 months from the date of this notification. Please do not hesitate to contact myself if you have any further queries

Yours sincerely

Stephen Thorpe Managing Director CME McKinley UK Limited