Smiths Medical International, Ltd
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URGENT FIELD SAFETY NOTICE

FOR OMNIFUSE & OMNIFUSE PCA SYRINGE PUMPS

Affected Devices:	**Omnifuse and Omnifuse PCA Syringe Pumps**
Type of Action:	Urgent Field Safety Corrective Action – Correction
Date:	25 July 2011
Attention:	Risk/ Safety Managers, Clinicians/ Biomedical Engineering, Nursing, Pharmacy, Pain Management and Anesthesia Professionals, Medical Equipment Rental Companies, Distributors and other users of these devices
Details on affected devices:	All Omnifuse and Omnifuse PCA Syringe Pumps

Smiths Medical would like to make users aware of new information regarding System Fault Codes and the operation of Omnifuse and Omnifuse PCA Syringe Pumps ("Omnifuse Pumps").

Possible Impact of Significant Vibration or Jarring to Omnifuse Pumps

Due to sensitivities of the precision accuracy detection mechanisms within Omnifuse Pumps, certain levels of vibration or jarring during transport can induce a system fault code. An example of the type of vibration or jarring that may induce a System Fault Code would be transporting a pump across an uneven surface (e.g., block paving).

When transporting a patient during operation of an Omnifuse Pump, users should discontinue use of the Pump during transport and restart the Pump once transport is completed; or when no alternative is available, be aware that vibrations during transport may trigger a System Fault Code, causing the Pump to alarm and stop delivery of the infusion. If a System Fault Code occurs during transport, the user can follow the instructions on the attached Customer Information Bulletin ("CIB") for resetting the Pump to clear the System Fault and continue with the infusion.

Affect on the Totaliser Display - After Resetting the Pump to Clear a System Fault

If a System Fault Code occurs during an infusion and the Pump is reset (as described in the attached CIB), the totaliser display will not include the most recent infusion data.

Therefore, if the clinician chooses to clear the System Fault and continue with the infusion, the totaliser must be reset and the manual records referenced to prevent using incorrect medication delivery totals. The downloadable history on the Pumps still maintains the correct medication delivery totals. However, the downloadable history is only accessible through the Pump's PC software program, typically maintained by the facility's biomedical department.

Smiths Medical is in the process of making changes to the Instruction Manuals supplied with these Pumps, to provide users with this new information regarding System Fault Codes and the operation of these Pumps, including the addition of two new Warnings:

> **WARNING:** When transporting a patient during operation of an Omnifuse or Omnifuse PCA Syringe Pump, users should either: a) discontinue use of the Pump during transport and restart the Pump once transport is completed; or b) be aware that vibrations during transport may trigger a

System Fault Code, causing the Pump to alarm and stop delivery of the infusion. A delay or interruption in therapy may result in patient injury or death.

WARNING: Failure to reset the cumulative total as advised in the 'clearing system fault codes' process may result in inaccurate infusion data being displayed by the totaliser function. The use of inaccurate infusion data in clinical decisions may result in inappropriate or unnecessary clinical intervention which could lead to patient injury or death.

Advice on Action to be Taken by the User:

1) Circulate this Field Safety Notice and Customer Information Bulletin to all end users of Omnifuse Pumps;

2) Be aware that when transporting a patient during operation of an Omnifuse Pump, users should either: a) discontinue use of the Pump during transport and restart the Pump once transport is completed; or b) be aware that vibrations during transport may trigger a System Fault Code, causing the Pump to alarm and stop delivery of the infusion, and take appropriate precautions. A delay or interruption in therapy may result in patient injury or death;

3) Maintain good clinical practice by keeping manual records of infusions;

4) Be aware that failure to reset the cumulative total when following the 'clearing system fault codes' process will result in inaccurate infusion data being displayed in the totaliser function. The use of inaccurate infusion data in clinical decisions may result in inappropriate or unnecessary clinical intervention. Failure to reset the cumulative total following a system fault code may lead to patient injury or death; and

5) Complete and return the attached Confirmation Form (see Attachment 1) by Fax to +44 (0) 1582 430001 or by email to Omnifusevib@smiths-medical.com

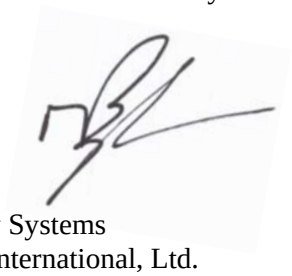
If you or your facility has distributed these Pumps to other persons or facilities, please promptly forward the recipients a copy of this Urgent Field Safety Notice.

If you have any questions regarding this information, please contact Smiths Medical at +44 (0) 1923 241411 and select Option 2, "Service" then Option 3, "Technical Support".

If you have non-technical questions regarding this information, please contact: UK Customers: +44 (0) 1233 722231; Northern and Southern Ireland Customers: 00 3531 2941133; or International Customers: please contact your local customer service representative.

Smiths Medical is committed to providing quality products and service to its customers. We apologize for the inconvenience this situation may have caused.

Sincerely,



Mick Boydon
Manager, Quality Systems
Smiths Medical International, Ltd.

Enclosures: Attachment 1: Urgent Field Safety Notice Confirmation Form
Attachment 2: CIB – Modifying Instruction When a System Fault Occurs