



Medical Devices Bureau, Ministry of Health Malaysia
 Level 5, Block E6, Complex E,
 Federal Government Administrative Centre,
 62590 Putrajaya, MALAYSIA.
 Tel: 03-8883 2248/2249/2264
 Fax: 03-8888 6184

Medical Device / Equipment **ALERT - Field Corrective Action**

Date Issued : 23rd July 2008

Ref:MDB/A/2008/010

IMMEDIATE ACTION	
ACTION	√
UPDATE	
INFORMATION REQUEST	√

PRODUCT	<p>Smiths Medical Graseby Omnifuse and Omnifuse PCA syringe pumps.</p> <p>All Graseby Omnifuse and Omnifuse PCA syringe pumps with the product codes listed as in <i>The Attachment</i> with pump software versions 9.1 or lower where drug protocols are used to set up the infusion.</p>
CLASS	Not Available
USE	Syringe Pump with Software.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	<p>Medicines and Healthcare products Regulatory Agency, United Kingdom's website, Date issued: 2nd July 2008</p>
ALERTING / RECALLING FIRM	Smiths Medical United Kingdom
REASON	<p>Possibility of patients being given an additional/unnecessary infusion when syringes are changed or infusions restarted when using DrugPro software.</p> <p>Smiths Medical has received customer reports of an inconsistency in the operation of the pump infusion totaliser when using pumps <u>with drug protocol (DrugPro) software and pump software versions 9.1 or less.</u></p> <p>If when using an Omnifuse or Omnifuse PCA pump with DrugPro software the user selects – but does not</p>

	<p>confirm – a drug protocol from the drug protocol library and the user resets/stops the pump (by pressing and holding the STOP key), the total from the previous infusion will not be added to the infused volume totaliser regardless of when that previous infusion was run.</p> <p>Smiths Medical will be providing corrected software and has issued an Urgent Field Safety Notice advising users of the problem and the appropriate action to take until the software is available (see Attachment).</p> <p>It is advisable for the distributors or sales representative of the abovementioned companies in Malaysia to respond to this alert notice.</p>
<p>SCENARIO IN MALAYSIA</p>	<p>No details available at this moment. For users, please check whether the device is available and contact the distributor.</p>
<p>ACTION</p>	<p><i>Recommendations For Healthcare Professionals</i></p> <ul style="list-style-type: none"> • Ensure that all relevant staff in your institution are informed of this safety alert/warning • Determine if you have the affected products • Locate and monitor the usage of the affected products • Determine how much of this product has been used • Follow the distributor / manufacturers recommendations for quarantine and disposal of product • Follow up patients as required.
<p>RECOMMENDATION</p>	<p>Users of the abovementioned device should contact the distributors/supplier of this device (if available) and inform the Medical Devices Bureau, Ministry of Health providing the following information:-</p> <ol style="list-style-type: none"> a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
<p>CONTACT/ENQUIRIES IN MALAYSIA</p>	<p>BUMI T. T. C. (SABAH) SDN BHD Erh-Ling Chang Shop No. 21 & 22, Kepayan Ridge Commercial Centre, Phase 2, Lrg. Bunga Tanjung 2,</p>

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Syarikat Perniagaan Miscell Sdn Bhd

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REFERENCES

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON020543>

Attachment

Urgent Field Safety Notice.

Graseby Omnifuse and Omnifuse PCA Syringe Pumps 2nd May 2008 Device Modification

Details of Affected Devices:

All product codes listed below with pump software versions 9.1 or less where drug protocols are used to set-up the infusion. Drug protocols are prepared using the Omnifuse Drug Protocol Software (Drug Pro) (Version 1.0 rev 1.1)

0152-0001	0153-0001	0157-0001	0158-0001	0159-0001
0152-0709	0153-0703	0157-0709	0158-0709	0159-0709
0152-0710	0153-0709	0157-0710	0158-0710	0159-0710
0152-0711	0153-0710	0157-0711	0158-0711	0159-0711
0152-0740	0153-0711	0157-0740	0158-0740	0159-0740
	0153-0740			

Description of the Problem:

Smiths Medical has received customer reports of an inconsistency in the operation of the pump infusion totaliser when using pumps with Drug Protocol (Drug Pro) Software and pump software versions 9.1 or less. If an Omnifuse or Omnifuse PCA pump are using the DrugPro software and the user selects, but does not confirm a Drug Protocol from the Drug Protocol Library and the user resets/stops the pump (by pressing and holding the STOP key), the total from the previous infusion will not be added to the totaliser regardless of when that previous infusion was run.

Results of Investigation:

Smiths Medical has not received any reports of adverse events associated with this totaliser issue. Although the correct totals do not appear in the main user display window they are still present in the infusion events recorded in the pumps main history; therefore, if it is necessary to perform totals auditing the information is still available within the pump event history.

Advice on Action to be Taken by the User:

Smiths Medical will be issuing a series of bulletins in relation to this issue:

1. This Urgent Field Safety Notice is intended to make all users aware of this issue.
2. Smiths Medical will be providing corrected software to eliminate this totaliser issue. We will confirm the release date of the corrected software and issue a fax form to collect your affected pump serial numbers and other information.
3. Smiths Medical will provide a CD-ROM with the corrected software and installation instructions to allow users to update their pumps on site.

Note

- If required the use of drug protocols on the pump can be disabled by entering the pump configuration menu and setting the option 'Use Drug Protocols?' to 'No'.

Please do not return any products for upgrades at this time.

Transmission of This Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisations where the affected devices have been transferred.

Contact Reference:

Please contact Smiths Medical International Limited Watford, Regulatory Affairs & Quality Assurance Department through fax: 01923 237576 or email: mwatcomplaints@smiths-medical.com If you require any further information

For technical information please contact Technical Support on +44 (0) 1923 241411 option 2 or via email at brian.lane@smiths-medical.com

Also, in order for Smiths Medical International to meet certain regulatory requirements and best assist its customers, please complete and return the fax confirmation for this notification found in Attachment 1 of this Field Safety Notice.

Smiths Medical apologises for any inconvenience this may cause. Thank you for your support in this matter.

Sincerely,

SMITHS MEDICAL INTERNATIONAL LTD

Jon Charters
Quality Assurance Manager

ATTACHMENT 1

Urgent Field Safety Corrective Action Notice
Acknowledgement

Upon completing the following information, please fax this sheet to the Smiths Medical International Limited, Watford, RA/QA Department at 01923 237576

E-mail mwatcomplaints@smiths-medical.com

Please check all of the relevant boxes, which relate to your affected product inventory:

Check the relevant box	
	We do not have any Omnifuse or Omnifuse PCA pumps in use with the Drug Protocols and we don't have version 1.1 DrugPro software available. We therefore do not require the software update as a result of this action. A list of serial numbers of our Omnifuse pumps is attached.
	We no longer have any Omnifuse pumps.
	We have Omnifuse or Omnifuse PCA pumps in use with drug protocols, and we will require the software update when it is available. A list of serial numbers is attached.

Please write on an additional sheet if necessary. Please print:

Note: The answers to these questions help Smiths Medical best assist you with replacement product.

Customer Name:	
Dept:	
Address:	
Phone Number:	
Fax Number:	
Email address:	

Customer Signature: _____

Date: _____