

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/053

Issued: 4th July 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section
<p>Medical Device/Equipment: Smiths Medical Graseby Omnifuse and Omnifuse PCA syringe pumps</p>	▶ ①
<p>Problem: Possibility of patients being given an additional/unnecessary infusion when syringes are changed or infusions restarted when using DrugPro software. If the user selects – but does not confirm – a drug protocol from the drug protocol library and then resets/stops the pump, the previously infused volume will not be added to the ‘total volume infused’ display.</p>	▶ ②
<p>Action by: Clinical and technical staff using or maintaining these pumps.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify any affected pumps and follow the advice given in Smiths Medical’s Urgent Field Safety Notice (see Appendix). 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>	
<p>Acknowledge Receipt of Alert: 8th July 2008</p>	▶ ⑦
<p>Action Under Way: 30th July 2008</p>	
<p>Action Complete: 27th August 2008</p>	

This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

All Graseby Omnicuse and Omnicuse PCA syringe pumps with the product codes listed below with pump software versions 9.1 or lower where drug protocols are used to set up the infusion.

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			

Drug protocols are prepared using the Omnicuse Drug Protocol Software (DrugPro) (Version 1.0 rev 1.1).

2. PROBLEM:

Smiths Medical has received customer reports of an inconsistency in the operation of the pump infusion totaliser when using pumps with drug protocol (DrugPro) software and pump software versions 9.1 or less. If when using an Omnicuse or Omnicuse PCA pump with DrugPro software 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 infused volume totaliser regardless of when that previous infusion was run.

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 Appendix).

3. ACTION BY:

Clinical and technical staff using or maintaining these pumps.

4. ACTION:

- Identify any affected pumps and follow the advice given in Smiths Medical's Urgent Field Safety Notice (see Appendix).

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- All clinical departments
- All wards
- Ambulance staff
- Biomedical engineering staff
- Biomedical science departments
- Clinical governance leads
- Day surgery units
- Directors of nursing
- EBME departments
- Intensive care units
- IV nurse specialists
- Maintenance staff
- Medical directors
- Maternity units
- Medical physics departments
- Neonatology departments
- Outpatient theatre managers
- Paediatric intensive care units
- Risk managers
- Special care baby units
- Theatre managers
- Independent Health and Social Care Providers
–Private Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Mrs D Lane
Smiths Medical International Ltd
Colonial Way
Watford
WD24 4LG
Tel: 01923 475 809
Fax: 01923 237 576

Mr J Tullett
Regulatory Affairs Manager
Smiths Medical International Ltd
Hythe
CT21 6JL

Tel: 01303 236 815 (ext 3202)

Fax: 01303 264 679

Email eu.rep@smiths-medical.com

Or

Enquiries to NIAIC should quote reference number MDEA(NI)2008/053 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

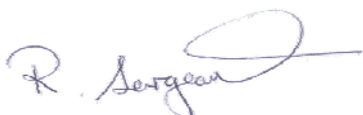
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
8th July 2008

Action Under Way:
30th July 2008

Action Complete:
27th August 2008



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

APPENDIX to MDEA(NI)2008/053

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: