

URGENT FIELD SAFETY NOTICE

**Affected devices: Graseby 500 & 505 Volumetric Pump
(Sold as Models 3000 and 3100 outside UK)**

Type of action: Field Safety Corrective Action

Date: 8th February 2008

Attention: CEO, Risk Managers, Clinicians, Nursing Staff and other users of the above products

Details on affected devices: All serial numbers of devices listed above.

Description of the problem:

Smiths Medical would like to make users of the above listed pumps aware of the possibility of delivering an unintended bolus if the pump door is opened and then immediately closed. This is due to a timing delay when the pumping mechanism resets itself.

There is the possibility of delivering an unintended 1.7ml bolus if the pump door is opened and then immediately closed following stoppage of the pump. This is due to there being a time lag as the pump mechanism sets itself up when switched on. If the pump door is opened and then closed too quickly, the pumping mechanism may be positioned such that there may be pressure applied to the administration set 'pillows'. This action can cause an immediate unintended bolus if the lower clamp is open. If the lower clamp is closed, then the fluid can become pressurised and allow an unintended bolus when the lower clamp is opened.

If the pumping mechanism is allowed sufficient time to reset between opening and closing the door, then no unintended bolus is delivered.

These devices have been used in the global market for over 25 years with a good reputation for safety and reliability. Smiths Medical is not aware of any clinical incidents relating to this issue and believes these pumps are safe and effective when used in accordance with the labelling and Operator's Manual, in addition to the new Warning outlined below.

Advice on action to be taken by the user:

As described in the pump's Operator's Manual, users should ensure that the roller clamp on the administration set is closed before opening the pump door to prevent accidental free flow.

Additionally, Smiths Medical will be updating the Operator's Manual to include the following additional Warning:

WARNING

Always wait for a count of at least 6 seconds after opening the pump door before closing it again. Opening the pump door and then closing the door immediately could cause the delivery of an unintended bolus dose to the patient, resulting in patient injury or death

All users should be made aware of the Operator's Manual Addendum containing this additional Warning. The Addendum should be copied and placed directly in the Operator's Manual for each pump.

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

Also, in order for Smiths Medical 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 letter. The action has been taken in conjunction with the MHRA.

Sincerely,
SMITHS MEDICAL INTERNATIONAL LTD



Quality Assurance Manager

**Graseby 500 & 505 Volumetric Pump (Sold as Models 3000 and 3100 outside UK)
possibility of delivering an unintended bolus**

ATTACHMENT 1

Field Safety Corrective action notice acknowledgement- February 2008

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			
	I have read and understand this notice; communicated this information to all users; and put the Operator's Manual Addendum into the Manual.		
	I have read and understand this notice; communicated this information to all users; and put the Operator's Manual Addendum into the Manual. I would like ___ additional copies of the Addendum for my pumps.		
	I have read and understood this notice; communicated this information to all users; and would like a copy of the updated Operators Manual when Available. (Please indicate in what format you would like this update)		
	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">I would like an electronic copy (please provide e-mail address below) <input type="checkbox"/></td> <td style="width: 50%;">I would like a printed copy (please provide name and postal address below) <input type="checkbox"/></td> </tr> </table>	I would like an electronic copy (please provide e-mail address below) <input type="checkbox"/>	I would like a printed copy (please provide name and postal address below) <input type="checkbox"/>
I would like an electronic copy (please provide e-mail address below) <input type="checkbox"/>	I would like a printed copy (please provide name and postal address below) <input type="checkbox"/>		

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

Note: The following information help Smiths Medical best assist you.

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

Customer Signature:

Date: