

# MEDICAL DEVICE ALERT

Issued: **20 December 2007** at 14:30      Ref: **MDA/2007/100**

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

<b>Device:</b> Volumetric infusion pump. Smiths Medical (Graseby) 500 and 505 volumetric infusion pumps – all models.									
<b>Problem:</b> There is the possibility of delivering an unintended 1.7 ml bolus if the pump door is opened and then immediately closed following a stoppage of the pump.	▶ Page 2								
<b>Action by:</b> Users of these pumps.									
<b>Action:</b> To prevent unwanted boluses being delivered to a patient, always wait for a count of at least six seconds after opening the pump door before closing it again.									
<b>Distributed to:</b> <table border="0"> <tr> <td>NHS trusts in England</td> <td>– Chief Executives*</td> </tr> <tr> <td>Commission for Social Care Inspection (CSCI)</td> <td>– Headquarters</td> </tr> <tr> <td>Healthcare Commission (CHAI)</td> <td>– Headquarters</td> </tr> <tr> <td>Primary care trusts in England</td> <td>– Chief Executives*</td> </tr> </table> <p style="text-align: right;">* via CE Bulletin</p>	NHS trusts in England	– Chief Executives*	Commission for Social Care Inspection (CSCI)	– Headquarters	Healthcare Commission (CHAI)	– Headquarters	Primary care trusts in England	– Chief Executives*	▶ Page 2
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<b>Contacts:</b> Details of manufacturer contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.	▶ Pages 2-3								
<b>Appendix:</b> Smiths Medical Customer Information Bulletin	▶ Page 4								

### Action deadlines for the Safety Alert Broadcast System (SABS)

**Deadline (action underway): 21 January 2008**

**Deadline (action complete): 20 February 2008**

This notice is also on our website: <http://www.mhra.gov.uk>

## Problem:

There is the possibility of delivering an unintended 1.7 ml bolus if the pump door is opened and then immediately closed following a 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 pressure is 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.

Smiths Medical has added the following to the user manual:

### '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.'

and issued a customer information bulletin (see appendix).

## Distribution:

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

### Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- All clinical departments
- All wards
- Ambulance staff
- Clinical governance leads
- Day surgery units
- Directors of nursing
- EBME departments
- Intensive care units
- IV nurse specialists
- Maintenance staff
- Maternity units
- Medical directors
- Medical physics departments
- Neonatology departments
- Outpatient theatre managers
- Paediatric intensive care units
- Risk managers
- Special care baby units
- Theatre managers

### Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes providing nursing care (adults)
- Nursing agencies

### Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospices
- Hospitals in the independent sector
- Independent treatment centres

### Primary care trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Community hospitals
- Equipment libraries and stores

## Contacts:

Enquiries to the manufacturer should be addressed to:

Jon Charters  
Smiths Medical International Ltd  
Colonial Way  
Watford  
WD24 4LG

Tel: 01923 475 809

Fax: 01923 237 576

E-mail: [jon.charters@smiths-medica.com](mailto:jon.charters@smiths-medica.com)

## Contacts (continued):

Enquiries to the MHRA should quote reference number **2006/007/020/401/003** and be addressed to:

### Technical aspects:

Mr J Lefever or Mr G Ali  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7084 3262 / 3102

Fax: 020 7084 3209

E-mail: jim.lefever@mhra.gsi.gov.uk  
geoff.ali@mhra.gsi.gov.uk

### Clinical aspects:

Mr J Plumb  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7084 3128

Fax: 020 7084 3111

E-mail: jonathan.plumb@mhra.gsi.gov.uk

### Change of address or removal from address list for CSCI and Healthcare Commission:

CSCI Customer Service Unit  
St Nicholas Building  
St Nicholas Street  
Newcastle-upon-Tyne  
NE1 1NB

Tel: 0845 015 0120

E-mail: enquiries@csci.gsi.gov.uk

Healthcare Commission  
Finsbury Tower  
103-105 Bunhill Row  
London  
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

## How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre  
Medicines and Healthcare products Regulatory Agency  
Market Towers, 1 Nine Elms Lane, London SW8 5NQ  
Telephone 020 7084 3080 or Fax 020 7084 3109  
or e-mail: [aic@mhra.gsi.gov.uk](mailto:aic@mhra.gsi.gov.uk)

(An answerphone service operates outside normal office hours)

**Medical Device Alerts are available in full text on the MHRA website:** <http://www.mhra.gov.uk>

Further information about **SABS** can be found at [www.info.doh.gov.uk/sar2/cmopatie.nsf](http://www.info.doh.gov.uk/sar2/cmopatie.nsf)

Smiths Medical Customer Information Bulletin

### **Product: - Graseby 500 & 505 Volumetric Pump (Sold as Models 3000 and 3100 outside UK)**

Smiths Medical would like to make customers 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.

If the pump door is opened and then closed too quickly, the pumping mechanism may be positioned such that pressure is 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. The unintended bolus can be up to 1.7ml each time the door is opened and quickly closed.

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

The Operator's Manual provided with these Graseby pumps provides a warning that the roller clamp should always be closed before opening the door to prevent accidental free flow.

These devices are long established in the market with a good reputation for safety and reliability. Smiths Medical is not aware of any clinical incidents relating to this matter. However, in order to help clarify this matter for users, Smiths Medical will be updating the Pump User Manual to include the following 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.**

For further information or advice, do not hesitate to contact the Technical Support Team at:-

Smiths Medical Ltd, Product Support Group.

Brian Lane: Tel/Fax +44 (0) 1923 475933 e-mail [brian.lane@smiths-medical.com](mailto:brian.lane@smiths-medical.com)