

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/113

Issued: 20th Dec 2007



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section
<p>Medical Device/Equipment: Volumetric infusion pump. Smiths Medical (Graseby) 500 and 505 volumetric infusion pumps – all models.</p>	▶ ①
<p>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.</p>	▶ ②
<p>Action by: Users of these pumps.</p>	▶ ③
<p>Action: 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.</p>	▶ 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 Hospices</p>	▶ ⑤
<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None Required</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Volumetric infusion pump. Smiths Medical (Graseby) 500 and 505 volumetric infusion pumps – all models.

2. 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).

3. ACTION BY:

All users of this device.

4. ACTION:

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.

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
- 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
- Independent Health and Social Care Providers – Private Hospitals, Clinics, and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to 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

Enquiries to NIAIC should quote reference number MDEA(NI)2007/113 and be addressed to:

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

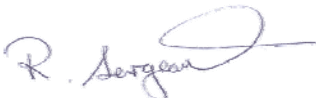
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None Required.



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)2006/01. 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)2007-113

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