

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/112

Issued: 18 December 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Enteral feeding pump. Fresenius Kabi Applix Smart pump – all models.</p>	▶ ①
<p>Problem: Misloaded or incorrectly fitted giving sets can permit free flow of feed to the patient with the possibility of fatal over-feeding.</p>	▶ ②
<p>Action by: All medical, nursing and allied health professional staff involved with the management and use of these and other enteral feeding pumps.</p>	▶ ③
<p>Action: Ensure that the giving set is correctly fitted in the lower tube guide and is slightly stretched in a straight line (further Actions found on page 2). See appendix for manufacturer's instructions for use.</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</p> <p style="text-align: right;">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:

Enteral feeding pump - Fresenius Kabi Applix Smart pump – all models.

2. PROBLEM:

Incidents have been reported to the MHRA where patients have received gross over-feeds from Fresenius Kabi Applix Smart feeding pumps. Two of them resulted in the patients' deaths. No faults were found with the pumps; however, it was shown that similar conditions could be simulated if the giving set was incorrectly fitted during set up. An incorrectly fitted giving set can allow free flow of the feed through the pump directly to the patient. The manufacturer has given explicit guidance in their instructions for use regarding the loading of the set i.e. pump users should ensure that the giving set is inserted in a straight line and slightly stretched through the tube guides. See appendix for full details.

NOTE: Over-feeding is possible with other makes of feeding pumps if the giving sets are not correctly fitted.

3. ACTION BY:

All medical, nursing and allied health professional staff involved with the management and use of these and other enteral feeding pumps.

4. ACTION:

- Ensure all staff/users are adequately trained, with regular assessment of their competencies prior to the use of this type of device.
- The manufacturer's instructions for use (IFU) must be available to end users at all times and users must adhere to the guidance provided by the manufacturer.
- Staff should visually check and record that the device is functioning correctly prior to leaving the device unattended.

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:

- Adult intensive care units
- All wards
- Chief pharmacists
- Clinical governance leads
- Dietetics departments
- Dieticians
- EBME departments
- Equipment stores
- Health and safety managers
- Hospital at home units
- Hospital pharmacists
- In-house maintenance staff
- Maintenance staff
- Medical directors
- Medical libraries
- Medical physics departments
- Nursing executive directors
- Nutrition nurses
- Independent Health and Social Care Providers
– Private Clinics, Residential and Nursing Homes through RQIA
- Paediatric intensive care units
- Paediatric nurse specialists
- Paediatric wards
- Palliative care teams
- Risk managers
- Practice Nurses
- Pharmacy Managers
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Day Care Centres
- Community children's nurses
- Community nurses
- District nurses
- Community Equipment libraries and stores
- Palliative care teams
- Care management team managers
- Community care staff

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Fresenius Kabi Ltd
Cestrian Court, Eastgate Way
Runcorn
Cheshire WA7 1NT

Tel: 01928 533 454

Fax: 01928 533 587

E-mail: Adrian.percival@fresenius-kabi.com

Enquiries to NIAIC should quote reference number MDEA(NI)2007/112 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

Extract from manufacturer's instructions for use

Installing the giving set in the pump

1. Unlock and open the pump door with the door lever.
2. Insert the tube clamp on the giving set into the pump in accordance with the arrow marking, with the clamp lever pointing upwards.
3. Guide the giving set over the pump mechanism and fix it in the lower tube guide ensuring that it is in a straight line and slightly stretched but not elongated.
4. Push the pump door shut and ensure that it engages properly.

