

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/083

Issued: 12th November 2008

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
<p>Medical Device/Equipment: Enteral feeding pump. ClearStar model M771 manufactured by Abbott Nutrition. Specific serial numbers.</p>	▶ ①
<p>Problem: Risk of under-infusion due to cracking/breaking of an internal adapter bracket.</p> <p>Following an initial service programme of these pumps in 2007 (see MDEA(NI)2007-066), Abbott has identified another 298 pumps that may be affected. Abbott is running a second service programme but is unable to locate 38 of these pumps (serial numbers listed in the appendix).</p>	▶ ②
<p>Action by: All staff responsible for prescribing and maintaining enteral feeding devices, particularly dietetic departments and EBME departments.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Check the list of serial numbers in the appendix. Contact Abbott to arrange exchange if the pump is listed. Ensure that users are aware of the manufacturer's customer notice. Where the location of the pump is known to Abbott, its customers will be contacted by Abbott (see appendix). 	▶ ④
<p>Distributed by NIAIC to:</p> <p>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>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>	
<p>Acknowledge Receipt of Alert: 14th Nov 2008</p>	▶ ⑦
<p>Action Under Way: 12th Dec 2008</p>	
<p>Action Complete: 23rd Jan 2009</p>	

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

1. DEVICE/EQUIPMENT:

Enteral feeding pump. ClearStar model M771 manufactured by Abbott Nutrition. Specific serial numbers.

2. PROBLEM:

Risk of under-infusion due to cracking/breaking of an internal adapter bracket.

Following an initial service programme of these pumps in 2007 (see MDEA(NI)2007-066), Abbott has identified another 298 pumps that may be affected. Abbott is running a second service programme but is unable to locate 38 of these pumps (serial numbers listed in the appendix).

3. ACTION BY:

All staff responsible for prescribing and maintaining enteral feeding devices, particularly dietetic departments and EBME departments.

4. ACTION:

- Check the list of serial numbers in the appendix. Contact Abbott to arrange exchange if the pump is listed.
- Ensure that users are aware of the manufacturer's customer notice. Where the location of the pump is known to Abbott, its customers will be contacted by Abbott (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:

- Clinical governance leads
- Dietetics departments
- Dieticians
- EBME departments
- Equipment stores
- Hospital at home units
- Hospital pharmacies
- Medical directors
- Nursing executive directors
- Nutrition nurse specialists
- Palliative care teams
- Risk managers
- Community children's nurses
- Community hospitals
- District nurses
- Independent Health and Social Care Providers – Private Hospital & Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Customer Services Department
Abbott Nutrition
Abbott Laboratories Ltd
Queenborough
ME11 5EL

Tel: 01795 593 312

Fax: 01795 593 340

E-mail: uksales@abbott.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/083 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

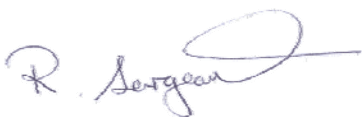
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
14th Nov 2008

Action Under Way:
12th Dec 2008

Action Complete:
23rd Jan 2009



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)2008/083

M771 ClearStar enteral feeding pump - Serial numbers of pumps whose location is unknown to Abbott Nutrition.

M5406594	M5406803
M5406624	M5406821
M5406652	M5406831
M5406662	M5406837
M5406671	M5406846
M5406683	M5406860
M5406691	M5406866
M5406693	M5406869
M5406698	M5406877
M5406718	M5406880
M5406730	M5406900
M5406741	M5406904
M5406750	M5406909
M5406752	M5406932
M5406753	M5406938
M5406762	M5406950
M5406766	M5406962
M5406788	M5406968
M5406999	M5406978

APPENDIX to MDEA(NI)2008/083

Abbott Nutrition
Abbott House
Vanwall Business Park
Vanwall Road
Maidenhead
Berkshire SL6 4XE

t 01628 773355
f 01628 644510



29 September 2008

Dear *insert customer name*,

Re: Voluntary Accelerated Service for ClearStar enteral feeding pump, List Number M771

Abbott Nutrition has identified an additional number of its ClearStar enteral feeding pumps that were not captured during a voluntary accelerated service programme carried out in 2007. Please be reassured that again there is no immediate safety concern and that only a small quantity of pumps with specific serial numbers are affected.

Those pumps affected have an internal adapter bracket that could crack or break, potentially resulting in an under-delivery of feed. In the United Kingdom, there are almost 12,000 ClearStar pumps in circulation and there has only been 1 reported case of under-delivery of feed that has been attributed to this defect.

Abbott Nutrition has implemented an action plan to arrange for the uplift and replacement of the affected pumps and chargers. You will therefore be contacted in due course to arrange this uplift and a replacement pump to be delivered.

For your information, the seven-digit serial number is located on the back of each pump (NOT the back of the charger) as illustrated in the pictures below.



Any patients that you have registered with Hospital to Home and have provided a pump from your buffer stock will be contacted directly. If you have any additional questions about this accelerated service plan, please contact our Customer Services team on 01795 593312 between 9.00am-5.30pm Monday to Thursday, and 9.00am-4.15pm on Fridays.

We appreciate your cooperation and apologise for any inconvenience this may cause you.

Yours sincerely,

Rupert China
QA Manager

 **Abbott**
Nutrition