

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/66

Issued: 23 December 2004

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



HEALTH ESTATES

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: Baxter 6060 solution sets and Sabraset administration sets for use with Baxter 6060 multi-therapy ambulatory infusion pump.</p>	▶ ①
<p>Problem: A missing component in the set prevents the infusion pump from controlling the flow. This could result in free-flow and an overdose of medication to the patient, with no audible alarm. The manufacturer has issued a recall notice (see Appendix).</p>	▶ ②
<p>Action by: All medical and nursing staff, in particular staff responsible for community patients with intravenous devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Ensure that all relevant users are aware of the manufacturer's recall notice and identify patients supplied with 6060 pumps and sets (see Appendix). • Check stock and remove sets from the affected lots from use. • Contact the manufacturer or homecare provider to arrange collection and replacement of stock. • If no alternative lot is available and continued use of the sets is essential, contact the manufacturer for appropriate advice. 	▶ 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 For onward distribution see Section 5</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts, NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Description	Code	Lots affected
Baxter labelled 6060 solution sets with auto clamp	2M9856, 2M9856K, 2M9858, 2M9858K, 2M9859, 2M9861, 2M9862, 2M9874K	Beginning R01, R02, R03*
Sabreset administration set with 100 ml bag and cassette	560500-100, 560500-250	All lots*
Sabreset obsolete codes	560112-GEL	All lots*

2. PROBLEM:

A missing component in the set prevents the infusion pump from controlling the flow. This could result in free-flow and an overdose of medication to the patient, with no audible alarm. The manufacturer has issued a recall notice (see Appendix).

3. ACTION BY:

All medical and nursing staff, in particular staff responsible for community patients with intravenous devices.

4. ACTION:

- Ensure that all relevant users are aware of the manufacturer's recall notice and identify patients supplied with 6060 pumps and sets (see Appendix).
- Check stock and remove sets from the affected lots from use.
- Contact the manufacturer or homecare provider to arrange collection and replacement of stock.
- If no alternative lot is available and continued use of the sets is essential, contact the manufacturer for appropriate advice.

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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSS Board R&I Units
- Practice Nurses
- Sterile Services Departments
- Operating Theatre Staff
- Accident & Emergency Departments
- Allied Health Professionals
- Coronary Care
- Adult & Paediatric Intensive Care
- Theatre Managers
- Resuscitation Officers
- Day Procedure Units
- Maternity Wards
- Paediatric Units
- Special Care Baby Units

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Customer Services
Baxter Healthcare Ltd
1 West Bank Road
Belfast
BT3 9JL

Baxter Healthcare Ltd
Medication Delivery Customer Services
Wallingford Road
Compton
Newbury RG20 7QW

Tel: 028 90777800

Tel: 01635 206 060

Enquires to NIAIC should quote reference number MDEA(NI)2004/66 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)2004/01. 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)2004/66

6th December 2004

**IMPORTANT
PRODUCT
RECALL**

Dear

Subject: 6060 Solution Sets with Auto Clamp Recall

Description	Code	Lots affected
Baxter labeled 6060 Solution Sets with Auto Clamp	2M9856,2M9856K, 2M9858, 2M9858K, 2M9859, 2M9861, 2M9862, 2M9874K	beginning R01, R02, R03*
Sabreset Administration set with 100 ml Bag and cassette	560500-100, 560500-250	All lots*
Sabreset Obsolete codes	560112-GEL	All lots*

*except those that have a suffix T and a colored sticker

Baxter Healthcare has received notification by US customer of free-flow situations that resulted in adverse events associated with the above products. Our investigation identified a missing component, a platen assembly, from a cassette on one of the sets. If a platen assembly is absent from the cassette, the infusion pump cannot occlude the tubing. This could result in a free-flow situation and lead to an overdose of medication to the patient with no audible alarm.

Please stop using the Codes/Lot numbers of product identified below immediately.

Baxter has instituted corrective action at the plant by adding a platen detection fixture to our assembly process to assure all sets are manufactured with the platen properly placed.

Baxter 6060 Solution Sets

Sets with lot numbers starting with R01 – R02 – and R03 – are affected by this action and must be returned, **except those that have a suffix T and a colored sticker***, as they have been re-inspected and are not impacted by this action.

Example of lot number to be returned : R03K14063.

Example of lot number that can be used : R03K14063T **and** coloured sticker on pouch.

Baxter and 6060 Solution Sets are registered trademarks of Baxter International

APPENDIX TO MDEA(NI)2004/66



Sabreset Administration sets

For Sabreset product codes 560500-100 and 560500-250 and Sabreset obsolete codes 560100, 560112-GEL, 560122-L, 567112-L, 560522-100, all lot numbers are affected by this action and must be returned, **except those that have a suffix T and a colored sticker*** as they have been re-inspected and are not impacted by this action

Example of lot number to be returned : 417518

Example of lot number that can be used : 417518T and coloured sticker on pouch.

Please complete the attached reply form and return it via fax to Baxter using the fax number indicated on the form. The completed response form will verify your receipt of this letter and confirm that the use of the above listed sets has been discontinued.

Once your reply form will be received you will be contacted by the Baxter Customer Service to organize return and replacement of the products.

If you have any questions on the return process or if this action will mean that you have no alternative product for use, please call Medication Delivery Customer Services on 01635 206060.

For medical or technical questions please call Surecall on 01604 704698

If you distribute the sets listed in this communication to other healthcare facilities, please notify your customers of this action.

Yours sincerely

A handwritten signature in black ink that reads "Lisa Benages".

LISA BENAGES

National Sales and Marketing Manager
Medication Delivery

Baxter and 6060 Solution Sets are registered trademarks of Baxter International

APPENDIX TO MDEA(NI)2004/66



CUSTOMER REPLY FORM
IMPORTANT PRODUCT RECALL – 6th December 2004 - 6060 SOLUTION SETS

Description	Code	Lots affected
Baxter labeled 6060 Solution Sets with Auto Clamp	2M9856, 2M9856K, 2M9858, 2M9858K, 2M9859, 2M9861, 2M9862, 2M9874K	beginning R01 -, R02 -, R03 -*
Sabreset Administration set with 100 ml Bag and cassette	560500-100, 560500-250	All lots*
Sabreset Obsolete codes	560112-GEL	All lots*

*except those that have a suffix T and a colored sticker

Please complete and fax to 01604 704688

Please fill in all blanks to acknowledge receipt of this Important Product Recall and confirm that the use of those products has been discontinued

Customer Name: _____

Address: _____

Postcode: _____

Customer Phone: _____

Customer Fax: _____

I have received the 6060 Solution Sets communication dated 6th December 2004 and confirm that we have discontinued the use of the above mentioned products and have checked with my Home patients regarding their stock.

I will return units

I have no remaining stock

Completed by :

Name _____ Date _____

Title _____

Signature _____

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