

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/011

Issued: 3rd Mar 2008

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
Medical Device/Equipment: Automated peritoneal dialysis systems. Homechoice/Homechoice Pro (Baxter Healthcare Ltd).	▶ ①
Problem: A potential for the unrecorded delivery of infused fluid during treatment.	▶ ②
Action by: Peritoneal dialysis staff, renal units, district nurses.	▶ ③
Action: Ensure that: <ul style="list-style-type: none"> all users and home dialysis patients are aware of the information listed in the attached manufacturer's advisory notice Baxter is made aware of Homechoice peritoneal dialysis devices used by neonates and paediatric patients so that the exchange of these devices can be prioritised. 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers General Medical Practices	▶ ⑤
Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.	▶ ⑥
Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)	
Acknowledge Receipt of Alert: 5 th March 2008	▶ ⑦
Action Under Way: 31 st March 2008	
Action Complete: 28 th April 2008	

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

1. DEVICE/EQUIPMENT:

Automated peritoneal dialysis systems. Homechoice/Homechoice Pro (Baxter Healthcare Ltd).

2. PROBLEM:

Baxter has identified that, during a fill cycle, in the event of a power failure or during powering down, the Homechoice system may not record the last stages (1-4 pump strokes) of treatment when power is restored. This may lead to the unrecorded delivery of 15 – 60ml of fluid into the patient when power is restored. This overfill can lead to respiratory distress particularly in neonate/paediatric patients.

Baxter is upgrading the software to correct this anomaly and will be contacting all users to arrange the software upgrade.

3. ACTION BY:

Peritoneal dialysis staff, renal units, district nurses.

4. ACTION:

Ensure that:

- all users and home dialysis patients are aware of the information listed in the attached manufacturer's advisory notice (see appendix)
- Baxter is made aware of Homechoice peritoneal dialysis devices used by neonates and paediatric patients so that the exchange of these devices can be prioritised.

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
- Chief pharmacists
- EBME departments
- Haemodialysis units
- Health and safety managers
- Hospital at home units
- Intensive care, directors of (adult/paediatric)
- Medical directors
- Neonatology departments
- Nursing executive directors
- Paediatric intensive care units
- Peritoneal dialysis units
- Pharmacists
- Renal medicine departments
- Renal medicine, directors of
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- District Nursing

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Surecall-Baxter Medical Information
Baxter Healthcare Ltd
Wallingford Road
Compton, Newbury
Berkshire RG20 7QW

Tel: 01635 206 345

Fax: 01635 206 071

Email: surecall@baxter.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/011 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

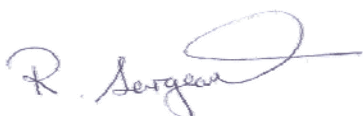
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
5th March 2008

Action Under Way:
31st March 2008

Action Complete:
28th April 2008



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



**IMPORTANT
PRODUCT
INFORMATION**

28th November 2007

Dear Peritoneal Dialysis Professional

Field Safety Notice HOMECHOICE/HOMECHOICE PRO System Automated Peritoneal Dialysis Systems

Baxter Healthcare Corporation is providing you with important information regarding the HOMECHOICE/HOMECHOICE PRO System Automated Peritoneal Dialysis Systems (HOMECHOICE system).

During internal testing, Baxter has identified that during a fill cycle, if the system is powered down or a power failure occurs, the HOMECHOICE system may not record the last 1-4 pump strokes infused into the patient when the power is restored. This situation may create a potential unrecorded delivery of approximately 15-60 mL of fluid being infused into the patient. Baxter has not received any reports of adverse events related to this specific issue.

Baxter is providing an updated software version, which corrects this potential discrepancy. We will contact you and/or your home patients in the near future to upgrade all the HOMECHOICE systems used in your clinic and by your home patients. We will prioritize the upgrade of HOMECHOICE devices used primarily for infants and kids, also known as "Low fill mode" in the HOMECHOICE programming screens. We will provide you and your home patients with HomeChoice systems that have been upgraded in exchange for your current HOMECHOICE systems.

Appendix to MDEA(NI)2008 - 011

Baxter

If you have provided HOMECHOICE/HOMECHOICE PRO System Automated Peritoneal Dialysis Systems to other services, facilities, or home patients, please forward this information as appropriate.

We apologize for any inconvenience you and your staff may experience as a result of this communication.

If you have any questions, please contact Surecall at Baxter Medical Information on 01635 206345.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'C. Forster', with a small flourish at the end.

Catherine Forster
Senior Product Manager
Renal Division
Baxter Healthcare Ltd