

1. DEVICE/EQUIPMENT:

Baxter Colleague volumetric infusion pumps: all models.

2. PROBLEM:

In February 2005 Baxter issued a customer letter and operator's manual addendum informing users of excessive discharge and other issues.

- Damaging discharges may occur when the pump is left on battery power for an extended period of time after the battery depleted alarm occurs.
- When batteries become damaged due to excessive discharge, the battery indicator will overstate the amount of charge remaining.
- Damaged batteries do not affect the pump's ability to function properly while on AC power, provided that no other failures or alarm conditions are present.

With some Colleague pumps at the end of the battery's life, the battery can swell; this can result in the pump's outer case becoming hot to the touch and cause internal damage to the pump.

3. ACTION BY:

All nursing, medical and technical staff using these devices.

4. ACTION:

For users and equipment libraries

- The pump should be connected to AC power when the battery low alert occurs. While in battery alert, a properly maintained battery will provide approximately 30 minutes of infusion time.
- With life supporting infusions users should not rely on the 30 minutes of infusion time following the battery low alert, and should ensure a back-up pump or mains supply is available.
- Never store the pump unplugged and powered on. The batteries may discharge completely, resulting in permanent damage. For pump and battery storage recommendations, see the operator's manual addendum.
- Always store the pump by plugging it into an AC power source, ensuring the pump is turned off and the AC power is turned on. Doing this will ensure the device is charged prior to use.

For maintenance and engineering staff

Excessive discharge problem

During preventative maintenance, it is important to look in the battery and pump history service screen to identify the number of discharges below the alarm threshold. If more than one excessive discharge is listed in the battery history log, Baxter recommend testing or replacing both batteries. Specifics concerning preventative maintenance and battery test/installation instructions are listed in the product service manual.

Swollen battery problem

Colleague volumetric infusion pumps with the following product codes and serial numbers do not have added protection to prevent this problem

Product code	Serial numbers below
HNM8151	13120001CG
WNM8151	13120001CD
2M8151K	13110438CK
2M8153K	13120001TK
FKM8151	all

- Identify affected pumps from the table above and have the replacement battery harness with

overcurrent protection circuit fitted during routine battery replacement or as part of the device's recommended annual preventative cycle. This has been routinely occurring since June 2005 at Baxter service centres.

- Those who do not have a service contract with Baxter should contact Baxter at the address below to obtain replacement battery harnesses at no charge.
- When required always replace both batteries at the same time, with new batteries.

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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Ambulance Staff and Paramedics
- Maternity Wards
- Independent Health and Social Care Providers – Private Clinics and Nursing Homes through HSSRIA
- Operating Theatre Staff
- Accident & Emergency Departments
- Adult & Paediatric Intensive Care
- Theatres
- Special Care Baby Units
- IV Specialist Nurses
- Equipment Libraries, Stores and EBME Departments
- All Wards

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Baxter Healthcare Ltd
1 West Bank Road
Belfast
BT3 9JL

Tel: 028 90777800
Fax: 028 90771100
Email: tom_richardson@baxter.com

Enquires to NIAIC should quote reference number MDEA(NI)2005/94 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
Operational Manager NIAIC

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)2005/01. 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