

**SN (NI) 2002/13**  
**DATE: 28 March 2002**

**For Attention and Action by:**  
**Chief Executive of each HSS Trust**  
**General Manager/Chief Executive of each HSS Board**  
**Chief Executive of each Agency**



**HEALTH ESTATES**  
**ESTATE POLICY**

**NORTHERN**  
**IRELAND**  
**ADVERSE**  
**INCIDENT**  
**CENTRE**

**TITLE:**

**BAXTER COLLEAGUE 1 AND 3 VOLUMETRIC**  
**INFUSION PUMPS: UNWANTED “POWER ON”**  
**OR “POWER OFF” DUE TO FLUID INGRESS**

**MANUFACTURER/SUPPLIER**

Baxter Healthcare Ltd

**PROBLEM**

Baxter Healthcare have identified that Colleague pumps may “power on” or “power off” without the user operating the controls, if fluid enters the main body of the pump. This may occur without any alert or alarm being registered by the pump. Baxter have issued an Urgent Device Correction letter to their customers.

**DISTRIBUTION**

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Medical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Radiation and Medical Oncology Units
- All other areas that use these pumps
- Delivery Units
- Maternity Wards
- Trust Pharmacy Managers
- Accident & Emergency Departments
- General Medical Practitioners
- Practice Nurses
- District Nurses
- Residential & Nursing Homes
- Hospices
- Private Clinics

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

**ACTION**

- Ensure users are aware of the Urgent Device Correction letter: if necessary request a copy from Baxter (contact details on page 2).
- Identify Baxter Colleague pumps with the following code numbers:

**FKM8151, 2M8151K and 2M8153K**

- Remove from service any Colleague pumps that show an unexpected “power on”, “power off” or similar anomalies and contact Baxter Technical Service at the address below.
- During the pump’s next service install an insulator in the area of the ribbon cable (as described in the Baxter Service Bulletin, “Colleague Pumps Keypad Flex Connector

**SAFETY**

**NOTICE**

Insulator Installation”). The insulator and installation instructions can be obtained at no cost from Baxter Technical Service (telephone 01604 704555).

In the interim:

- do not spray cleaning fluid onto the body of the pump or submerge it for cleaning;
- follow the pump cleaning instructions in Appendix 1 and display them in the pump cleaning area;
- use the panel lockout feature as described in the User Manual during infusions.

## BACKGROUND

Baxter Healthcare Ltd have identified that fluid ingress into the main body of the pump can cause a malfunction of the on/off circuitry. This may result in the pump turning itself on or off or rapidly cycling between on and off without giving any alerts or alarms.

Baxter Healthcare have issued an Urgent Device Correction letter informing users of the problem and providing details of the corrective action (fitting an insulator) and interim measures to be taken until the insulator is fitted.

Pumps seen by Baxter engineers or returned to Baxter will have the insulator fitted on a “next seen” basis.

## ENQUIRIES

Enquires to the manufacturer should be addressed to:

Ms Fiona Taylor  
Baxter Healthcare Ltd  
Caxton Way  
Thetford  
Norfolk  
IP24 3SE

Tel: 01842 767 000  
Fax: 01842 767 099

Enquires to the NIAIC should quote the reference number SN(NI) 2002/13 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US  
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714  
Fax: 02890 523900  
Email: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)

Brian Godfrey  
NIAIC 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 Safety Notice SN (NI) 2002/01. 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](http://www.dhsspsni.gov.uk/niaic)

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety  
Áisíneacht Feidhmeannach don Roinn Sláinte. Serbhísí Sóisialta agus Sábháilteacht Phoiblí*



HEALTH ESTATES  
ESTATE POLICY

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**SAFETY**

**NOTICE**

## APPENDIX 1 CLEANING INSTRUCTIONS



HEALTH ESTATES  
ESTATE POLICY

**Baxter**

### Colleague Volumetric Infusion Pump Cleaning Instructions

Please post in all pump cleaning areas.

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

Prior to cleaning the pump, read this procedure carefully. Follow this procedure to ensure that the pump is not damaged during cleaning and remains under Baxter warranty. Contact your authorised Baxter Service Centre for further information.

### CAUTIONS

- Do not use hard instruments for cleaning.
- Do not spray liquids or foam directly on the pump.
- Do not submerge the pump into liquids of any kind.
- Do not clean, disinfect, or sterilise any part of the pump by autoclaving or with the use of ethylene oxide gas. Doing so may damage the pump and void the warranty. Only external parts of the pump should be disinfected.
- Do not use the following chemicals on the pump, as they will damage the front panel: acetaldehyde, acetone, ammonia, benzene, hydroxytoluene, methylene chloride, or ozone. Do not use cleaners containing n-alkyl dimethyl ethyl benzyl ammonium chloride.

### Cleaning the Exterior

Clean the pump after each use with soapy water, a solution of 10% bleach and water, isopropyl alcohol (up to 95%), or a commercial cleaning solution that does not contain any of the ingredients listed above. Follow the manufacturer's dilution instructions for concentrated cleaners. Clean the exterior using a soft cloth sparingly dampened, **not soaked**, with cleaning solution. To clean pumps that have been in an isolation area, select a cleaner that cleans and disinfects.

*Colleague is a trademark of Baxter Healthcare Corporation*

**SAFETY**

**NOTICE**