

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/65

Issued: 31 August 2005

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<p><b>Medical Device/Equipment:</b> Baxter Healthcare Colleague volumetric infusion pumps product code 2M8151K, FKM8151 and 2M8153K – Recall.</p>	▶ ①
<p><b>Problem:</b> Due to a problem with a clocking circuit, the internal communications in some Colleague pumps can be disrupted. If the internal communications are disrupted, the pumps are designed to alarm, stop infusing and display a failure code. This could interrupt critical therapy.</p>	▶ ②
<p><b>Action by:</b> All nursing and medical personnel using these devices.</p>	▶ ③
<p><b>Action:</b> Baxter is asking Trusts to take out of service Colleague pumps that have <b>stopped</b> and <b>alarmed</b> showing any of the following failure codes: 402, 403, 532, 533, 534, 535, 599, 702, 703, 704, 720, 804:21, 804:22, 804:24, 804:29, 804:34, 804:52, 804:54, 804:58 and 12:303:xxx:006. Follow the advice in Baxter's Recall letter originally distributed 25 July 2005. (See appendix).</p>	▶ ④
<p><b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers Hospices</p>	▶ ⑤
<p><b>Contacts</b> Details of manufacturer contacts, NIAIC contacts for technical aspects.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b></p>	▶ ⑦

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

## 1. DEVICE/EQUIPMENT:

Baxter Healthcare Colleague volumetric infusion pumps product code 2M8151K, FKM8151 and 2M8153K – Recall.

## 2. PROBLEM:

Due to a problem with a clocking circuit, the internal communications in some Colleague pumps can be disrupted. Global data have indicated that the incident rate is less than 0.5% of the population of devices in the market place.

If internal communications are disrupted, the pumps are designed to alarm, stop infusing and display a failure code. Because this could interrupt critical therapy Baxter is asking Trusts to take out of service pumps that have displayed any of the failure codes 402, 403, 532, 533, 534, 535, 599, 702, 703, 704, 720, 804:21, 804:22, 804:24, 804:29, 804:34, 804:52, 804:54, 804:58 and 12:303:xxx:006 associated with the problem.

Baxter issued a recall letter in July 2005 advising users of the problem, how to access pumps' event logs in order to check failure codes and return affected pumps.

## 3. ACTION BY:

All nursing and medical personnel using these devices.

## 4. ACTION:

- Ensure the recommendations in the Baxter recall letter have been carried out.
- Areas using Colleague pumps should ensure a back-up pump is available and if a pump stops and shows the failure code it should be removed from use and the engineering department informed.
- Engineering/EBME departments should check the pumps' logs and pumps displaying or having displayed these codes should be withdrawn from use and returned to Baxter Healthcare's service centre.
- Users who are unable or who do not have the resources to access the pump's memory in order to check for the indicated failure codes, or who have no alternative pumps (should they be needed) should contact Baxter for assistance.

## 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
- 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 HSSRIA
- Operating Theatre Staff
- Accident & Emergency Departments
- Coronary Care
- Intensive Care
- Day Procedure Units
- Special Care Baby Units
- Maternity Wards
- Paediatric Units

## 6. CONTACTS:

Enquiries to the manufacturer in Northern Ireland should be addressed to:

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

Tel: 028 90777800  
Fax: 028 90771100

Email: [customer\\_orders\\_belfast@baxter.com](mailto:customer_orders_belfast@baxter.com)

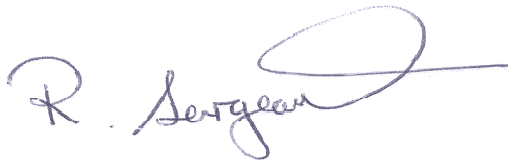
Enquires to NIAIC should quote reference number MDEA(NI)2005/65 and be addressed to:

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](mailto: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)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](http://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)2006-65

## Appendix

**Baxter**

July 25, 2005

**RECALL  
URGENT  
SAFETY  
INFORMATION**

Dear Chief Executive, Director of Nursing, EBME Manager

**RE: COLLEAGUE VOLUMETRIC INFUSION PUMP, PRODUCT CODES  
2M8151K, FKM8151, 2M8153K**

Baxter Healthcare Corporation is sending this communication to provide you with Urgent Safety Information concerning a recall of COLLEAGUE Infusion pumps. We have detected a design issue with the COLLEAGUE Infusion pumps, which may have been associated with three patient deaths. This design issue involves a clocking circuit contained in the pump that can disrupt internal communications in some devices.

Any pump that displays any of the following failure codes: 402, 403, 532, 533, 534, 535, 599, 702, 703, 704, 720, 804:21, 804:22, 804:24, 804:29, 804:34, 804:52, 804:54, 804:58 and 12:303:xxx:0006 should be taken out of service and inspected by authorized service personnel. Failure codes 402, 403, 533, 535 and 599 were previously mentioned in our Important Product Information letter dated May 10th, 2005. You should also review the event history of your pumps and any pumps with a previous history of the aforementioned failure codes should be taken out of service. If you have any questions on how to access the event history, please refer to the enclosed page from the Service Manual or call Surecall – Baxter Medical Information on 01635 206345.

If you provide COLLEAGUE infusion pumps to other services or facilities, please forward this information as appropriate. It is imperative that all end users of COLLEAGUE pumps be notified.

COLLEAGUE pumps are designed to alarm, stop infusing, and display a failure code if it detects an abnormal situation. Because this situation can occur during an infusion, it is imperative that

- Institutions have a contingency plan to mitigate any disruptions during infusion therapy (e.g. have an alternative model available).
- Where an alternative model is not available, particularly where a delay may be life threatening, the trust should conduct a local risk assessment.

All pumps currently being processed through Baxter's service operations will be checked by reviewing the event history, before return to the customer, for any of the failure codes listed above. If a pump is

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found to have any of these failure codes, it will not be returned to you until a corrective action has been implemented. The company will voluntarily hold shipments of new COLLEAGUE pumps until the issue is resolved.

Baxter is currently developing an aggressive action plan to address this issue and we will immediately notify you once it is finalized.

Please complete the attached reply form confirming your receipt of this letter and fax it back to Baxter at the number provided on the form within 2 days of receipt. Returning the form promptly will prevent you from receiving a repeat notice.

We apologize for any inconvenience this will cause you and your staff. If you have questions regarding this communication, please contact Surecall – Baxter Medical Information on 01635 206345.

The Medicines and Healthcare products Regulatory Agency (MHRA) has been notified of this action.

Yours sincerely

**COLIN EDMONDSON**  
National Sales and Marketing Director  
Medication Delivery

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COLLEAGUE VOLUMETRIC INFUSION PUMP, PRODUCT CODES  
2M8151K, FKM8151, 2M8153K

*Customer Reply Form*  
*(Important Safety Information letter dated July 2005)*

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

**028 90771100**

Facility Name and Address:	
Reply Confirmation Completed By: <i>(Please print name)</i>	
Title: <i>(Please print)</i>	
Telephone Number (including Area Code):	

We understand the contents of the letter, performed the actions as outlined in the letter as needed, and have disseminated this information to our staff and to other services or facilities, as applicable.

**Signature/Date:**

MIRED FIELD

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