

Quality and Safety Branch
8 February 2006

Safety Advocate



ALERT

Action Required by:

- Directors of Clinical Governance

Distributed to:

- Directors of Clinical Governance

We recommend you also inform:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations
- Area Directors of Nursing
- Heads of Biomedical Engineering
- Clinical Products Nurses
- Directors of Nursing
- Senior Nurse Managers
- Nursing Unit Managers

Contacts:

Baxter Colleague Volumetric Infusion Pumps & Baxter PCA 11 Infusion Pumps

Susana Catelan


Telephone: (02) 8845 1500

Quality and Safety Branch
NSW Department of Health

Telephone:
02 9391 9200

email:
quality@doh.health.nsw.gov.au

BAXTER INFUSION PUMPS

There are two sets of issues related to Baxter Infusion Pumps as detailed below and overleaf. 

1. Baxter Healthcare Colleague Volumetric Infusion Pumps

Area Health Services have been notified of a number of issues about the Baxter Colleague Volumetric Infusion pumps. For a copy of the letters please contact Baxter Healthcare or the Quality and Safety Branch at the Department of Health.

A table of the product codes and the associated issues identified in each of these notifications follows.

Product codes	Issues and Actions Required:
<ul style="list-style-type: none"> • 2M8151K • 2M8151K-EY • 2M8151K-NP -Aust R70607 • 2M8163-AUST R 79257. 	<ul style="list-style-type: none"> • Battery undercharging; • Generation of False Air Detected Alarm due to IV administration set tugging; • Gearbox wear; • Under infusion; • Non-Detection of upstream occlusion – modification to this section. <p>For information: Baxter provided Area Health Services with information to address or minimise these issues.</p>
<ul style="list-style-type: none"> • 2M8151K • 2M815K-EY • 2M8151K-NP_AUST R 70607 • 2M8163_AUST R 79257 	<ul style="list-style-type: none"> • Colleague Clocking Circuit that can disrupt internal communications in some devices. <p>Action required:</p> <ul style="list-style-type: none"> • AHS were advised to take out of service pumps displaying 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 12:303xxx:006; • Pumps displaying the following codes be removed from service: 810:04, 810:11 until inspected by authorised personnel; • Pump event histories were to be reviewed and any pumps exhibiting these failure codes were to be taken out of service; • Health services were advised to not use Colleague Volumetric Infusion Pumps if a replacement pump was not available.
<ul style="list-style-type: none"> • 2M8151K • 2M8151KEY • 2M8163 	<ul style="list-style-type: none"> • Inadvertent power off <p>Action required: Users may inadvertently press on/off key instead of Start key when attempting top start an infusion. Always verify that the pump is infusing after pressing the start key.</p> <ul style="list-style-type: none"> • External communication port failures – <p>Action required: always follow the Colleague Volumetric Pump Service Manual</p> <ul style="list-style-type: none"> • Pumps exhibiting failure codes beginning with 402,403,533, 535, 599 and 810:04 and 810:11 <p>Action required: remove from service and have inspected by authorised personnel.</p>
<ul style="list-style-type: none"> • 2M8151K • 2M8151KEY • 2M8163 	<ul style="list-style-type: none"> • Battery service life, replacement and pump storage • Swollen battery • Excessive discharge <p>For information: Baxter provided Area Health Services with information to address or minimise these issues. This information does not apply to the following serial numbers and those numerically higher</p> <ul style="list-style-type: none"> • 13110338TC • 13120001CK

ACTION SUGGESTED FOR AREA HEALTH SERVICES

1. Ensure that the information from Baxter Healthcare Pty Limited about the Baxter Colleague volumetric Infusion pumps has been received.
2. Ensure that appropriate action has been taken to address the issues identified by Baxter Healthcare concerning Colleague Volumetric Infusion Pumps.

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2. Baxter Healthcare PCA11 Infusion Pumps Code 2L3104

Baxter Healthcare issued an Alert about reports received of the **PCA 11 Infusion Pumps** delivering unrequested PCA doses. This problem is due to an electrical short in the PCA circuit stimulating repeated pressing of the PCA button. The unrequested bolus doses will not exceed the programmed prescription limits. For a copy of the letter please contact Baxter Healthcare or the Quality and Safety Branch at the Department of Health.

Baxter has identified three circumstances that can produce an electrical short in the PCA circuit simulating repeated pressing of the PCA Button and provided information to address these problems. These three issues and a summary of the actions are identified below.

Issue 1: Damaged PCA cord or button

Action required: Prior to or after each use ensure that the PCA cord is intact and has no cuts or missing insulation, and that the PCA connector and the button are securely attached to the cord.

Issue 2: Partial Sticking of the PCA button

Action required: If the Pump displays "RELEASE THE PCA BUTTON" and the PCA button is not being intentionally pressed, there may be a mechanical fault in the PCA button. Should this be the case then the pump is to be taken out of service IMMEDIATELY for repair.

Issue 3: Fluid ingress into pump or PCA button

Action required: Avoid getting liquids into the Pump or permanent damage may result. This is especially important while cleaning the device, as cleaners must not be sprayed directly onto the pump or the PCA cord and button.

ACTION SUGGESTED FOR AREA HEALTH SERVICES

1. Ensure that the information from Baxter Healthcare Pty Limited about the Baxter Healthcare PCA 11 Infusion Pump Product Code 2L3104 has been received.
2. Develop an action plan and ensure that appropriate action has been taken to address the issues identified by Baxter Healthcare concerning Baxter Healthcare PCA 11 Infusion Pump Product Code 2L3104