

Urgent Field Safety Notice

12th January 2015

Subject: Important Product Information - Colleague – Increase in Manual Tube Release (MTR) Use Error complaints

Product codes: vP1.7 COLLEAGUE Pump. Please see Attachment 1 for a listing of all product codes

Serial numbers: All

Dear Customer,

Baxter Healthcare Corporation is issuing this communication for the COLLEAGUE Pump to remind users to reset the Manual Tube Release (MTR) when it is left in the open position. Users that do not follow the labeled instructions for resetting the MTR prior to use will be unable to power on the device.

**Hazard
Involved**

This has the potential to lead to a delay in therapy as the device will not power on. A delay in therapy has the potential to cause harm when life supporting therapies are intended to be administered. Baxter has received complaints for this issue; however, no adverse events have been reported.

**Action to be
taken by
customers**

Customers are reminded to follow the instructions for resetting the MTR prior to use. Instructions are located on the pump head module next to the MTR knob (figure 1) and in the operator's manual in section 11-17.

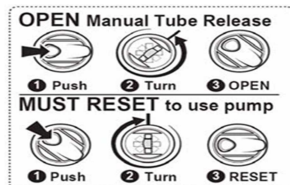


Figure 1

**Action to be
taken in
response to
this notification**

Baxter is kindly requesting that you take the following actions in response to this notification:

1. Acknowledge your receipt of this Field Safety Notice by completing the attached Customer Reply Form (Attachment 2) and return it to Baxter by either faxing it to 01 206 5577 or scanning and e-mailing it to QA_Dublin@baxter.com. Returning the Customer Reply Form promptly will prevent you from receiving repeat notifications.
2. If you distribute this product to other facilities or departments within your

institution, please forward a copy of this letter to them to ensure that they are aware of this communication.

3. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this action.

Further information and support If you have questions regarding this communication, please contact your local Baxter Representative.

The Health Products Regulatory Authority (HPRA) has been notified of this action.

Sincerely,



Ian Gavigan
Quality Systems Manager
Baxter Healthcare Ltd.
Deansgrange Business Park
Blackrock
Co. Dublin
Ph: 00353 1 206 5500

Attachment 1: vP1.7 COLLEAGUE Pump. Product Code Listing
Attachment 2: Customer Reply Form



ATTACHMENT 1
Urgent Field Safety Notice
vP1.7 COLLEAGUE Pump Product Code Listing

Product Code#	Product Name	Affected Serial Numbers
2M81517	Colleague Single Channel Mono Chrome Pump v1.7	All
2M81517K	Colleague Single Channel Mono Chrome Pump English v1.7	
2M81537K	Colleague Triple Channel Mono Chrome Pump English v1.7	
2M91617	Colleague Single Channel CXE Pump v1.7	
2M91637	Colleague Triple Channel CXE Pump v1.7	



Attachment 2
CUSTOMER REPLY FORM

(URGENT FIELD SAFETY NOTICE DATED 12TH JANUARY 2015)

vP1.7 COLLEAGUE PUMP

Product code: 2M81517, 2M81517K, 2M81537K, 2M91617, 2M91637

Serial Number: All

Please complete and return one copy of this form per facility either by fax (Fax :01 206 5577) or by e-mail (QA_Dublin@baxter.com) as confirmation that you have received this notification.
A fax cover sheet is not required.

Facility Name and Address: <i>(Please Print)</i>	
Reply Confirmation Completed By: <i>(Please Print Name)</i>	
Title: <i>(Please Print)</i>	
Email and/or Telephone Number (Including Area Code):	

- We have received the above mentioned letter and have disseminated this information to our staff, other services and facilities.
- We have received the above mentioned letter and have disseminated this information to customers.

Signature/Date: REQUIRED FIELD	_____
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