

12<sup>th</sup> December 2014

**Subject: Important Product Information** - Colleague – Backlight complaints

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

**Serial numbers:** All

Dear Customer,

Baxter Healthcare is issuing this communication for the COLLEAGUE Pump vP1.7 to clarify the life expectancy of the display back light used in the COLLEAGUE vP1.7 infusion pumps with monochrome displays. The display backlight has been designed to have an average life of 10,000 hours. If the back light is left powered on 100% of the time, the light may burn out in less than 2 years.

**Hazard  
Involved**

Back light failures of the COLLEAGUE volumetric pump may prevent the user from reading/visualizing the relevant therapy information in low lighting conditions. This hazard will not impact the pump functionality, yet the user may be tempted to turn off the device which could result in delay of therapy.

**Action to be  
taken by the  
Healthcare  
providers**

Customers are encouraged to ensure that the back light is turned off when not required. The location of the back light key may be found in the COLLEAGUE operations manual. If the back light fails, customers should not be tempted to turn off the device, as the back light failure does not impact pump functionality. Customers should rather ensure the pump is used in an adequately lit environment until the main display can be replaced.

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

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

- Acknowledge your receipt of this Important Product Information 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.
- 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.  
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 call... (to be adapted locally)

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

Sincerely,

A handwritten signature in black ink, appearing to read 'I. Gavigan', is positioned above a horizontal line.

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

Attachment 1: COLLEAGUE Pump P1.7 Product Code Listing  
Attachment 2: Customer Reply Form



**ATTACHMENT 1**  
**Important Product Information**  
**COLLEAGUE Pump P1.7 Product Code Listing**

| Product Code# | Product Name                       | Affected Serial Numbers |
|---------------|------------------------------------|-------------------------|
| 2M81517K      | U.K. English Colleague Pump v1.7   | All                     |
| 2M81537K      | U.K. English Colleague 3 Pump v1.7 |                         |



**Attachment 2**  
**CUSTOMER REPLY FORM**

(IMPORTANT PRODUCT INFORMATION LETTER DATED 12<sup>TH</sup> DECEMBER 2014)

**COLLEAGUE PUMP P1.7**  
**Product code: 2M81517K & 2M81537K**  
**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:<br><i>(Please Print)</i>            |  |
| Reply Confirmation Completed By:<br><i>(Please Print Name)</i> |  |
| Title:<br><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.

|  |       |
|--|-------|
| <b>Signature/Date:</b><br>REQUIRED FIELD | _____ |
|--|-------|