



**Medical Devices Bureau, Ministry of Health Malaysia**  
 Level 5, Block E6, Complex E,  
 Federal Government Administrative Centre,  
 62590 Putrajaya, MALAYSIA.  
 Tel: 03-8883 2248/2249/2264  
 Fax: 03-8888 6184

**Medical Device / Equipment ALERT : Field Corrective Action**

**Date Issued : 11 JULY 2008**

**Ref:MDB/A/2008/008**

<b>IMMEDIATE ACTION</b>	
<b>ACTION</b>	√
<b>UPDATE</b>	√
<b>INFORMATION REQUEST</b>	

<b>PRODUCT</b>	<b>Baxter Colleague Triple Channel Mono, CX and CXE Volumetric Infusion Pumps – Product Codes: 2M8163 – upgrading to the latest software.</b>
<b>CLASS</b>	Not Mentioned
<b>USE</b>	Infusion Pump.
<b>SOURCE OF MEDICAL DEVICE RECALL / ALERT</b>	<b>Attachment(s) from Baxter Healthcare (M) Sdn. Bhd. via electronic mail.</b>
<b>RECALLING / ALERTING FIRM</b>	<b>Baxter Healthcare (M) Sdn. Bhd. Suite 12.01, Level 12 The Gardens, South Tower Mid Valley City, 59200 Kuala Lumpur Malaysia</b>
<b>REASON FOR RECALL/ALERT</b>	<b>- Refer the attached Notification Letter -</b>
<b>SCENARIO IN MALAYSIA</b>	<b>- Refer the attached Notification Letter -</b>
<b>ACTION</b>	<b>- Refer the attached Notification Letter -</b>
<b>RECOMMENDATION</b>	Users of the abovementioned device should contact the distributors/supplier of this device (if available) and inform the Medical Devices Bureau, Ministry of Health providing the following information:-  a. Name of healthcare centre/hospital/clinic b. Contact person and contact number

	c. Numbers of units available
<b>CONTACT/ENQUIRIES</b>	<b>Ng Yu Seen,</b> <b>Baxter Healthcare (M) Sdn. Bhd.</b> <b>Suite 12.01, Level 12</b> <b>The Gardens, South Tower</b> <b>Mid Valley City,</b> <b>59200 Kuala Lumpur</b> <b>Malaysia</b>  <b>Tel:- 03-22676015</b>
<b>REFERENCES FOR DETAILS</b>	<b>- Refer the attached Notification Letter -</b>



July 11, 2008

Assistant Director  
Medical Device Bureau  
Level 4 & 5, Block E6, Parcel E, Precinct 1,  
Federal Government Administration Centre,  
62590 Putrajaya

Attn: En Hirsham Junaidi

**Subject: Colleague 3 Volumetric Infusion Pump Buffer Overflow Issue - Product code: 2M8163**

Dear En Hirsham,

Baxter Healthcare Corporation is sending the attached communication to provide customers with important information regarding the corrective actions planned on COLLEAGUE triple channel Volumetric Infusion pumps to address the Buffer Overflow issue described in our letter of October 2007.

If you have any questions about this communication, please contact NG YU SEEN at 03-22676015.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ng Yu Seen', is written over a light blue horizontal line.

NG YU SEEN  
Assistant Manager, Regulatory Affairs

Attachment:  
*Customer 2008 letter; Subject: COLLEAGUE Triple Channel Mono, CX and CXE Volumetric Infusion Pumps*



July 11, 2008

**Product Manager  
T-Medic Sdn Bhd  
H-2-11, Jalan Sri Hartamas 1 (1/70A)  
60, Plaza Damas Sri Hartamas  
Taman Sri Hartamas  
50480 Kuala Lumpur**

**IMPORTANT  
PRODUCT  
INFORMATION**

**Attn: Ms Tan Poh Hiok**

**Subject: COLLEAGUE Triple Channel Mono, CX and CXE Volumetric Infusion Pumps  
Product Codes: 2M8163**

Dear Poh Hiok,

In June 2007 Baxter Healthcare Corporation identified a processing anomaly related to a buffer overflow condition, which could cause the triple channel pump to stop infusing. Under certain circumstances, this anomaly could occur in COLLEAGUE® triple channel pumps with software version 5.07.

Our investigations led to the issuance of a Field Corrective Action (FCA) in October 2007, which described the conditions under which the buffer overflow issue could occur and warned against the use of triple channel pumps under these conditions.

The purpose of this communication is to inform you that we have identified the root cause, fixed the software issue and have made additional modifications to improve product reliability. With these modifications complete, we are pleased to inform you that Baxter is ready to initiate the upgrade of COLLEAGUE triple channel pumps to the latest software release, beginning in March of 2009.

The upgrade activity will include the following changes:

**Software upgrades:**

- Correction to address the potential buffer overflow issue identified in triple channel pumps
- The addition of a power-on speaker safety test
- New battery management diagnostics and messaging to improve battery life and utilization



**Hardware upgrades:**

- Upgraded gaskets for improved EMC (Electro-Magnetic Compatibility) compliance
- Plastic prisms to be replaced with glass prisms, where appropriate, to prevent potential degradation of the pump's slide clamp sensing capabilities due to use of some cleaning agents
- New batteries and battery harness
- New power cord label to reinforce the importance of plugging the pump in to AC power

We sincerely apologize for the delay in the resolution of this issue and any inconvenience this may have caused you and your staff. Patient safety is our first priority and it has taken several months to thoroughly verify and validate the pump's safety and reliability through simulated-use testing, as well as live-use evaluation in clinical environments. We are pleased to report that the customers who participated in live-use evaluations reported high levels of satisfaction with the pumps.

Our objective is to return all COLLEAGUE triple channel pumps to full service as quickly as possible with minimal disruption. Your local Baxter representative will be informing you of timelines and other pertinent details for your facility.

Please complete the attached Customer Reply Form confirming your receipt of this letter and fax it back to Baxter at the number provided on the form. Returning the form promptly will prevent subsequent notices being sent to you. If you believe that your facility is not impacted by the issue described above, we ask that you still return the Customer Reply Form to acknowledge receipt.

We thank you for your continued loyalty and support. Our goal is to *restore* and *renew* your confidence in us as a trusted partner. If you have additional questions, please contact Ng Yu Seen at 03-2267 6015.

The Medical Device Bureau has been notified of this action.

Sincerely,

Ng Yu Seen  
Assistant Manager, Regulatory Affairs



**COLLEAGUE Triple Channel Mono, CX, CXE Volumetric Infusion Pumps**

**Product Codes: 2M8163**

*Customer Reply Form (Important Product Information letter dated July 11, 2008)*

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

**Fax : 03-2283 1784**

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

We have received the letter and have disseminated this information to our staff and to other services or facilities, as applicable.

Signature/Date: \_\_\_\_\_