

10 June 2010

Zul Hirsham bin Junaidi
Medical Device Bureau, Ministry of Health Malaysia
Level 5, Bangunan Plot 3C4,
No. 26, Jalan Persiaran Perdana
Precinct 3, 62675
Putrajaya

Dear Encik Hirsham

On May 3rd 2010, Baxter announced the planned recall of COLLEAGUE infusion pumps in the United States. This announcement affects the U.S. market ONLY and will be carried out over a period of time.

As previously disclosed, Baxter entered into a consent decree, a legal agreement with the FDA under which the company has been pursuing remediation of the infusion pumps. The decree permits the FDA to require the recall of the pumps, and the FDA has exerted that right.

This development is not the result of any new quality issues and has no impact on the ongoing deployment activities in Malaysia or on the use of the COLLEAGUE infusion pumps in Malaysia.

In Asia Pacific, Baxter has worked with Ministries of Health and deployed software upgrades that have corrected a number of previously identified safety issues. These upgrades were not fully deployed in the U.S. given the requirements imposed as a result of the consent decree. Additionally in Asia Pacific, the next Colleague upgrade (P1.7) is currently being developed and is scheduled for release later this year.


All COLLEAGUE infusion pumps in Malaysia have upgraded versions than those which are present in US. All triple channel pumps are upgraded to P1.5 configuration which is 2 versions ahead of US and all single channel pumps are upgraded to Vista Balance or Colleague 2006 configurations which are 1 to 2 versions ahead of US.

The COLLEAGUE infusion pump continues to be safe and effective to use if used in accordance with the operators' manual, as well as additional instructions contained in Field Corrective Actions (letters to customers).

Baxter is a longstanding leader in the infusion pump market and remains committed to offering customers advanced infusion technologies. The company remains committed to supporting COLLEAGUE and our COLLEAGUE customers in Asia Pacific for many years to come.

If you have further questions, please contact the undersigned at telephone number +603 2267 6015

Yours sincerely,



Ng Juwin
QA/PV Specialist