Medication Delivery

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Baxter

March 18, 2009

Dear Valued Customer,

In response to your request, the following is confirmation regarding actions related to Baxter Healthcare Corporation's COLLEAGUE Field Corrective Action (FCA) letter of January 23, 2009.

The U.S. Food and Drug Administration (FDA) assigns a recall classification for all FCA notifications. In a press release issued by Baxter on March 11, 2009, the company announced that FDA had classified the COLLEAGUE Urgent Device Correction letter dated January 23, 2009 as a Class I recall. Although this is the most serious of classifications, this does not require the return of infusion pumps, and does not require any actions or measures by customers beyond the instructions previously provided by Baxter in the January 23, 2009 FCA letter.

The COLLEAGUE Volumetric Infusion Pumps, when used in accordance with all labeling and any additional instructions provided in FCA communications, including the January 23, 2009 letter, are safe and effective for use and can continue to remain in service.

Should you have any further concerns, please do not hesitate to contact your local Baxter sales representative.

Best regards,

Wendy Kollross, RN

Wendy Kollross, RN, BSN, MBA
Director, Field Corrective Action, Corp Quality
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David H Barch MD

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