



[FDA](#) > [CDRH](#) > [Medical Device Recalls](#) > Class 1 Recall: Baxter Colleague Single and Triple Channel Volumetric Infusion Pumps

## Class 1 Recall: Baxter Colleague Single and Triple Channel Volumetric Infusion Pumps

**Date Recall Initiated:** January 23, 2009

**Product:** Baxter Colleague Single and Triple Channel Volumetric Infusion Pumps

Model numbers: Mono 2M8151 and 2M8153, CX 2M8161 and 2M8163, and CXE 2M9161 and 2M9163

These products were manufactured and distributed from February, 1997 through December, 2008.

**Use:** Electronic infusion pumps deliver controlled amounts of medications or other fluids to patients through an intravenous (IV), intra-arterial (IA), epidural, and other acceptable routes of administration.

**Recalling Firm:** Baxter Healthcare Corp.  
Rt. 120 & Wilson Rd.  
Round Lake, Illinois 60073

**Reason for Recall:** The company identified software and battery usage failures that result in a delay in or interruption of infusion that may cause serious injury and/or death.

**Public Contact:** Customers may call Baxter Healthcare Corp. at 1-800-843-7867

**FDA District:** Chicago

**FDA Comment:** On January 23, 2009, the company sent a correction letter to all of its customers about failures that could lead to:

- interruption of therapy
- damaged battery messages
- smoke and fire hazards
- serious injury and/or death

The letter also:

- advised institutions to have contingency plans to verify that back-up pumps are available
- provided new steps for addressing an interruption of therapy with any failure code
- provided instructions for addressing damaged battery messages
- provided instructions for proper device cleaning

For more information about this recall, please see the company's press release at: [http://www.baxter.com/about\\_baxter/news\\_room/news\\_releases/2009/03\\_11\\_09\\_colleague.html](http://www.baxter.com/about_baxter/news_room/news_releases/2009/03_11_09_colleague.html)

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of the product will cause serious injury or death.

Health care professionals and consumers may report adverse reactions or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

- Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- Regular Mail: use postage-paid FDA form 3500 available at: [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm)  
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- FAX: 1-800-FDA-0178

Updated March 11, 2009