



VITALS

A Weekly Safety Newsletter For Medical Transport Professionals

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Urgent Device Correction Classified by FDA to a Class 1 Recall

On January 23, 2009, Baxter sent an Urgent Device Correction letter regarding the COLLEAGUE Volumetric infusion pump. Affected models include 2M8151 and 2M8183, CX 2M8161 and 2M8163, and CXE 2M9161 and 2M9163. Since there have been serious injuries and/or deaths associated with failures identified in the letter, the FDA issued the Class 1 Recall on March 11, 2009.

The complete Urgent Device Correction letter is available at www.baxter.com.

Even if you don't have these pumps, this 17-page letter contains some useful information regarding pump maintenance and troubleshooting. Adverse reactions to the use of these products should be reported to the FDA's MedWatch Program at www.fda.gov/medwatch/report.htm. Baxter also receives reports and questions at 1-800-843-7867 between 0700 and 1700 CDT.

According to the Baxter Press Release: "Baxter notified customers about failure codes in COLLEAGUE pumps that cause them to alarm and stop infusing while delivering critical medication and fluids to patients. This information also includes the possibility of overheating in the device, resulting in smoke and fire if improperly cleaned and/or if there is compromised battery harness insulation. Additionally, Baxter notified customers about a high occurrence of damaged battery messages related to the use of the pump as a battery-operated device. The letter reminds customers that safe and effective use of COLLEAGUE pumps is dependent on specific battery care practices as described in the operator's manual."

One recommendation to ensure safety is to have a back-up infusion pump available. If this is not practical, there should be policies and procedures for your personnel to follow when dealing with a pump failure. In addition to pumps, do your personnel know what to do when any piece of equipment fails? Are your maintenance, cleaning and inspection practices regarding medical devices compliant with the manufacturers' guidelines, up to date, documented and enforced? Include equipment failures when you do scenarios as part of your continuing education next time.

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