



MEMORANDUM

To: Clinic Manager/Administrator

From: Shean Strong, Quality Improvement Director
Lisle Mukai, Quality Improvement Coordinator

Subject: **Urgent Recall**

Date: January 29, 2010



Urgent Recall: Edwards Lifesciences Aquarius Hemodialysis System

FDA and Edwards Lifesciences notified healthcare professionals of a Class I recall of the Aquarius Hemodialysis System due to reports of clinically significant fluid imbalance and the potential for users to repeatedly override the fluid imbalance alarm. This could result in a decrease or increase in the volume of the circulating blood, which may result in serious injuries or death.

The recall includes model numbers: **GEF08200, GEF09500, GEF09600, GEF09700, and GEF09800**, using Software version 6.00.04. The product was distributed from July 12, 2007 through March 18, 2009. Baxter International, Inc. is the U.S. distributor of the Aquarius.

The company notified its customers of a planned software upgrade to prevent users from bypassing the fluid balance alarm more than five times in a 20-minute period.

The company received reports of clinically significant fluid imbalance.

When a certain level of fluid imbalance is detected the Aquarius will trigger an alarm. However, users are able to override this alarm and continue therapy. By repeatedly overriding the balance alarm without solving the issue, such as a closed clamp or kinked line, it is possible to remove too much fluid from or replace too much fluid to the patient. In extreme cases, this could result in a decrease or increase in the volume of the circulating blood, which may result in serious injuries or death.

Public Contact:

Baxter International, Inc. is the U.S. distributor of the Aquarius. For questions regarding the Aquarius, contact the Baxter Clinical Help Line at (888) 736-2543.

Mission Statement

To provide leadership and assistance to renal dialysis and transplant facilities in a manner that supports continuous improvement in patient care, outcomes, safety and satisfaction.