

Medical Devices

Edwards Lifesciences Inc., Aquarius Hemodialysis System

Recall Class: Class I

Date Recall Initiated: January 11, 2010

Product Name: Aquarius Hemodialysis System

Model Numbers: GEF08200, GEF09500, GEF09600, GEF09700, and GEF09800, using Software version 6.00.04

This product was manufactured from July 12, 2007 through March 18, 2009 and distributed from July 12, 2007 through March 18, 2009.

Use:

A Hemodialysis system is used to clean waste products and extra fluid from the body after the kidneys have failed. It also monitors the fluid going into and out of the patient.

Recalling Firm:

Edwards Lifesciences, LLC
1 Edwards Way
Irvine, California 92614-5688

Reason for Recall:

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 1-888-736-2543.