



Edwards

UPDATE Field Safety Notice 2008-11-20

Total Fluid Loss and Substitution Fluid Nonconformance Update for the Aquarius Device Platform 4, software 4.01.11 and 4.01.12

«CENTRE»

«ADRESSE»

«CITY», «STATE» «ZIP_CODE»

July 29th, 2009

In November 20th 2008 Edwards initiated a Field Safety Notice for the Aquarius hemofiltration machines with Software 4 and 6 - TOTAL FLUID LOSS (TFL) 2008-11-20.

In the Field Safety Notice, you were instructed not to override fluid balance alarms as this could potentially result in hypovolemia or hypervolemia and in extreme cases lead to death or serious injuries.

Despite clear instructions in the operating manual (see attachment 1) and help screens instructing the user in the case of balance alarms, Edwards planned to develop an upgrade of software versions 4 and 6 in order to prevent repeated overriding of fluid balance alarms.

After careful consideration, Edwards has decided that instead of a software 4 upgrade, a specific warning label will be placed on every Aquarius machine with software 4.

Technical Service will contact you for implementation of this action.

Please note that software 6 machines will be upgraded as originally communicated.

Sincerely yours,

Frédérique Pedretti
Director Quality Europe



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Attachment 1 - Erratum for the Aquarius Device Platform 4 OPM

Erratum 4

The following warning has been added to section 4.1 Description of Alarm Operation, on page 39 of the OPM.



Warning! Repeated override of the Fluid Balance Alarm during treatment may result in a patient losing or gaining excessive amounts of fluid. Hypovolemia (excessive fluid loss) or hypervolemia (excessive fluid gain) can lead to serious patient injury.

Please correct a fluid balance alarm. Options for error removal are shown on page 40.

If a fluid balance alarm issue cannot be resolved immediately, end the treatment and remove the Aquarius system from use until the device is properly calibrated by an Edwards Lifesciences certified technician.