Extract:

The FDA has identified the occurrence of Situation 1, 2 and 3 as a Class I recall, the most serious type of recall.

Use of these devices may cause serious injuries or death. The FDA has identified the occurrence of Situation 4 as a Class II recall and use of these devices may cause temporary or medically reversible injury.

BD/CareFusion 303 is recalling the Alaris Infusion Pump System due to the following hardware situations:

Situation 1: Damaged Inter-Unit Interface (IUI) Connectors (Class 1 Recall)

Damaged IUI connectors may lead to interruption of communication or power between PC Unit and modules, which could result in an infusion that stops with an alarm on the PC Unit and an interruption of therapy or monitoring.

Situation 2: Broken elements on Alaris™ Pump Module platen (Class 1 Recall)

A broken upper hinge post, lower hinge, and/or membrane frame on the Alaris™ pump module may prevent the device from delivering an accurate amount of fluid, which may result in an over infusion, free-flow conditions, or under infusion without an alarm.

Situation 3: Improperly secured PC unit Battery (Class 1 Recall)

If the battery is not properly secured to the Alaris™ PC Unit that is running on battery power, the system may experience a power loss with a prolonged, non-silenceable alarm. Power loss may result in an interruption of patient therapy or monitoring.

Situation 4: Dim Segment (Class 2 Recall)

The LED display on the module may have some segments that appear dim, and therefore, the number may not be clearly displayed. The purpose of this display is to provide the clinicians with infusion or patient monitoring values associated with the type of module. If this dim segment is discovered during clinical use, it may cause slight user confusion or inconvenience when noticed.

Full Alert