

October 15, 2010

FDA Safety Announcement: CareFusion Corporation Alaris PC Units (Model 8015): Recall - Potential for Delay or Interruption of Therapy

AUDIENCE: Risk Manager

ISSUE: Under certain wireless network conditions, a communication error can occur, which freezes the PC Unit screen. This error may result in a delay of therapy and inability to make programming changes to current infusions.

If the communication error occurs during infusion, infusion continues on all channels, as originally programmed, but cannot be modified. When this error occurs, stopping the infusion to make any modification or programming changes causes the PC unit to shut down resulting in a delay or interruption in therapy. This could lead to serious injury and/or death. These devices were manufactured from December 20, 2008 through September 8, 2009 and distributed from December 20, 2008 through June 28, 2010.

BACKGROUND: Electronic infusion pumps deliver controlled amounts of medications or other fluids to patients through an intravenous (IV), intra-arterial (IA), epidural, and other acceptable routes of administration.

RECOMMENDATION: If users experience the problem, they are to remove the device from service and contact the CareFusion Recall Center immediately. The corrective action will require a hardware update to all affected units. CareFusion does not require that the devices be returned.

Medical device recall information and Q&A:

For the most current information or answers to questions, please contact the CareFusion Recall Center at 888.562.6018 or via email at SupportCenter@carefusion.com

Adverse Reports:

If you have any adverse reports related to any of our infusion pumps please use our main business line to contact CareFusion Customer Advocacy at 800.854.7128, Option 1, then Option 1, then Option 3, or via email at customerfeedback@carefusion.com.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm229767.htm>

www.kcercoalition.com/alerts.htm



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