

March 3, 2011

FDA Safety Announcement: B. Braun Outlook 400ES Safety Infusion System, Model Number 621-400ES: Class I Recall - Hardware May Become Unresponsive



AUDIENCE: Risk Manager, Patient

ISSUE: Infusion systems upgraded with Motorola compact flash hardware and supporting software, when used in a network environment that utilizes Temporal Key Integrity Protocol (TKIP) authentication, are at risk of a memory leak that can cause the Management Processor to fail. When this occurs, normal operation is disrupted (i.e. the pump fails to continue delivering medicine) as indicated by an audible back-up alarm. Please note there is not a visual warning system to alert the user the pump is not functioning properly.

BACKGROUND: The B. Braun Outlook 400ES Safety Infusion System is meant for use with B. Braun Medical Inc. Horizon Pump IV Sets to regulate the flow of primary and secondary fluids when positive pressure is required. The infusion system is capable of delivering fluid when the IV fluid container is lower than the pump and provides the accurate volume of all standard IV fluid, including blood, lipids, and Total Parenteral Nutrition (TPN).

RECOMMENDATION: It is recommended that customers deactivate the wireless communication on their pumps and return them to the manufacturer B. Braun.

B. Braun Phone Number: 972-245-2243

Recalling Firm: B. Braun Medical, Inc.
1601 Wallace Dr. Ste 150
Carrollton, Texas 75006

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/ucm241637.htm>

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www.kcercoalition.com/alerts.htm