# Sigma Spectrum Infusion Pump Model 35700: Class 1 Recall: Risk of Over-Infusion

U.S. Food & Drug Administration

**Issue:** FDA notified healthcare professionals of the class 1 recall of the SIGMA Spectrum Infusion Pump Model 35700. These units may fail suddenly, causing inaccurate flow conditions during use, ranging from back flow to over-infusion, including free flow. The pump does not issue an alarm when this occurs. These conditions could result in serious injury or death.

**Background:** The recalled pump is intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural, or irrigation routes of administration. The recall was initiated September 15, 2010 and includes serial numbers from 706497 to 724065.

**Recommendations:** Sigma has instructed healthcare facilities to verify whether the serial numbers for their infusion pumps fall within the range of pumps being recalled and is requiring the return of the recalled devices. Sigma has instructed users to not use the infusion pumps on patient populations, including neonatal patients, where inaccurate flow, ranging from back flow to over-infusion, including free flow, could result in serious adverse health consequences or death.

[11/12/2010 - Recall Notice [1] - FDA]

SOURCE [2]

**Source URL (retrieved on *01/29/2015 - 7:38am*):**
http://www.mdtmag.com/news/2010/11/sigma-spectrum-infusion-pump-model-35700-class-1-recall-risk-over-infusion

**Links:**
[1] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm233683.htm
[2] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm233747.htm