### Class 2 Recall

**Animas Vibe Insulin Infusion Pump**

**Date Posted**: January 30, 2015  
**Recall Status**: Open  
**Recall Number**: Z-1034-2015  
**Recall Event ID**: 6929923  
**Premarket Approval PMA Number**: P13000724  
**Product Classification**: Pump, Infusion, Insulin, To Be Used With Invasive Glucose Sensor - Product Code OYC26  
**Product**: Animas Vibe Insulin Infusion Pump. This product is indicated for continuous subcutaneous infusion of insulin for the treatment of diabetes and has a continuous glucose monitoring feature.  
**Recalling Firm/Manufacturer**: Animas Corporation  
200 Lawrence Dr  
West Chester, Pennsylvania 19380-3428  
**For Additional Information Contact**: Customer Support  
610-644-8900  
**Manufacturer Reason for Recall**: The intended calibration factors set in the pump were overwritten with default values during a subsequent pump programming step during manufacture. This created a situation in which the force sensor could send a lower signal value to the pump processor than optimal, causing potential problems with loss of prime warnings, occlusion alarms and the inability of the pump to detect a cartridge during insertion.  
**FDA Determined Cause**: DESIGN: Software Design (Manufacturing Process)  
**Action**: The field action is comprised of communication to patients and distributors using email, letters and verbal communication. In addition, notifications were sent to those Health Care Professionals who have patients that are affected by this field action. Health Authorities will be notified in those countries where the pump has been distributed or is in the hands of patients. Replacement product will be provided to distributors and end users, who have been identified as having affected product.  
**Quantity in Commerce**: 1235  
**Distribution**: No US distribution, Distributors are located in France, Germany, Sweden and United Kingdom.  
**Total Product Life Cycle**: TPLC Device Report  

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55

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http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=130189  
2/4/2015