Class 2 Recall
Animas Vibe Insulin Infusion Pump

See Related Information[22]

Date Posted	January 30, 2015
Recall Status[1]	Open
Recall Number	Z-1034-2015
Recall Event ID	69299[23]
Premarket Approval PMA Number	P130007[24]
Product Classification	Pump, Infusion, Insulin, To Be Used With Invasive Glucose Sensor[25] - **Product Code** OYC[26]
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.
Code Information	Model Number(s): 100515-63 100510-63 100514-63 100512-63 100511-63 101200-03 100201-03 101202-03 101204-03 101205-03 101200-53 101202-53 101205-53 101200-02 101200-57 101201-57 101202-57 101204-57 101205-57 101200-63 101201-63 101202-63 101204-63 101205-63 101206-63
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 t
FDA Determined Cause [2]	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[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]