See Related Information[21]

Class 2 Recall
Medtronic Advanced Energy
Aquamantys3 Pump Generator

Date Posted	January 31, 2014
Recall Status[1]	Open
Recall Number	Z-0905-2014
Product Classification	Electrosurgical, Cutting & Coagulation & Accessories[22] - **Product Code** GEI[23]
Product	Medtronic Advanced Energy Aquamantys3 Pump Generator; Product Catalog Number: 10-1357 (Generator assembly), 40-404-1(as shipped, including accessories) The Aquamantys3 System combines radio frequency (RF) energy and saline to reduce blood loss during and after surgical procedures. This patented Transcollation technology has been shown to reduce transfusion rates and may also reduce the need for other blood management procedures.
Code Information	lowest serial number is GN001141; the highest is GN001704 (non-consecutive)
Recalling Firm/ Manufacturer	Medtronic Advanced Energy, LLC 180 International Dr Portsmouth, New Hampshire 03801-6837
Manufacturer Reason for Recall	The internal protection circuitry on the electrosurgical output that prevents a patient from exposure to DC voltage when the device is activated is being compromised during normal use.
Action	Medtronic sent an Urgent Product Removal Notification on November 12, 2013, via Next Day FEDEX. The communication advises users to immediately stop using the affected AQM3 electrosurgical generators and quarantine them until they can be returned to Medtronic Advanced Energy. Medtronic field personnel will collect them in order to remove them from service and return them to Medtronic Advanced Energy. Customers with questions were instructed to contact Customer Service at 866-777-9400. For questions regarding this recall call 866-777-9400.
Quantity in Commerce	242 devices
Distribution	Nationwide Distribution including CA, MO, PA, NJ, NY, OH, VA, TX, NC, DE, KS, TN, LA, IL, MI, SC, WI, and FL.
Total Product Life Cycle	TPLC Device Report[24]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[25]

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