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Medical Device Recalls

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Class 2 Recall
ZOLL E Series
Defibrillator/Pacemaker/Monitors

See Related Information

Date Posted	May 07, 2010
Recall Number	Z-1547-2010
Product	ZOLL E Series Defibrillator/Pacemaker/Monitors, BLS Model, with software versions 4.XX, 6.XX and 7.0X. Zoll Medical Corporation, Chelmsford, MA. Intended for the purpose of converting ventricular fibrillation to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.
Code Information	Software versions 4.XX, 6.XX and 7.0X in the E Series BLS Model.
Recalling Firm/ Manufacturer	ZOLL Medical Corporation, World Wide Headquarters 269 Mill Rd Chelmsford, Massachusetts 01824
For Additional Information Contact	Paul Dias 978-421-9413
Reason for Recall	Device issued Shock Advised message but failed to auto-charge the defibrillator.

Action	Zoll Medical Corporation issued an "Urgent Medical Device Correction" notification dated March 26, 2010 via certified mail to consignees who have received affected product. Customers will be contacted and given the option to have a software upgrade kit to update their devices or return devices to the firm to have the device upgraded. For further information, contact Zoll Medical Corporation 24/7 Technical Support at 1-800-348-9011 or 1-978-421-9460.
Quantity in Commerce	1383 units
Distribution	Worldwide Distribution -- United States, Australia, Germany, Libyan Arab Jamahiriya, Malaysia, Singapore, United Arab Emirates and the United Kingdom.