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Important Notification: FDA Final Order, M Series and E Series Defibrillators

Dear Valued Customer;

On February 3, 2015, the Food and Drug Administration (FDA) issued the Final Order requiring premarket approval (PMA) applications to be filed for defibrillators with an automated external defibrillator (AED) mode. Since the 2012 discontinuation of the M Series and E Series monitor/defibrillators ZOLL has made every effort to continue to support the operation of these legacy devices.

However, in a recent letter from the FDA, further clarification of this Order specifies that ZOLL will be unable to support these devices with service or accessories after February 3, 2021.

If you are on record as having a discontinued monitor/defibrillator from ZOLL, your local representative will contact you directly to assist you with this transition. To verify that your equipment is on the FDA-approved AED list, that includes both AEDs and professional defibrillators, please reference the following link: https://www.fda.gov/medical-devices/cardiovascular-devices/automated-external-defibrillators-aeds.

In order to make this transition simple and cost-effective, we currently have upgrade programs available for your consideration. For hospital customers and clinics, we offer the R Series® Monitor Defibrillator that can be configured similarly to your existing M Series. For EMS and Fire customers, we offer the X Series® Monitor/Defibrillator. For additional information regarding these programs, please contact your local sales representative.

If you have any questions or require additional information, please contact your local sales representative or our Customer Service Department at 800-348-9011.

Sincerely,

Paul Dias

Vice President, Quality and Regulatory Affairs
ZOLL Medical Corporation