269 Mill Road
Chelmsford, Massachusetts 01824-4105
978.421.9655 *(main)*
978.421.0025 *(fax)*
www.zoll.com
An Asahi Kasei Group Company

Urgent Medical Device Correction

ZOLL AED PRO Product Family

Certain devices shipped between March 2018 to June 2019

June 12, 2019

Dear Customer,

ZOLL Medical Corporation is voluntarily recalling a limited number of AED PRO devices. This letter describes the issue and actions that must be taken to address the problem.

We have recently received a field report of the AED PRO prompting "Unit Failed" during a defibrillation shock attempt. Our investigation of this report traced the problem to an area of an internal circuit board that is susceptible to isolation breakdown. If the isolation breakdown occurs during a shock attempt, the device will issue the "Unit Failed" message and prevent delivery of the energy to the patient. We have isolated this potential fault to some of the AED PRO units shipped between March 2018 and June 2019. A hardware update is required in order to prevent the defect from occurring. We are asking customers with affected units to complete the attached response form to arrange for the hardware update.

AFFECTED DEVICES

All **AED PRO units shipped between March 2018 and June 2019**. Please refer to Page 2 of the attached Form for a complete list of affected serial numbers shipped to your location.

REQUIRED ACTIONS

Customers who have affected devices should immediately take the following steps:

(1) Alert all AED PRO users to this problem.
(2) Locate the affected devices.
(3) Complete and return the attached form via e-mail, fax or regular mail.

We have notified the FDA and other regulatory agencies of this corrective action and expect it to be classified as a recall.

We apologize for any inconvenience this may cause you and thank you in advance for assistance in implementing this corrective action. Avoiding this problem during clinical use is our highest priority. Our 24/7 technical support numbers **1 (800) 348-9011** or **+1 (978) 421-9460** are available to assist users with any aspect of this notice.

Sincerely,

Paul Dias
VP Quality Assurance & Regulatory Affairs

Urgent Device Corrective Action

Customer Response Form for ZOLL AED Pro Defibrillator

Part Number	GTIN
90010200499991010	00847946016128
90010400499991010	00847946016142
70010400499991010	00847946015138
90010202499991010	00847946016135
90010600499991010	00847946016166

Listed on the next page, please review the Serial Numbers affected by this Corrective Action. Please check the box next to each serial number to confirm you have located & contained the devices. Please complete this form in its entirety and return **both** pages to regulatoryteam@zoll.com or fax to (978) 421-0038

Customer Account Information		
Customer Account Name		*Account Number*
Ship To Address		
City	*State*	*Postal Code*

Customer Contact Details	
Individual completing this form (please print)	*Title*
E-Mail Address	*Phone Number*

Product Inventory Status

☐ Our facility has located all or some of the devices on the Serial Number list and have indicated this by checking the box next to each serial number.

☐ The devices have been internally transferred or distributed/sold and a copy of this corrective action has been provided to the party in possession of the device(s). To facilitate locating the product, I am providing ZOLL with contact details below.

Facility/Org: Address:

Contact Name: Email: Phone:

Ship To (only required if you have located devices & your return shipping address is different from above)	
	PO No. (if reqd. to receive product):

Print Name:	**Sign:**	**Date:**

Please return to regulatoryteam@zoll.com or fax to (978) 421-0038

Urgent Device Corrective Action

Customer Response Form for ZOLL AED Pro Defibrillator

Serial Number List

Please check the box next to each serial number to confirm you have located & contained the devices.
Please complete this form in its entirety and return **both** pages to regulatoryteam@zoll.com or fax to (978) 421-0038
