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an Asahi Kasei company

Urgent Corrective Action

ZOLL G5 Semi-Automatic AED Product Family

Serial Number Range: D00000276194-D00000343449

Dear Customer,

ZOLL Medical Corporation is voluntarily recalling a limited number of G5 Semi-Automatic AED devices. This letter describes the issue and actions that must be taken to address the problem.

The G5 Semi-Automatic AED is shipped, with a protective film over its front panel, to protect the screen and shock button from cosmetic damage during shipping. It has come to our attention that customers may not be removing the protective film during deployment of the product. If the protective film is left adhered to the front bezel it may prevent the user from actuating the shock button. This may lead to a delay or prevent delivery of defibrillation therapy to a victim suffering from sudden cardiac arrest. We are asking customers with affected units to ensure the protective film has been removed in accordance with the provided photos in **Appendix A**.

AFFECTED DEVICES

For specific G5 Semi-Automatic device serial numbers that may be impacted by this Urgent Corrective Action, refer to the accompanying Customer Response Form.

REQUIRED ACTIONS

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

(1) Alert G5 Semi-Automatic AED users of this problem.
(2) Locate the affected devices.
(3) Remove the protective film in accordance with Appendix A.
(4) Respond to ZOLL via the customer notification form acknowledging that the protective film has been removed.

We have notified the appropriate 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 is our highest priority. Our 24/7 technical support number is 1 (866) 442-1011 or intlservice@zoll.com and are available to assist users with any aspect of this notice.

Sincerely,

Anne E Nadeau

Anne Nadeau
Manager of Post Market Surveillance

Appendix A

Figure 1: Device with the protective film over the front panel, if present.

Figure 2: Remove the protective film by lifting it from its edge, if present.

Figure 3: Discard the protective film.