14/39 Herbert Street
St Leonards NSW 2065

1800 605 555 (main)
info.aus@zoll.com (email)
zoll.com

an Asahi Kasei company

21st June 2024

URGENT SAFETY ALERT

TGA Recall Reference Number RC-2024-RN-00503-1
ZOLL Medical G5 Semi-Automatic AED Product Family

Dear Customer,

ZOLL Medical Australia, following agreement with the Therapeutic Goods Administration (TGA), is conducting a Safety Alert of the G5 Semi-Automatic AED devices.

The potentially affected product may have been supplied to your organisation.

AFFECTED DEVICES

Serial Number Range: D00000276194-D00000343449

What is 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.

REQUIRED ACTIONS

Customers who have affected devices should take the following steps:

(1) Inspect your stock immediately and identify if any of the serial numbers within the serial number range is within your stock. Ensure all packaging material, including the screen protective film is removed.
(2) Complete the attached Customer Response Form, even if you do not have any affected stock and email it to tmerry@zoll.com as soon as possible so ZOLL can reconcile this process.
(3) Ensure relevant staff members are informed of this safety alert, to ensure they are aware of the safe distance requirements and are trained to these guide updates.
(4) If you have supplied or transferred any potential affected G5 Semi-Automatic Defibrillator to another facility or organisation, provide that facility with a copy of this letter immediately.
(5) Place this letter in a prominent position for at least one month.

This action has been undertaken following consultation with the TGA..

We apologize for any inconvenience this may cause you and thank you in advance for your assistance. Avoiding any problem during clinical use is our highest priority.

For further information, please contact either Tristana Merry on 0451 373 150/ tmerry@zoll.com or our 24/7 technical support team on +1 (866) 442-1011 or intlservice@zoll.com, both available to assist with any aspect of this notice.

Sincerely,

Trevor Macleod
Managing Director
ZOLL Medical Australia & New Zealand

Appendix A

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

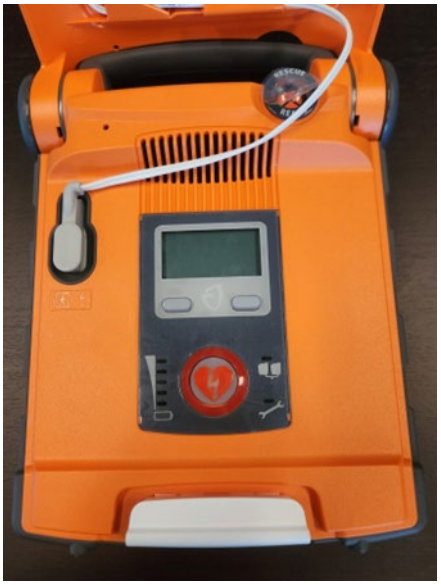

Figure 2: Remove the protective film by lifting it from its edge, if present.

Figure 3: Discard the protective film.