



121 Gamma Drive  
Pittsburgh, Pennsylvania 15238

800.543.3267 (main)  
866.567.7615 (fax)  
www.zoll.com

January 18, 2018

Re: FDA Safety Communication on LifeVest Wearable Cardioverter Defibrillator

Dear Health Care Provider,

On January 17, 2018 the FDA published a Safety Communication regarding revised patient training for a Service Code that can appear on the LifeVest Wearable Cardioverter Defibrillator. The communication outlines information and recommendations regarding the ZOLL LifeVest 4000 due to concerns that the device may fail to deliver treatment to a patient if the device is not replaced soon after displaying a “Call for service – Message Code 102”. It is very rare for a “Call for service – Message Code 102” to be associated with a device issue that would prevent the device from being able to deliver a treatment shock. Additionally, this code can be displayed for reasons that do not impact the device’s ability to deliver a treatment shock.

The “Call for service – Message Code 102” has existed as a service code since the LifeVest 4000 was approved by the FDA in 2009. The unfortunate single death associated with this issue, as referenced in the FDA communication, occurred when a patient did not call ZOLL after receiving prompts for 10 consecutive days by the “Call for Service – Message Code 102” displayed on the device.

In response to this rare, but potentially serious situation, ZOLL decided to modify the instructions for patients if a “Call for service – Message Code 102” is displayed on the LifeVest device. In the event this code is displayed, patients are instructed to call ZOLL immediately at 1-800-543-3267 for a replacement LifeVest. A replacement device will be provided as soon as possible, and within 24 hours at worst. All LifeVest patients have received revised training since September 2017, first in the form of a safety alert sent to all active patients on September 12, 2017 and all new patients since that date as part of their LifeVest materials, and second, as of January 8, 2018, as additional information as part of their initial live training during their fitting.

Less than 0.05% of patients per year will receive a “Call for service – Message Code 102” that could result in the device not being able to deliver a needed treatment.

Importantly, no product is being proactively removed from the field and patients should continue to use the LifeVest as prescribed by their physician. No action is required unless a patient receive a “Call for service – Message Code 102.” In the communication, the FDA refers to this action as a “Device Recall”. In this instance, the FDA is referring to the change in patient training only.



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Patient safety and product quality are our primary focus at ZOLL. If you have any questions or concerns, please feel free to contact your ZOLL LifeVest representative or ZOLL Technical Services at 1-800-543-3267.

Sincerely,

A handwritten signature in black ink that reads "Jason T. Whiting". The signature is written in a cursive style with a clear, legible font.

Jason T. Whiting  
President  
ZOLL LifeVest