



ZOLL Circulation – San Jose
2000 Ringwood Ave.
San Jose, California 95131
(408) 541-2140
www.zoll.com

September 26, 2022

Attention: Chairman Medical Board, Head of Department, Clinical Personnel, Risk Managers, Biomedical Personnel, Nursing

RE: FIELD SERVICE NOTICE (FSN)

Affected Products: AutoPulse Platform (AP) Li-Ion Batteries MODEL 100 (REF: 8700-0752-All Languages)

Suspect Serial Number Range: Between 06530 and 13184 inclusive

Dear Valued Customer,

The purpose of this letter is to advise you that ZOLL Circulation is voluntarily replacing the AP 100 Li-Ion batteries within the serial range of 06530 and 13184 inclusive that were shipped prior to June 17, 2022. Our records indicate that you may have purchased one or more of these batteries from us.

Background:

ZOLL Circulation's Post Market Surveillance Team observed an increase in battery complaints starting in May 2022. Customers reported that fully charged batteries were not powering on the AutoPulse Platform. Batteries returned to ZOLL from customers operated without issue when tested at ambient temperatures. ZOLL was able to replicate the reported failure mode by storing these batteries at elevated temperatures prior to testing in the AutoPulse Platform.

Storing affected batteries in a hot environment prior to use such as in a hot vehicle, in the sun, or in a hot room may prevent the battery from powering on the AutoPulse Platform. Affected batteries will power on the AutoPulse Platform after the batteries are allowed to cool. This failure mode only occurs during initial power on. Once the AutoPulse Platform is powered on, it operates without issue even when ambient temperatures are elevated.

The cause of this issue was traced to a supplier switching to an alternate approved electrical component and thermal variation within specification of a second electrical component. The supplier changed to the alternate component due to a supply shortage resulting from Covid-19 impacts. The original component functions as intended through a high temperature range. ZOLL has sourced the original electrical component, included inline screening for the failure mode, and has resumed battery production in late June 2022.

This battery failure mode occurs prior to the start of treatment allowing the user time to apply manual CPR. If a battery fails to turn on the AutoPulse Platform, immediately revert to manual CPR as the AutoPulse platform is an adjunct treatment, and manual CPR is still the standard of care.

Actions Required by the Affected Customer/User:

Complete the Customer Acknowledgement/ No-Charge Battery Replacement Request Form (page 3) and email it to Vivian.tan@zoll.com as soon as possible.

To best support you, our customer, ZOLL will replace your affected batteries free of charge. Additionally, to assist you in the removal of these batteries and to ensure that only non-affected batteries are utilized, we will provide you with pre-paid packaging to easily return any affected batteries you have. Instructions to return your affected batteries to ZOLL will be provided when you receive your replacement batteries.

While waiting for the replacement batteries to arrive, please do not store your affected batteries in a hot environment prior to use such as in a hot vehicle, in the sun, or in a hot room. Storing the affected batteries in a hot environment may prevent the batteries from powering on the AutoPulse Platform. Please also note that the affected batteries will power on the AutoPulse Platform after they are allowed to cool.

Immediate Actions Taken by ZOLL to Address Issue:

- (1) ZOLL started manufacturing batteries using the original electrical component in late June 2022.
- (2) ZOLL has implemented screening tests for this failure mode on the battery manufacturing line.

We apologize for any inconveniences that our supply chain related issue may have affected you. We are committed to making sure that we will ship you the replacement batteries as quickly as possible

Sincerely,

Doug Lam Digitally signed by Doug
Lam
Date: 2022.09.16 13:49:41
-07'00'

Doug Lam
Director of Quality and Regulatory Compliance



Customer Acknowledgement/Free-of-Charge Battery Replacement Request Form

1. Customer Details	
Healthcare Organization Name	
Organization Address	
Contact Name	
Title or Function	
Telephone Number	
Email	

2. Customer action undertaken on behalf of Healthcare Organization	
<input type="checkbox"/>	I confirm receipt of the Customer Communication Letter and I have read and understood its content.
<input type="checkbox"/>	The information has been brought to the attention of all relevant device users.
Print Name	
Title or Function	
Signature	
Date	

3. Request for Free-of-Charge Battery Replacement (Prepared by Customer/User)	
List Serial Numbers to be Replaced:	
Ship Replacements To:	Attn: Address:

It is important that your organization takes the actions detailed in the Customer Communication letter and confirms that you have received the Customer Communication Letter.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.