VOLUNTARY MEDICAL DEVICE CORRECTION

Welch Allyn Patient Cables or Lead Sets

March 23, 2020

Dear Valued Customer,

Welch Allyn, Inc. is issuing a **voluntary medical device correction notification** to inform you that specific patient cables or lead sets, in certain circumstances, may not meet the labeled performance claims. This notification details the issue and the steps for you to perform.

Background:

Internal testing has indicated that, in extremely rare cases, impacted Welch Allyn products may not meet the "Defibrillation Withstand" requirements of EN/IEC 60601-2-25 Medical Electrical Equipment, Particular Requirements for the Safety of Electrocardiographs, a standard the product claims to meet.

When the electrocardiograph leads remain on a patient during defibrillation, the electrocardiograph lead set may be damaged, impacting the performance of the device and/or the amount of energy delivered to the patient. However, our assessment indicates the likelihood of patient harm is improbable. To date, there have been more than 162,000,000 estimated patient experiences with the impacted products and Welch Allyn has not received any reports of patient injury.

The products associated with this notification were manufactured between October 12, 2015 and September 10, 2019. A list of the affected part numbers is provided in Table 1.

Actions for End Users:

Welch Allyn is informing you of the issue because the product may not meet the performance claims in our device literature. However, based on our risk assessment, the device continues to be safe and effective for use.

Please ensure all users in your organization are informed of the contents of this letter. If you have questions regarding the continued safe use of your products, please contact our Technical Support Team.

Actions for Distributors:

If you have further distributed this product, immediately notify your accounts of this medical device correction notification.

Contact Information:

If you have any questions regarding this notification, please contact Hillrom Technical Support using the number or email provided below.

Region/Country	Technical Support Phone	Technical Support Email
United States	1.888.667.8272	mor_tech.support@welchallyn.com

Welch Allyn considers patient safety and customer satisfaction our top priorities. We appreciate your time and attention in reading this important notification.

Sincerely,

Mark Elliott
Director, Quality Assurance

Table 1: Affected Product

Part Number	Description
9293-046-XX	WAM/AM12/AM15 Leads, Banana
9293-047-XX	WAM/AM1 Leads, Clip
9293-017-XX	H12+/X12+ Leads, Snap
9293-026-XX	H12+/X12+ Leads, Snap, XL
9293-061-XX	S4 Leads, Snap (10-wire)
9293-033-XX	S12/S19 Leads, Snap
9293-034-XX	X12+ Leads, Snap
S4-Q-ASX-XXX	S4 TRANSMITTER 5-WIRE ECG SpO2 GEN2
S4-Q-AXX-XXX	S4 TRANSMITTER 5-WIRE NO SpO2 GEN2
S4-P-A	S4 TRANSMITTER 5-WIRE ECG GEN1

Hillrom™

Medical Device Correction Return Form

Please complete and sign this form to acknowledge you have received this voluntary medical device correction notification. Return the signed form electronically to mod1299@hillrom.com.

Signature:_____ Date:_____

Name of Signer (Printed) _____

Title of Signer: _____