

Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls,
NY 13153 USA

URGENT: Field Safety Notice

MOD1299

April 23, 2020

WA-MOD1299-5359
LEVITT SAFETY LIMITED
ATTN: RECEIVING
9241 - 48 STREET
EDMONTON AB T6B 2R9
CANADA

Commercial name of affected product:
Welch Allyn Patient Cables or Lead Sets

Type of action: Voluntary Field Action

Dear Welch Allyn Customer,

Details on affected devices: Refer to list of device models as per Table 1.

Description of the problem:

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. These are particular requirements for the Safety of Electrocardiographs; a standard the product claims to meet.

Potential Risk:

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.

Affected Product:

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.

Advise on action to be taken by the user:

- 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.
- This notice needs to be passed on to all those who need to be aware within your organisation, or to any organisation where the potentially affected devices have been transferred.
- If you have further distributed this product, forward this Field Safety Notice, in its entirety, to your end-users.

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Contact Reference Person:

Should you have any questions regarding this notification, please contact Hillrom/Welch Allyn Technical Support, using email or number below.

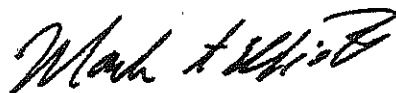
Region/Country	Technical Support Phone	Technical Support Email
CANADA	1.888.667.8272	mor_techsupport@hillrom.com

Please ensure this notice is circulated to all appropriate personnel. This may include, but is not limited to:

• A&E departments	• In-house maintenance staff
• Adult intensive care units	• IV nurse specialists
• All wards & Clinics	• Medical directors
• Biomedical engineering staff	• Nursing executive directors
• Clinical governance leads	• Oncology units
• Day case theatres	• Pediatric intensive care units
• EBME departments	• Risk managers
• Equipment stores & Libraries	• Supplies managers
• Health and safety managers	• Theatres

The undersign confirms that this notice has been communicated to your local Regulatory Agency

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

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<u>Associated Product</u>	
ELI10-XXX-XXXXX	ELI 10 Electrocardiograph
ELI150C-XXX-XXXXX ELI250C-XXX-XXXXX	ELI 150c/250c Electrocardiograph
ELI230-XXX-XXXXX	ELI 230 Electrocardiograph
ELI280-XXX-XXXXX	ELI 280 Electrocardiograph
ELI350-XXX-XXXXX	ELI 350 Electrocardiograph
ELI380-XYZZ	ELI 380 Electrocardiograph
RSCRIBE-XXX-XXXXX	RScribe Electrocardiograph
11066-XXX-50 41000-029-XX	ELI PC Electrocardiograph
H12PLUS-XXX-XXXXX	H12+ Holter ECG Recorder
T12-XXX-XXXXX T12S-XXX-XXXXX	T12 Wireless Telemeter
X12PLUS-XXX-XXXXX	X12+ Wireless Telemeter
S4-P-X S4-Q-XXX-XXX	S4 Wireless Telemeter
SUR12-XXX-XXXXX SUR19-XXX-XXXXX	S12/S19 Bedside Patient Monitor
QS-6XX-XXXXX	Q-Stress Cardiac Stress System
XSCRIBE-5XX-XXXXX XSCRIBE-6XX-XXXXX	XScribe Cardiac Stress System

