

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	URGENT: Field Safety Notice	MOD1299
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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
AUSTRIA	+43 1 795 67 186	eme.techsupport@hillrom.com
BENELUX	+31 20 206 13 60, Option 3	eme.techsupport@hillrom.com
DENMARK	+45 38 48 73 57	eme.techsupport@hillrom.com
EUROPE (OTHER)	+353 46 90 67790, Option 3	eme.techsupport@hillrom.com
FINLAND	+358 969 379 386	eme.techsupport@hillrom.com
FRANCE	+33 1 57 32 49 94, Option 3	eme.techsupport@hillrom.com
GERMANY	+49 6950 985 132, Option 3	eme.techsupport@hillrom.com
IBERIA	+34 91 7 4 99 357, Option 3	eme.techsupport@hillrom.com
INDIA	+353 46 90 67790, Option 3	eme.techsupport@hillrom.com
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ITALY	+39 0269682425, Option 3	eme.techsupport@hillrom.com
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SWITZERLAND	+41 44 6545315	eme.techsupport@hillrom.com
UK	+44 207 365 6780, Option 3	eme.techsupport@hillrom.com

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

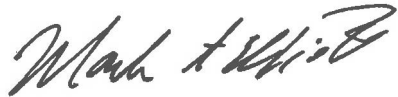
• A&E departments	• In-house maintenance staff
• Adult intensive care units	• IV nurse specialists
• All wards & Clinics	• Medical directors
• Biomedical engineering staff	• Nursing executive directors
• Clinical governance leads	• Oncology units
• Day case theatres	• Pediatric intensive care units
•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

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• 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

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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