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| Welch Allyn, Inc.<br>4341 State Street Road<br>Skaneateles Falls,<br>NY 13153 USA | **URGENT: Field Safety Notice** | **MOD1299** |

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 |
| IRELAND | +353 46 90 67790, Option 3 | eme.techsupport@hillrom.com |
| ITALY | +39 0269682425, Option 3 | eme.techsupport@hillrom.com |
| MIDDLE EAST | +353 46 90 67790, Option 3 | eme.techsupport@hillrom.com |
| NORWAY | +47 23 16 25 27 | eme.techsupport@hillrom.com |
| SOUTH AFRICA | +27(0)1000 17788 | eme.techsupport@hillrom.com |
| SWEDEN | +46 8 5853 6551 | eme.techsupport@hillrom.com |
| 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:

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| • 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 |