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| Welch Allyn, Inc.  4341 State Street Road Skaneateles Falls,  NY 13153 USA | **URGENT: Field Safety Notice** | **MOD1326** |

Date

WA-MOD1326-XXXX

Customer name Customer Street Address Customer Country, Zip

Commercial name of affected product:

## Welch Allyn AM12M Patient Acquisition Module

Type of action: Field Safety Corrective Action – Return/Exchange of device

Dear Welch Allyn Customer,

## Description of the problem:

The AM12M is a patient acquisition module used with the S12/S19 Patient Monitor and the ELI380 and ELI280 Resting Electrocardiographs. The Internal testing of the AM12M Acquisition Module, identified that the AM12M was manufactured with incorrect firmware. Impacted Welch Allyn products do not meet the “ECG defibrillation protection” requirements of IEC 60601-2-27, Particular Requirements for the Basic Safety and Essential Performance of Electrocardiographic Monitoring Equipment and IEC 60601-2-25 Basic Safety and Essential Performance of Electrocardiographs standards which the product claims to meet. These standards require the ECG to recover within 5 seconds, however, with the incorrect firmware it may take several minutes to recover.

## Potential Risk:

If the AM12M does not recover within the required 5 seconds, the following risks may potentially occur:

* Surveyor S12/S19: There may be a delay in critical care/cardiac monitoring of patients being monitored with the Surveyor S12/S19.
* ELI280/ELI380: As the ELI280/ELI380 are ECG devices and not intended to be used as vital signs monitors, there is no associated risk.

## Affected Product:

All S12/S19 Patient Monitors, ELI 280 Electrocardiographs, ELI 380 Electrocardiographs and AM12M kits manufactured or sold with the AM12M PN 9293-065-50. The products associated with this Field Safety Notice were manufactured between 19 May 2016 and 12 Nov 2020. A list of the affected part numbers is provided in Table 1.

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## Action to be taken by the user:

Welch Allyn is informing you of the issue because the product does 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 identify if you have any affected product. Complete the attached response form and return to hillrom5373@stericycle.com, irrespective of whether you have the affected product or not. Welch Allyn will arrange the return of your affected devices.

In the interim, when devices are in use, we recommend the following:

* Leave the defibrillation device on the patient until confirmation that the S12/S19 patient monitor display is functioning within 5 seconds after the defibrillation is completed.
* If the defibrillation device does not have a display in which to monitor the patient’s cardiac status, have a backup patient monitor accessible.

## Actions being taken by Hillrom:

Hillrom is working to resolve this issue as quickly as possible.  Once you have identified units affected by this field corrective action and you have returned the response form, you will be contacted by Hillrom or an official Hillrom distributor, to schedule the replacement.

## 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** |
| CZECH REPUBLIC | +353 (0) 46 90 67 790, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| GERMANY | +49 6950 985 132, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| ITALY | +39 0269682425, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| NETHERLANDS | +31 (0) 20 206 13 60, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| BELGIUM | +31 20 206 13 60, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| SLOVENIA | +353 (0) 46 90 67 790, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| RUSSIA | +353 (0) 46 90 67 790, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| POLAND | +353 (0) 46 90 67 790, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| FRANCE | +33 1 57 32 49 94, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| LATVIA | +353 (0) 46 90 67 790, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| TURKEY | +353 (0) 46 90 67 790, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| MOROCCO | +353 (0) 46 90 67 790, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| CROATIA | +353 (0) 46 90 67 790, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| PORTUGAL | +353 (0) 46 90 67 790, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| UNITED KINGDOM | +41 44 6545315 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |
| SWITZERLAND | +44 207 365 6780, Option 3 | [eme.techsupport@hillrom.com](mailto:eme.techsupport@hillrom.com) |

## Transmission of this Field Safety Notice:

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

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| --- | --- | --- |
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# Table 1: Affected Product

|  |  |  |  |
| --- | --- | --- | --- |
| Surveyor S19 | Surveyor S12 | ELI 380 | AM12M Kits |
| SUR19-CDH-XXXAX | SUR12-FDH-XXXAX | ELI380-ACX32 | 41000-037-50 |
| SUR19-FDH-XXXAX | SUR12-FDH-XXXBX | ELI380-DAX3X | 41000-037-51 |
| SUR19-LDH-BXXAX | SUR12-LDH-BXXAX | ELI380-DBX32 |  |
| SUR19-LDH-XXXAX | SUR12-LDH-XXXBX | ELI380-DCX32 | AM12M Module |
| SUR19-LDH-XXXBX | SUR12-RAG-EXABX |  | 9293-065-50 |
| SUR19-SDH-XXXAX | SUR12-RDF-XXXAX | ELI 280 |  |
| SUR19-TDH-XXXAX | SUR12-RDH-BXAAX | ELI280-LDB-ADAAX |  |
| SUR19-TDH-XXXBX | SUR12-RDH-XXXBX | ELI280-LDD-AAABX |  |
| SUR19-XDH-BAXAX | SUR12-SDH-XXABX | ELI280-LDX-ADABX |  |
| SUR19-XDH-XXXAX | SUR12-SDH-XXXBX | ELI280-LDX-ADCBD |  |
| SUR19-YAG-EXXBX | SUR12-TDH-XXAAX | ELI280-LDX-ADFBD |  |
| SUR19-YDH-XXXAX | SUR12-TDH-XXXBX | ELI280-LDX-ADFBG |  |
| SUR19-ZAG-EXXBX | SUR12-UDH-XXXBX |  |  |
| SUR19-ZDH-XXXAX |  |  |  |
| SUR19-ZDH-XXXBX |  |  |  |

**Response Form / Receipt**

**Subject: AM12M Patient Acquisition Module (MOD1326)**

**It is important** that you return this form as acknowledgement of your receipt and provide us with the necessary information.

Please complete the following with the correct information and **return this Response Form** within one month. Upon receipt of this Response Form, Welch Allyn will contact you when a replacement device is available for exchange. See specific instructions at bottom of page. Thank you!

Hillrom/Welch Allyn account number (if known): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of the facility:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address of the facility: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City: Zip: Country:

Facility Contact Person Name: (print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: Date: \_\_\_\_/\_\_\_\_/

Title: Phone:

Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Check actions taken**:

We have reviewed and understand the attached Urgent Field Safety Notice. □ Yes □ No

Results from the inspection of our product inventory show:

☐ We **do not have** any affected products.

☐ We **have** affected products. Quantity \_\_\_\_\_\_\_\_\_\_\_\_\_

**Please identify the impacted serial numbers in the table below.**

|  |  |
| --- | --- |
| **Serial Number** | **Serial Number** |
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|  |  |

Response form shall be returned to [hillrom5373@stericycle.com](mailto:hillrom5373@stericycle.com) within one month.