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
GERMANY	+49 6950 985 132, Option 3	eme.techsupport@hillrom.com
ITALY	+39 0269682425, Option 3	eme.techsupport@hillrom.com
NETHERLANDS	+31 (0) 20 206 13 60, Option 3	eme.techsupport@hillrom.com
BELGIUM	+31 20 206 13 60, Option 3	eme.techsupport@hillrom.com
SLOVENIA	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
RUSSIA	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
POLAND	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com

FRANCE	+33 1 57 32 49 94, Option 3	eme.techsupport@hillrom.com
LATVIA	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
TURKEY	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
MOROCCO	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
CROATIA	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
PORTUGAL	+353 (0) 46 90 67 790, Option 3	eme.techsupport@hillrom.com
UNITED KINGDOM	+41 44 6545315	eme.techsupport@hillrom.com
SWITZERLAND	+44 207 365 6780, Option 3	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

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

Response form shall be returned to hillrom5373@stericycle.com within one month.