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:
AM12M Patient Acquisition Module

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

Dear Distributor,

Welch Allyn has become aware of a potential safety issue related to the AM12M Patient Acquisition Module. Our records indicate that your facility has purchased one or more affected devices for distribution. Please distribute the attached letter to your consignees requesting they follow the instructions outlined in the communication. Please read this Field Safety Notice carefully and take all necessary actions.

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.

Action to be taken by the distributor:

There are two options you may choose from:

- Please add your contact information and email address to the customer letter and response form at the end of this letter. Forward a copy of the customer letter (added further down in this letter) and response form to your customers with affected products. Update Hillrom on the status of the Field Corrective Action weekly- the update shall include the of number of customers that have responded and the number of customers that have not responded as a % of the total impacted product. Updates on the status of the Field Corrective Action shall be provided until 100% of the customers have responded or customers have been contacted three times without response

- Alternatively, you can provide Hillrom a listing of your affected consignees for follow-up.

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

Fill out the distributor response form below and return it to hillrom5373@stericycle.com **within 15 days.**

Important: The distributor response form gives Hillrom/Welch Allyn information on the development of the Field Corrective Action. It is mandatory to return the response form to Hillrom/Welch Allyn.

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

Sincerely,

.....
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			

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

Distributor 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 15 Days. See specific instructions at bottom of page. Thank you!

Hillrom account number (if known): _____

Name of the distributor:_____

Address of the distributor: _____

City:_____ Zip: _____ Country: _____

Distributor Contact Person Name: (print)

_____

Signature: _____ Date: ____/____/ _____

Title:_____ Phone: _____

Email: _____

Check actions taken:

☐ We confirm the receipt of this letter, we have added our contact information and email address to the customer letter and response form and have forwarded the information to the affected customers.

☐ We do not have or have not distributed any affected units

☐ We will forward you a list of our consignees for Welch Allyn to contact for affected product.

Name / Contact: _____

Address:_____

City / State: _____

Phone: _____

Response form shall be returned to hillrom5373@stericycle.com within 15 Days.

Date:

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.

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 ,

irrespective of whether you have the affected product or not. Affected units will be requested to be returned.

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,

.....
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			

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

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, you will be contacted 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 | | within one month.