Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	**URGENT: Field Safety Notice Follow-up**	**MOD1299R**

Date

WA-MOD1299R-XXXX
Customer name
Customer Street Address
Customer Country, Zip

Commercial name of affected product:
Welch Allyn Patient Cables or Lead Sets

Type of action: Device Recall

Dear Welch Allyn Customer,

In April 2020, you received a Field Safety Notice from Welch Allyn (*see* Appendix E). The notice advised you that certain patient cables and lead sets may not meet the stated ECG performance claims if your device is used during an external defibrillation event. After discussion with our lead Competent Authority in Europe, Health Products Regulatory Authority (HPRA), we are notifying you that the field action has changed from an advisory notice to a product recall in the European market.

The specific description of the problem, potential risk(s) and affected product(s) are restated below. This Follow-Up Field Safety Notice provides further clarification on the potential impact to the ECG waveform after a defibrillation event (*see* 'Potential Risk' section). This Follow-up Field Safety Notice also provides instructions on how to replace your product and a reminder of the importance of following the indicated use stated in the device user manuals (*see* 'Advise on action to be taken by the user' section).

Description of the problem:

Welch Allyn's internal testing indicates that, in extremely rare cases, Welch Allyn products using impacted patient cables or lead sets 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. Specifically, during a defibrillation event the ECG waveform may not recover, or the waveform amplitude could be reduced. If the leads are damaged and it is not detected by the user during defibrillation, the device could be used on additional patients after defibrillation impacting diagnosis and treatment. 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.

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Affected Product:

The products associated with this notification were manufactured between October 12, 2015 and September 10, 2019. Lots manufactured and products purchased after September 10, 2019 meet the EN/IEC 60601-2-25 standard. A list of the affected part numbers is provided in Appendix B. A photo of the lot number markings is in Appendix C for ease in identifying the product in your possession.

Advise on action to be taken by the user:

- To request replacement of your products, complete the acknowledgement form in Appendix A and return to Welch Allyn **within the next two weeks.** Welch Allyn will reply with a confirmation note indicating when replacements will be available for shipment. Once you receive the replacements, the affected cables need to be immediately destroyed. The affected cables should not be returned to Welch Allyn.

- Follow the instructions below for safe use of your medical device until replacements are provided:

    1. Carefully read the 'Potential Risk' section above. Understand how the ECG waveform could potentially be altered after a defibrillation event.

        - The ECG waveform could become noisy
        - The ECG waveform may stop being displayed
        - The amplitude of the ECG signal could be reduced

    2. Ensure trained personnel or physicians follow the 'Indications for Use' section of your user manual and understand the impact to the ECG waveform.

        - Your ECG device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.

        - The ECG interpretations are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.

- This notice should be sent to anyone who needs to be aware within your organization, or to any organization where the potentially affected devices have been transferred. If you are a distributor, please review Appendix D for recommendations on how to execute this Field Safety Notice with your customers.

Contact Reference Person:

Should you have any questions regarding this notification, please contact Hillrom/Welch Allyn Technical Support, using email or number below.

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	**URGENT: Field Safety Notice Follow-up**	**MOD1299R**

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
IBERIA	+34 91 7 4 99 357, 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
NORWAY	+47 23 16 25 27	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:

• 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,

xxx

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	**URGENT: Field Safety Notice Follow-up**	**MOD1299R**

Appendix A
MOD1299R Field Safety Notice Confirmation Form

According to our records, you have received one or more impacted patient cables or lead sets:

WA-MOD1299R-XXXX
Customer name
Customer Street Address
Customer Country, Zip

Complete, sign and return this form to mod1299@hillrom.com **within 2 weeks of receipt.**

1. We have reviewed and understand the attached Field Safety Notice. ☐ Yes ☐ No
2. We have carefully read the 'Potential Risk' section and understand how the ECG waveform could potentially be altered after a defibrillation event. ☐ Yes ☐ No
3. We have ensured trained personnel/physicians follow the 'Indications for Use' section of the device user manual and understand impact to the ECG waveform. ☐ Yes ☐ No
4. We have reviewed the impacted products in Appendix B and verified all affected inventory still in our possession that needs to be replaced. ☐ Yes ☐ No
5. Indicate below the part number and quantity of impacted product that needs to be replaced. Upon receipt of this form, Welch Allyn will reply with a confirmation note indicating when replacements will be available for shipment.

Part Number	Qty

Part Number	Qty

By signing below, you are confirming you have read the instructions above, have accounted for all product subject to this recall and will immediately destroy the affected cables when replacements are received.

Signature:_____ Date:_____

Phone Number: _____ Email Address: _____

Name of Signer (Printed) _____

Title of Signer: _____ Customer Account #: _____

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Appendix B: Affected Product

Part Number	Description	Used with*	Bag/Flag Label	Impacted Range**	Device Marking	Marking Configuration	Impacted Range**	Expected Replacement Date
9293-017-50	PAT CBL 10WIRE LEADFORM AHA SNAP	H12+/X12+	(10) MMYY	1015 - 1219	Stamp	MM, YY	10, 15 - 12, 19	01/09/2020
9293-017-51	PAT CBL 10WIRE LEADFORM IEC SNAP	H12+/X12+	(10) MMYY	1015 - 1119	Stamp	MM, YY	10, 15 - 12, 19	30/04/2021
9293-026-51	PAT CBL 10WIRE LEADFORM XL IEC SNAP	H12+/X12+	(10) MMYY	1015 - 0120	Stamp	MM, YY	1015 and later	01/09/2020
9293-028-51	PAT CBL 6WIRE IEC SNAP	H12+	(10) MMYY	1015 and later	Date Code Wheel	MMYY	1015 and later	13/05/2021
9293-032-51	PAT CBL 10WIRE IEC BANANA JSCREW	ELI 10/ELI 350	(10) MMYY	1015 and later	Date Code Wheel	MMYY	1015 and later	01/09/2020
9293-032-52	PAT CBL 10WIRE AHA BANANA JSCREW	ELI 10/ELI 350	(10) MMYY	1015 and later	Date Code Wheel	MMYY	1015 and later	01/09/2020
9293-032-53	PAT CBL 10WIRE IEC BANANA JSCREW	ELI 10/ELI 350	(10) MMYY	1015 and later	Date Code Wheel	MMYY	1015 and later	29/03/2021
9293-033-53	PAT CBL 10WIRE IEC SNAP JSCREW	S12/S19	(10) MMYY	1015 and later	Date Code Wheel	MMYY	1015 and later	29/03/2021
9293-046-60	LD SET WAM/AM12 10 WRE AHA BANA GRY	WAM/AM12	(10) MMYY	1015 - 1019	Printed	YYWW	1542 - 1940	01/09/2020
9293-046-61	LD SET WAM/AM12 10 WRE IEC BANA GRY	WAM/AM12	(10) MMYY	1015 - 1119	Printed	YYWW	1542 - 1944	30/04/2021
9293-046-63	RPLCE LD SET WAM/AM12 LIMBS IEC BANA GRY	WAM/AM12	(10) MMYY	1015 – 0320	Printed	YYWW	1542 - 2009	30/04/2021
9293-046-65	RPLCE LD SET WAM/AM12 C1-C3 IEC BANA GRY	WAM/AM12	(10) MMYY	1015 – 0320	Printed	YYWW	1542 - 2009	30/04/2021
9293-046-67	RPLCE LD SET WAM/AM12 C4-C6 IEC BANA GRY	WAM/AM12	(10) MMYY	1015 – 0220	Printed	YYWW	1542 - 2005	30/04/2021
9293-046-81	LEAD SET AM15 13-WIRE BANANA IEC GRAY	AM15	(10) MMYY	1015 and later	Printed	YYWW	1542 and later	01/09/2020
9293-046-82	RPLCE LD SET AM15E, E2-E4, BANANA	AM15	(10) MMYY	1015 and later	Printed	YYWW	1542 and later	01/09/2020
9293-047-60	LD SET WAM/AM12 10 WRE CLIP AHA GRY	WAM/AM12	(10) MMYY	1015 - 1119	Printed	YYWW	1542 - 1944	01/09/2020
9293-047-61	LD SET WAM/AM12 10 WRE CLIP IEC GRY	WAM/AM12	(10) MMYY	1015 - 1119	Printed	YYWW	1542 - 1944	30/04/2021
9293-047-63	RPLCE LD SET WAM/AM12 LIMB CLIP IEC GRY	WAM/AM12	(10) MMYY	1015 – 0420	Printed	YYWW	1542 - 2014	01/09/2020

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Part Number	Description	Used with*	Bag/Flag Label	Impacted Range**	Device Marking	Marking Configuration	Impacted Range**	Expected Replacement Date
9293-047-65	RPLCE LD SET WAM/AM12 C1-C3 IEC CLIP GRY	WAM/AM12	(10) MMYY	1015 – 0420	Printed	YYWW	1542 - 2014	01/09/2020
9293-047-67	RPLCE LD SET WAM/AM12 C4-C6 CLIP IEC GRY	WAM/AM12	(10) MMYY	1015 – 0420	Printed	YYWW	1542 - 2014	01/09/2020
9293-047-70	LD SET WAM/AM12 10 WRE SHORT AHA CLIP	WAM/AM12	(10) MMYY	1015 - 1119	Printed	YYWW	1542 - 1944	30/04/2021
9293-047-71	LD SET WAM/AM12 10 WRE SHORT IEC CLIP	WAM/AM12	(10) MMYY	1015 - 1119	Printed	YYWW	1542 - 1944	01/09/2020
9293-061-50	CABLE 10 WIRE LF ECG SNAP ENDS AHA GRAY	S4	(10) WWYY	4215 and later	No Marking	N/A	N/A	09/05/2021
9293-061-51	CABLE 10 WIRE LF ECG SNAP ENDS IEC GRAY	S4	(10) WWYY	4215 and later	No Marking	N/A	N/A	09/05/2021
9293-061-53	CBL 10WIRE LF LRG ECG SNAP ENDS IEC GRAY	S4	(10) WWYY	4215 and later	No Marking	N/A	N/A	09/05/2021
S4-Q-AXX-XXX	S4 TRANSMITTER 5-WIRE NO SpO2 GEN2	Surveyor Central System	N/A	N/A	Label	(21) 1YYWWXXXXXXX	SN 11542XXXXXXX - SN 11937XXXXXXX	01/09/2020

** Note: WAM, AM12 and AM15 acquisition modules are sold with the ELI 150c, 250c, 230, 280, 350, 380, RScribe, ELI PC, XScribe and Q-Stress medical devices.*

Note: Your patient cable or lead set is not impacted by this recall if the Proof of Purchase was after September 10, 2019. If the polybag of your patient cable or lead set has a orange "PASS" sticker as shown below, this inventory has been tested to meet the EN/IEC 60601-2-25 standard and* ***is not *impacted by this recall.*

DIR XXXXXXXXX Ver A

7865 North 86th Street, Milwaukee, WI 53224
Telephone 800.231.7437
www.welchallyn.com

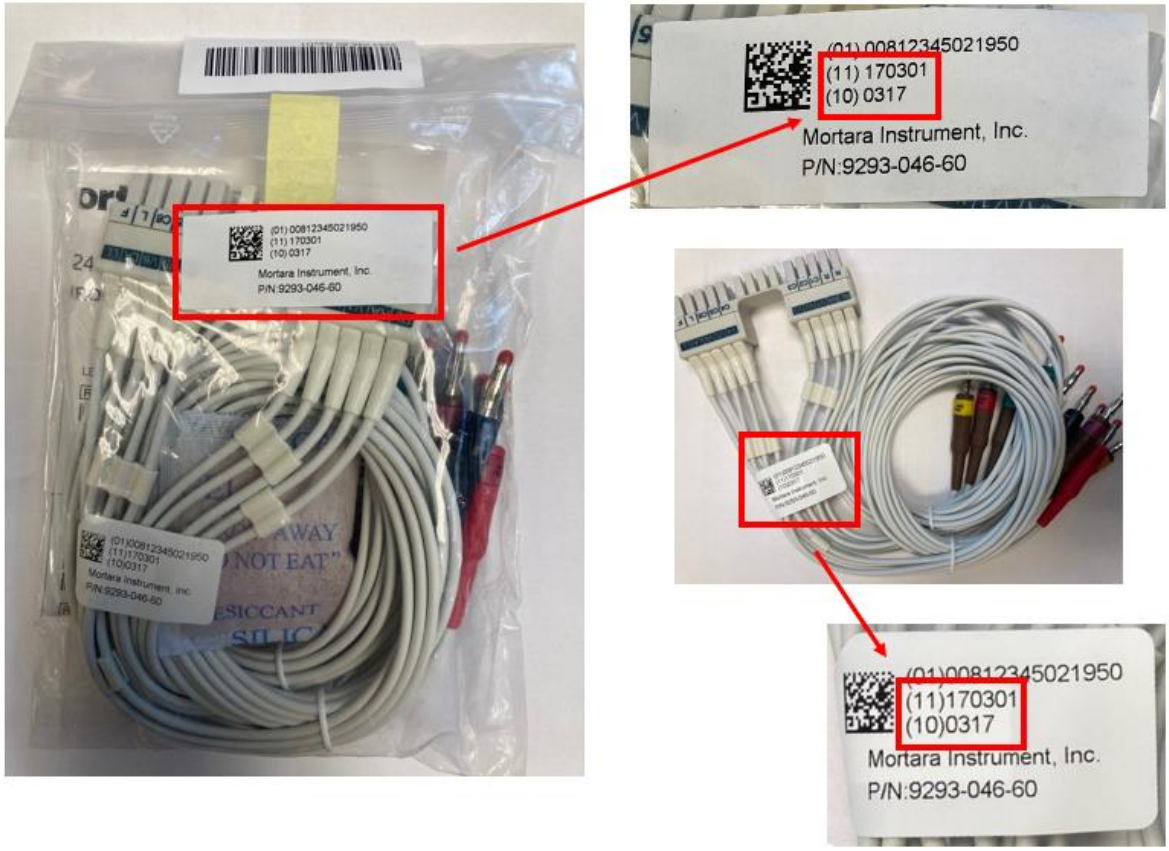
Hillrom™

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	**URGENT: Field Safety Notice Follow-up**	**MOD1299R**

Appendix C: Lot Number Markings

Bag Labels and Flag Labels

The Lot Number or Production Date can be found on either the outside of the polybag **OR** on the wire flag label as shown below. Refer to **Appendix B** to identify the appropriate data delimiter and impacted range for inspecting your inventory.



Device Markings

If the polybag has been discarded or the flag label is not available, inspect the permanent markings on the patient cables or lead sets as shown below. Refer to **Appendix B** to identify the impacted range for inspecting your inventory.

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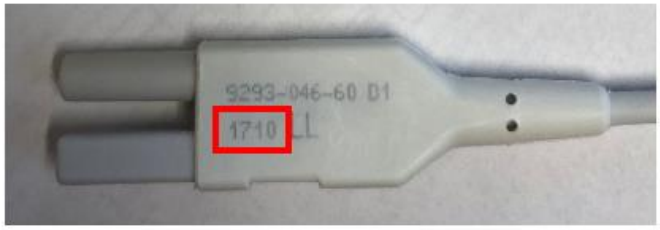
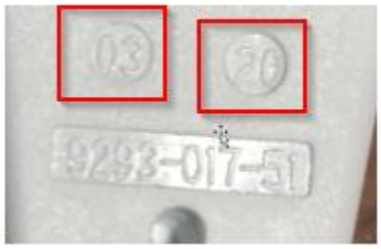
Device Marking	Part Numbers	
 *Figure 1: Printed YYWW*	9293-046-60 9293-046-61 9293-046-63 9293-046-65 9293-046-67 9293-046-81 9293-046-82	9293-047-60 9293-047-61 9293-047-63 9293-047-65 9293-047-67 9293-047-70 9293-047-71
 *Figure 2: Date Code Wheel MMYY*	9293-028-51 9293-032-51 9293-032-52 9293-032-53 9293-033-53	
 *Figure 3: Stamp MM and YY*	9293-017-50 9293-017-51 9293-026-51	

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Device Marking	Part Numbers	
 *Figure 4: S4 Telemeter SN Label*	S4-Q-AXX-XXX	

Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	**URGENT: Field Safety Notice Follow-up**	**MOD1299R**

Appendix D: Distributor Recommendations

If you have further distributed the impacted products, please ensure any communication with your customers instruct them to send all information directly to you, and not to Welch Allyn, Inc. The response form attached to our letter (Appendix A) should not be sent as written to your customers.

Please modify the response form as follows:

1. Change the red text below to your contact information so you receive your customer data directly.

   Complete, sign and return this form to mod1299@hillrom.com within 2 weeks of receipt.

2. Change the red text below from Welch Allyn to your company name.

   Indicate below the part number and quantity of impacted product that needs to be replaced. Upon receipt of this form, Welch Allyn will reply with a confirmation note indicating when replacements will be available for shipment.

3. Include any other instructions to your customer regarding replacements. Welch Allyn will not be shipping replacements directly to your customers. Any requests will need to be managed between the end user and your company as the seller.

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Appendix E: Original FSN (enclosed)

WA-MOD1299R-XXXX
Customer name
Customer Street Address
Customer Country, Zip

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.

Appendix E: Original FSN (continued)

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

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

Appendix E: Original FSN (continued)

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