

Overview

Welch Allyn, Inc. issued a voluntary medical device correction notification to inform customers that specific patient cables or lead sets used with resting ECG, stress, holter, and patient monitoring devices, in certain circumstances, may not meet the labelled performance claims. Internal testing has indicated, in extremely rare cases, impacted Welch Allyn products may not meet the “Defibrillation Withstand” requirements of EN/IEC 60601-2-25.

Beginning Wednesday March 25th, a certified letter will be mailed to all identified customers. The letter communicates our findings and provides the customer a summary of what was identified during our investigation.

The customer letter outlines contact information for the Milwaukee Cardio team as the primary point of contact for this Field Action.

Finding SAP Documents:

MOD1299 Customer Letter_US_Final, DIR 80026524

FAQ_MOD1299_US_Final, DIR 8026537

Materials/Or Options

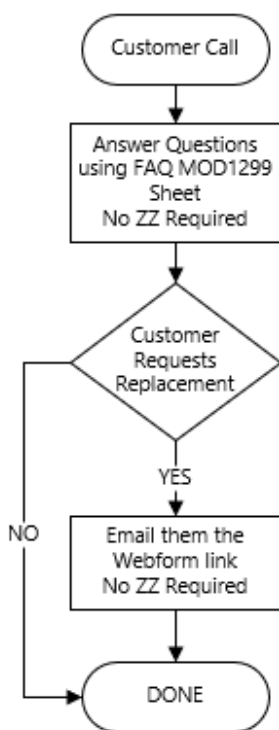
The impacted products were distributed between October 12, 2015 and September 10, 2019. The following table identifies the affected part numbers.

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

The patient cables are safe to use. Welch Allyn informed customers of the issue because the product may not meet the performance claims in our device literature. Based on our risk assessment, the device continues to be safe and effective for use. As a result, we should not offer replacement of product as an option for customers. However, if a customer prompts you for a replacement of the impacted cables reference FAQ MOD1299 sheet for next steps.

Technical/Customer Service

Our primary responsibility is to answer customers questions regarding this Field Action by using the provided FAQ MOD1299 Sheet. Some of the team may be assigned RMAs or Orders to assist with if the replacement is approved. You will be notified directly and assigned a customer interaction. If you are not assigned a customer interaction do not issue an RMA or place a replacement order for customer if it is associated to this Field Action.



Scenario 1: Customer contacts the call center with general questions

- ZZ Service Notification is not required to log an interaction with the customer for general questions regarding this Field Action unless the customer indicates any allegation of deficiency or wishes to have documentation of the call.
- Reference the FAQ MOD1299 Sheet for what can be communicated.

Scenario 2: Customer requests replacement

- Do not offer replacement cables to a customer. Reference the FAQ MOD1299 Sheet for what can be communicated regarding replacement lead set. See question **"Can I receive a replacement lead set?"**
- ZZ Service Notification is not required to log this interaction with the customer unless the customer indicates any allegation of deficiency. A ZZ Service Notification will be created when the customer responds to the webform.
 - If you create a ZZ Service Notification as a result of an allegation of deficiency, provide it to the customer to submit on the webform along with their replacement request.

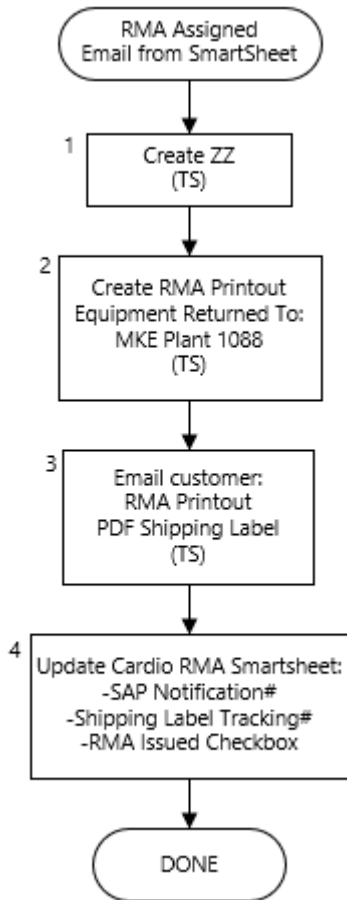
Scenario 3: Customer request escalation

- Notify your Manager or Supervisor via email for customers that have escalated. Please provide the customers confirmed Name, Email Address, and Phone Number. Inform the customer that a Manager or Supervisor will contact them directly.

Customer ZZ/Sales Order

Remember!

You should only issue an RMA or place an Order related to this Field Action if it is assigned to you by your Manager or Supervisor. RMA and Order assignments will be **limited to the Milwaukee Cardio Team**.



Scenario 1: RMA Assigned

You will receive an email notification from SmartSheet with the information needed to create a ZZ Service Notification and issue an RMA. If for any reason a notification was created as a result of an allegation of deficiency reported, continue processing within the existing ZZ Service Notification, you do not need to create a new one.

Follow all standard Service Processing instructions as outlined in the Customer Care Desk Reference for creating a ZZ Service Notification.

Use the table below as a reference for setting specific data/fields in the Service Notification as applicable to this Field Action.

1. Create ZZ Service Notification (Use details below)
2. Issue an RMA (Printout). Returning equipment should be sent to Plant 1088 (Milwaukee)
3. Email the customer both the RMA Printout and PDF Shipping Label (Use email template below)
4. Update Smartsheet to indicate completion of this step. Sheet: 2-Cardio Patient Cables-RMA

Service Notification and ETQ Complaint Information Tab	
Short Text	MOD1299
Subject Coding	Technical Support Rendered
ETQ Complaint Information Tab	Injury or Death: N No Keyword: 01 None Service Type: 02 Routine Customer Instruction /Working as Intended Source of Complaint: 01 Customer Status: Not an ETQ Complaint Note: You may need to use the Device Age Override option if Status = ETQ Complaint. This complaint coding is

Corrective Notification

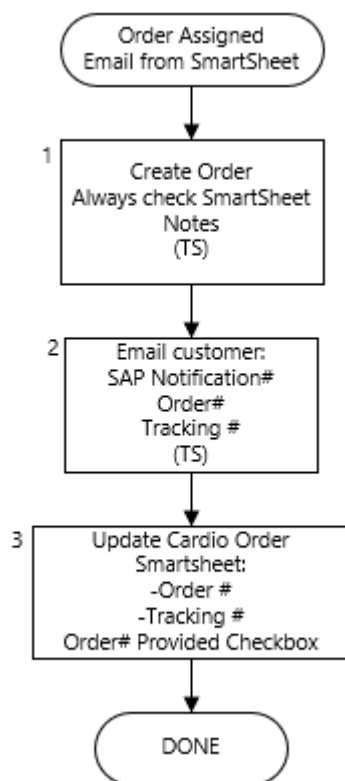
Welch Allyn Cardio Patient Cables

	only for RMAs associated to the Field Action where there is <u>no</u> allegation of deficiency. If there is an allegation update the fields as reported by the customer.
ZZ Long Text	This Service Notification is associated with Parts associated with MOD1299. As a result, this is not considered a product complaint. Issuing RMA for return of the following equipment: <Cable P/N, Lot Code or Proof of Purchase, Quantity Requested> Note: Add the line above, enclosed in <>, for every individual Part Number as applicable.
RMA	
Facility product is being returned to	Plant 1088 7900 North 86 th St Milwaukee, WI 53224
FedEx Shipping Label	
1. Return Package To	
Contact Name	Update this field from the Contact Name to the RMA Number.
Company	Welch Allyn Inc.
Address 1	7900 North 86 th St
ZIP	53224
City	Milwaukee
State	Wisconsin
5. Billing Details	
RMA no.	Update this field to include the RMA Number.
6. Complete your Shipment	
Print to PDF	Check the Generate label(s) and document(s) in PDF format. Box
2. Package & Shipment Details	
Return Label Type	Change s this option to Print.
Prepare a Shipment	
Return Label(s)	Be sure to check this box
Customer Email Notification	
CC:	mor_tech.support@hillrom.com
Subject Line:	ZZ#, Return Material Authorization
Body:	<Insert CustomerName>, You recently contacted us requesting a replacement for your Welch Allyn Cables. Attached you will find a shipping lable that you can use to send us your unopened/unused cables for inspection.

Corrective Notification

Welch Allyn Cardio Patient Cables

	Once your cables are received to our facility and inspected we will reach out to you and provide an additional update on the replacement order requested. If you have any questions please feel free to let me know via this email thread or by calling 888-667-8272 option 2. Thank you,
Attachments:	Shipping Label, RMA Printout
SmartSheet Update – Update after you have sent Customer Email Notification	
SmartSheet Name	2-Cardio Patient Cable – RMA
SAP Notification#	Insert the SAP Notificaiton number
Shipping Label Tracking #	Enter the shipping label tracking #
RMA Issued	Check this box to indicate completion of Issueing the RMA for this customer. You should only check this after the SAP record is created and updated and the Email notification to the customer that includes the Shipping lable and RMA Letter is sent.



Scenario 2: Order Assigned

You will receive an email notification from SmartSheet with the information needed to place an order for an existing ZZ Service Notification.

Follow all standard Sales Order Processing instructions as outlined in the Customer Care Desk Reference for creating a sales Order.

Use the table below as a reference for setting specific data/fields in the Order as applicable to this Field Action.

1. Create a ZWRO Order (use details below)
2. Email the customer the order and tracking number (Use email template below)
3. Update Smartsheet to indicate completion of this step. Sheet: 5-Cardio Patient Cables-Order

Order	
Order Type	ZWRO



Corrective Notification

Welch Allyn Cardio Patient Cables

Authorizing Partner	504857
Vendor Code	P1088
Text Notes	MOD1299
Shipping	Ground
Customer Email Notification	
CC:	mor_tech.support@hillrom.com
Subject Line:	ZZ#, Replacement Order
Body:	<Insert CustomerName>, We have placed a replacement order for your Welch Allyn Cardio Patient Cables. Below you will find your order number and tracking information. Order#: <Insert Order #> Tracking #: <Insert Tracking #> If you have any questions please feel free to let me know via this email thread or by calling 888-667-8272 option 2. Thank you,
SmartSheet Update – Update after you have sent Customer Email Notification	
SmartSheet Name	5-Cardio Patient Cable – Order
Order #	Enter the Order #
Tracking #	Enter the Tracking #
Order # Provided	Check this box to indicate that you have sent the Order # and Tracking information to the customer.
	NOTE: when these items are entered the Smartsheet row will automatically move to the Closed list.