

URGENT Field Safety Notice: RA2020 - 2246951

FSCA identification: Product recall RA2020 - 2246951

Action type: Field Safety Corrective Action

Affected items: See attached list

Product description: LIFEPAK® 15 Monitor/Defibrillator

January 2020

Dear Customer,

Stryker is conducting a Voluntary Correction for specific LIFEPAK 15 Monitor/Defibrillator devices (Part Number V15-2-XXXXXX) that may not deliver a shock after the “Shock” button on the keypad is pressed. The affected population includes devices which were either manufactured with or received an upgrade kit that contained an affected keypad. Please forward this notice to all your sites, trainers and users.

Description of Issue

The company has become aware that certain LIFEPAK 15 Monitor/Defibrillators may not deliver a defibrillation shock when the device “Shock” button is pressed as a result of oxidation that has formed over time within the button. The hard paddle shock button is not affected by this issue. There have been two Adverse Event Reports submitted for this failure mode where the shock button did not deliver one shock out of a series of defibrillation shocks, however the patients ultimately expired.

Identification of Impacted Product

The 29,952 impacted LIFEPAK 15 Monitor/ Defibrillators have part numbers beginning with V15-2. The part number of the device is located on the serial label as shown in the figure below.



LIFEPAK 15 devices with Part Numbers beginning with V15-5 or V15-7 are not impacted by this issue.

Stryker UK

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Stryker's Planned Actions

The Company is contacting customers with impacted devices to schedule the correction of their device(s). Stryker anticipates that all devices subject to this field action will be serviced by June 30, 2021.

Required customer actions

We request that you read this notice carefully and complete the following actions:

1. **You may continue to use your LIFEPAK 15 Monitor/Defibrillator according to the Operating Instructions until the correction can be completed. The other functions of the device are not affected by this issue.**

The majority of complaints associated with this issue were detected prior to patient use. Routine testing of your device may detect this fault condition. You should continue to perform the daily check as described in the Operator's Checklist, specifically, the QUIK-COMBO therapy cable check as described in the General Maintenance and Testing Section (pages 10-4 and the LIFEPAK 15 Monitor/Defibrillator Operator's Checklist, number 7). If the device fails the test, a "disarming" message will be displayed, and the service light will be illuminated. Contact Stryker Technical Support immediately to report the incident.

If the issue occurs during patient use, a "disarming" message will be displayed, and the service light will illuminate. Immediately repeat your charge and shock cycle according to the Operating Instructions. If you receive the "disarming" message again, utilize hard paddles or a backup device. If hard paddles or a backup device are not available, continue the charge and shock cycles per the Operating Instructions. Upon completion of the patient case, remove the LIFEPAK 15 from service and contact Stryker Technical Support immediately to report the incident.

2. Circulate this Field Safety Notice internally to all interested/affected parties.
3. Maintain awareness of this notice internally until all required actions have been completed within your facility.
4. Inform Stryker if any of the subject devices have been distributed to other organisations.
 - a) Please provide contact details so that Stryker can inform the recipients appropriately.
 - b) If you are a Distributor, note that you are responsible for notifying your affected customers.
5. Please inform Stryker of any adverse events concerning the use of the subject devices.
6. Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority.

7. **Complete the attached customer response form.** It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete even if you no longer have any of the subject devices in your physical inventory.
8. Return the completed form to your nominated Stryker Representative (indicated below) for this PFA
 - a) On receipt of the form, a Stryker Representative will contact you to organise any applicable ongoing actions.

We request that you respond to this notice within 7 calendar days from the date of receipt. The target date for completion of this action is 30 June 2021 and your timely response will enable us to ensure that we meet this target.

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name Sharun Thavarajan
Position Senior RAQA Specialist
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In line with the recommendations of the Meddev Vigilance Guidance document Ref 2.12-1, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

On behalf of Stryker we thank you sincerely for your help and support in completing this action within the target date and regret any inconvenience that may be caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards, remain on the market.

Yours faithfully,



Sharun Thavarajan
Regulatory Affairs and Quality Assurance

RA2020-2246951

Affected serial numbers in EMEA region

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42840024	42840244	42840263	42851326	42851639	42852115	42852162	42852260
42852593	42853054	42853086	42853090	42853132	42853144	42854479	42854780
42854941	42854954	42855002	42855045	42855063	42855070	42855088	42855102
42855168	42855193	42855231	42855255	42855268	42855314	42855344	42855408
42855416	42855497	42856017	42856080	43110461	43137417	43157364	43158400
43158432	43158716	43158748	43158782	43158923	43159045	43159102	43159148
43159211	43159279	43159344	43159397	43810170	43810365	43936584	45307376
45584203							

Acknowledgment of Field Safety Notice: RA2020 - 2246951**FSCA identification:** Product recall RA2020 - 2246951**Action type:** Field Safety Corrective Action**Affected items:** See attached list**Product description:** LIFEPAK 15 Monitor/Defibrillator

I acknowledge receipt of the Field Safety Notice for RA2020 – 2246951 and can confirm that:

We have not located any of these devices in our inventory: <i>(please delete if not applicable)</i>		
We have located the following devices:		
Product Description	Product Reference	Serial Number
We have further distributed subject devices to the following organisations:		
Facility Name		
Facility Address		

Please sign and return this form to acknowledge receipt of product notice.			
Name of Hospital / Organisation		Department	
Contact Name		Address	
Contact Title			
Contact Signature		E-mail Address	
Contact Phone No.		Date	

**PLEASE COMPLETE AND FAX THIS FORM TO 01635 580 300
OR EMAIL TO raqa.uk@stryker.com**

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