

XX July 2021

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 Keypad

Dear Valued Customer,

In January 2020, Stryker initiated a Voluntary Correction to notify customers that specific LIFEPAK 15 Monitor/Defibrillator devices may not deliver a shock after the “Shock” button on the keypad is pressed. The affected population included devices which were either manufactured with or received an upgrade kit that contained an affected keypad. If you were identified as having possession of affected LIFEPAK 15 devices or upgrade kits, you would have already been notified of this correction.

Since the original customer notifications for this issue was completed, Stryker has identified that additional keypads, which are sold as individual units that could later be installed into LIFEPAK 15 devices, are also included in scope of this voluntary correction. You are receiving this notification because our records indicate you may have received keypads associated with this issue. Please forward this notice to all your sites, trainers and users.

Description of Issue

As described in the original customer notification letter, Stryker 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.

Identification of Impacted Product

For our customers in the xxxxxx, the affected product associated with the scope of this notification are identified in the following table:

Keypad Configuration	Catalog Number	Part Number
V1 English NIBP	21330-001252	3207079-001
V1 English NIBP	21330-001252	3207079-005
V1 English	21330-001261	3207079-002
V1 English	21330-001261	3207079-006
V2 English NIBP	21330-001496	3302470-002
V2 English NIBP	21330-001496	3302470-004
V2 English	21330-001497	3302470-003
V2 English	21330-001497	3302470-005

Stryker's Planned Actions

The Company is contacting customers with affected LIFEPAK 15 keypads to notify them of the issue and to take the required actions specified in this notification letter.

Required customer actions

For the following required customer actions, please refer to the Affected Keypad Acknowledgement Form attached to this notification.

- Review your inventory to determine if you have any affected product.
- Scrap any affected product in your inventory.
- Review your LIFEPAK 15 device service records to determine if any affected part numbers were installed into devices.
 - 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.
- Return the acknowledgement form according to the instructions provided and Stryker will provide replacement keypads at no charge.

We request that you respond to this notice within 7 calendar days from the date of receipt.

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:	XXXXX
Position:	XXXXX
Telephone:	XXXXX
E-mail:	XXXXX

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,



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 Keypad

Customers must complete this form and return in order to receive replacement product.

Customer label will be placed here —	Customer information
	Name of person completing this form: _____
	Title: _____
	Phone Number: _____
Email: _____	

The quantities indicated below will be replaced upon receipt of this acknowledgment form. This form must be returned in order to receive replacement product.

Original Stryker Item Number	Original Stryker Catalog Number	Original Quantity Shipped	New Stryker Item Number	New Stryker Catalog Number	New Quantity To Be Shipped To You
3207079-001 3207079-005	21330-001252		3207079-007	21330-001575	
3207079-002 3207079-006	21330-001261		3207079-008	21330-001576	
3302470-002 3302470-004	21330-001496		3302470-006	21330-001603	
3302470-003 3302470-005	21330-001497		3302470-007	21330-001604	

I have read and understand the instructions provided including the requirement to scrap any affected product in my inventory. I acknowledge receipt of the Medical Device Correction notification regarding the **LIFEPAK 15 Keypad Replacement** by signing below.



I also agree to further distribute and communicate this important information from this letter to those whom withinmy organization I have distributed any of the **LIFEPAK 15 Keypads** noted in this letter.

Name (print)_____Signature_____Date_____

PLEASE COMPLETE AND FAX THIS FORM TO XXXXXX
OR EMAIL TO XXXXX