State of New Hampshire
Department of Safety

Division of Fire Standards and Training & Emergency Medical Services
98 Smokey Bear Boulevard, Concord, New Hampshire
Mailing Address: 33 Hazen Drive, Concord, New Hampshire 03305-0002

Business: (603) 223-4200 Fax: (603) 271-1091

Robert L. Quinn
Commissioner

Richard C. Bailey, Jr. and Perry E. Plummer
Assistant Commissioners

Deborah A. Pendergast
Director

CLINICAL BULLETIN

Bulletin #	Title			Date Issued
62	LIFEPAK 15 Monitor/Defibrillator Recall Failure to Deliver Shock			January 13, 2020
Superseded	**Released By**	**Approved By**	**Source**	
	Vicki Blanchard, Captain	Justin Romanello, Chief	FDA	

TOPIC: LIFEPAK 15 Monitor/Defibrillators by Stryker: Recall - Due to failure to deliver a defibrillation shock after the “Shock” button on the keypad is pressed

AUDIENCE: Cardiology, Health Professional, Risk Manager

BACKGROUND: LIFEPAK 15 is a complete acute cardiac care response system designed for basic life support and advanced life support patient management protocols.

ISSUE: Stryker is notifying a population of LIFEPAK 15 customers of an issue that may cause their devices to fail to deliver a defibrillation shock after the “Shock” button on the keypad is pressed. This is a result of oxidation that may have formed over time within the “Shock” button.

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

RECOMMENDATION: Stryker is instructing customers to continue to use their LIFEPAK 15 monitor/defibrillator according to the operating instructions until the correction can be completed. Customers 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).