URGENT MEDICAL DEVICE SAFETY NOTICE & CORRECTION

ACTION REQUIRED

Masimo Rainbow Reusable DCI Sensor Recall

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your **Masimo Rainbow Reusable DCI Sensors used on the LIFEPAK 15 device**.

August 31, 2020

Dear Valued Customer,

Stryker has been notified by its supplier, Masimo Corporation, of a voluntary correction for specific Rainbow Reusable DCI Sensors that were manufactured by Masimo Corporation. This affects certain lots of DCI Rainbow Sensors manufactured between November 2019 and March 2020. These sensors are designed for use with the LIFEPAK 15 monitor/defibrillator. As a distributor of this Masimo product, Stryker has identified that your organization may have been a recipient of one or more affected lots of this product.

Description of issue

Masimo received complaints indicating that certain Rainbow Reusable DCI sensors did not function with certain LIFEPAK 15 devices. When present, this issue is immediately apparent upon connection of the sensor to a device. The device displays a "Replace Sensor" or "Incompatible Sensor" message and the sensor cannot be used. Reporting practitioners completed the procedures by using an alternate sensor.

Masimo determined this is related to a software issue within the sensor that was used in the specific part numbers and lots codes manufactured between November 2019 and March 2020 as listed below. No patient injuries have been reported associated to this issue.

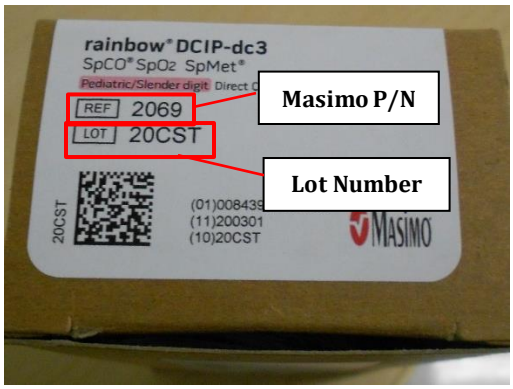
Identification of impacted product

This action affects only the item Part Numbers/Catalog Numbers and Lots Numbers listed below:

Stryker P/N	Stryker Catalog Number	Masimo P/N & Description	Lot Numbers
3201655-127	11171-000049	**P/N 2696:** Rainbow DCI, Adult Reusable Sensor, SpO2/SpCO/SpMet, 3Ft M-15 Connector; 1/Box, Masimo	19NEY 20ALN 20BZJ E19MUM

Required customer actions

1. Inspect your Masimo Rainbow DCI Sensor inventory to determine if you have any affected product identified in this letter. If you identify affected product, destroy per your local process. Note: only inventory with the specific lot codes listed in the table above will need to be identified.
2. Your distributor will provide you with replacement sensors and will provide the quantity they've identified as having distributed to you from their affected product.



Stryker's planned actions

The company is notifying all customers that have received potentially affected Masimo Rainbow Reusable DCI Sensors. Replacement sensors will be provided at no charge.

If you have any questions about this matter contact Stryker at 1 800 787 9537, option 2, 8:00 A.M. to 7:00 P.M. (Eastern Time), Monday – Friday or by email at medtechsup@stryker.com.

In addition to contacting Stryker, any potential quality problems or adverse reactions or events associated with the use of a product from Stryker may be reported to the U.S. Food and Drug Administration's MedWatch Safety Information and Adverse Event Reporting Program online at https://www.fda.gov/safety/medwatch/, by phone 1 800 332 1088 or fax 1 800 FDA 0178.

Sincerely,

Kathryn E. Janecke

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