MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Customer ID: «ID»

Urgent: Medical Device Recall Notice

Radius VSM® ECG Electrodes and Pressure Cuffs (see Attachment 1 for Affected Part and Lot Numbers)

«Letter_Date»

«CUSTOMER»
«Address1»
«Address2»
«Address3»
«CITY», «STATE» «ZIP»
«COUNTRY»

Attention: Clinical Engineering/Biomedical Department

Customer ID: «ID»

Reason for Recall:

Masimo made the decision to initiate a voluntary product recall of select Radius VSM ECG electrode assemblies and blood pressure cuffs.

Masimo has received some customer reports of Radius VSM devices used with its ECG feature (using ECG electrodes) of false positive extreme tachycardia, bradycardia, and atrial fibrillation (AFib) alarms. Customers reported that the Radius VSM ECG feature incorrectly detected extreme bradycardia and tachycardia events and triggered an alarm on patients with a normal heart rate.

In addition, Masimo identified certain Radius VSM small- and medium-size blood pressure cuffs containing rough edges. Prolonged rubbing against the rough edge of a Radius VSM blood pressure cuff may result in localized skin irritation or redness. There is no performance impact of the cuffs due to the rough edge.

Please refer to **Attachment 1** for a listing of the Radius VSM® ECG Electrodes and Pressure Cuff devices shipped to «CUSTOMER» subject to this Recall Notice.

Risk to Health:

The need to manage false positive alarms may distract clinicians away from the management of true positive alarms. The immediate health consequence could be that an extreme tachycardia, bradycardia, or AFib condition could be overlooked, resulting in delayed treatment. Prolonged skin contact to a rough edge of the Radius VSM Cuff may result in localized skin irritation or redness. Skin irritation is generally self-limiting and transient without long-range health concerns.

No Impact to Other Products:

There is no impact to any other Masimo products.

Actions to be taken by Customer:

- Please assess your inventory to confirm if you have the 1) Radius VSM ECG electrode assemblies or the 2) Radius VSM small- and medium-size blood pressure cuffs listed in Attachment 1-part number(s) and lot number(s).
- Always pay attention to alerts and alarms displayed and post this notice as a constant reminder for those using the devices.
- Read through the notice and be aware of the potential issues associated with the devices. Please circulate this notice to all relevant stakeholders, and be sure to include all sites that have assumed custody or transfer of the affected devices.
- Sign and return **Attachment 1**

If you wish to return the impacted devices, please contact Masimo Technical Services and we will arrange for the return of the affected part and lot number (s) for replacement. Replacement products are unaffected by the issue.

Please see Masimo's Website for contact information and hours of operations for your local Technical Service Office at
https://www.masimo.com/contact-support/support/technical-services/

Type of Action by the Company

As per Masimo's commitment to patient safety and quality, we are conducting a thorough investigation into these events, a root cause investigation in on-going. To mitigate potential risk, and consistent with the current instructions for use continue to attend to Radius VSM devices alarms. Prior to use, please inspect the pressure cuffs that may display rough edges.

Any adverse reaction or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Please see www.fda.gov/medwatch/report.htm for additional details.

Masimo is committed to consistently providing high quality products and services to you, our customers. We apologize for any inconvenience this issue may have caused.

Sincerely,

Rishi Jain VP, Quality Compliance Masimo Corporation

MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Customer ID: «ID»

Attachment 1

Action to be taken:

1. **Please follow the steps below**

   Read through the notice to be aware of the potential issues. Contact Masimo's Technical Services to request replacement of the affected part and lot numbers (s), as necessary.

   Post this notification as a constant reminder for anyone using the devices. Please circulate this notice to all relevant stakeholders, and be sure to include all sites that have assumed custody or transfer of the affected devices.

   If you have any questions, please contact Masimo's Technical Service: https://www.masimo.com/contact-support/support/technical-services/

   For international customers, local contact information can be found at https://www.mymasimo.com/contact-us/.

   Complete the bottom portion of this **Attachment 1**, then email it to CustomerNotice@masimo.com or Fax it to 1-949-297-7575 **by «Response_Date».**

2. On behalf of my facility, I acknowledge that I have received, read and understood this recall notification titled **Radius VSM® ECG Electrodes and Pressure Cuffs** and have followed the actions listed in the notification.

   Any adverse events associated with the recalled product? ☐ Yes ☐ No

   If yes, please provide details: _____

   Select **one**.

   ☐ I am not returning any devices.

   ☐ I am returning devices and have contacted Masimo's Technical Services to arrange for replacement of the affected lot number(s). Please fill out the table below:

Impacted Part (s) and Lot (s)		Customer To Complete	
Part Number	Lot Number	Quantity to be Returned	RMA Number
«Part1»	**«Lot1»**		
«Part2»	**«Lot2»**		
«Part3»	**«Lot3»**		
«Part4»	**«Lot4»**		

3. Sign below, then Email this attachment to CustomerNotice@masimo.com, or Fax it to 1-949-297-7575 **by «Response_Date».**

Contact Information and Authorization	**Customer Name**	**Customer ID**
	«CUSTOMER»	«ID»

→ _____ _____ _____

Printed Name Title Signature Date

Email Address: