

Rev 1: February 2026

**FSN Ref:** HHE-1088 & HHE-1089B



**FSCA Ref:** MD26.035.

**Date:** 24/02/2026

## **Urgent Field Safety Notice** **Device Commercial Name**

**For Attention of\*:** Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

Please see attached MD26.035 Impacted Customer List

**Contact details of local representative (name, e-mail, telephone, address etc.)\***

<b>Masimo Corporation, 52 Discovery, Irvine, CA 92618, customernotice@masimo.com</b>
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**Urgent Field Safety Notice (FSN)**  
**Device Commercial Name**  
**Risk addressed by FSN**

<b>1. Information on Affected Devices*</b>	
1	<b>1. Device Type(s)*</b>
.	Radius VSM – ECG Electrode Set is a wearable, battery operated, patient monitoring system which is capable of continuous multimodal measurements. Radius VSM Blood Pressure Cuffs are accessories intended to be used with a non-invasive blood pressure measurement system to measure blood pressure.
1	<b>2. Commercial name(s)</b>
.	See Appendix A
1	<b>3. Unique Device Identifier(s) (UDI-DI)</b>
.	See Appendix A
1	<b>4. Primary clinical purpose of device(s)*</b>
.	See HHE-1089B for the Radius VSM ECG Electrodes and HHE-1088 for Radius VSM Blood Pressure Cuffs
1	<b>5. Device Model/Catalogue/part number(s)*</b>
.	Add as Appendix if necessary.
1	<b>6. Software version</b>
.	Only where relevant.
1	<b>7. Affected serial or lot number range</b>
.	See Appendix B
1	<b>8. Associated devices</b>
.	The recall notice applies to specific part numbers and lot numbers identified in this communication.

<b>2 Reason for Field Safety Corrective Action (FSCA)*</b>	
2	<b>1. Description of the product problem*</b>
.	Radius VSM devices used with its ECG feature (using ECG electrodes) of false positive extreme tachycardia, bradycardia, and atrial fibrillation (AFib) alarms. 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.
2	<b>2. Hazard giving rise to the FSCA*</b>
.	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. The Radius VSM Cuff prolonged skin contact to rough edges may result in localized skin irritation or redness. Skin irritation is generally self-limiting and transient without long-range health concerns. Details of the greatest hazard to the patient/end user that the advice/action is intended to mitigate. Make clear whether risk is to user, patient or both. Should also try to indicate the residual risk if the FSN advice/action is taken.
2	<b>3. Probability of problem arising</b>
.	Provide an indication (from incident data or prospective modelling) of the likelihood the problem will arise.

2	<b>4. Predicted risk to patient/users</b>
.	From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect).
2	<b>5. Further information to help characterise the problem</b>
.	Include any further relevant statistics to help convey the seriousness of the issue.
2	<b>6. Background on Issue</b>
.	Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc.
2	<b>7. Other information relevant to FSCA</b>
.	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

<b>3. Type of Action to mitigate the risk*</b>	
<b>3.</b>	<p><b>1. Action To Be Taken by the User*</b></p> <p> <input type="checkbox"/> Identify Device                    <input type="checkbox"/> Quarantine Device                    <input checked="" type="checkbox"/> Return Device                    <input type="checkbox"/> Destroy Device             </p> <p> <input type="checkbox"/> On-site device modification/inspection             </p> <p> <input type="checkbox"/> Follow patient management recommendations             </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)             </p> <p> <input type="checkbox"/> Other                      <input type="checkbox"/> None             </p> <p>Provide further details of the action(s) identified.</p>
<b>3.</b>	<p><b>2. By when should the action be completed?</b></p> <p style="text-align: right;">Specify where critical to patient/end user safety</p> <p style="text-align: center;">April 30, 2026</p>
<b>3.</b>	<p><b>3. Particular considerations for:</b></p> <p style="text-align: right;">Choose an item.</p> <p>Is follow-up of patients or review of patients' previous results recommended?</p> <p>No</p> <p>Provide further details of patient-level follow-up if required or a justification why none is required</p>
<b>3.</b>	<p><b>4. Is customer Reply Required? *</b></p> <p>(If yes, form attached specifying deadline for return)</p> <p style="text-align: right;">Yes April 30, 2026</p>
<b>3.</b>	<p><b>5. Action Being Taken by the Manufacturer</b></p> <p> <input type="checkbox"/> Product Removal                      <input checked="" type="checkbox"/> On-site device modification/inspection                 </p> <p> <input type="checkbox"/> Software upgrade                      <input type="checkbox"/> IFU or labelling change                 </p> <p> <input type="checkbox"/> Other    <input type="checkbox"/> None                 </p> <p>Provide further details of the action(s) identified.</p>
<b>3</b>	<p><b>6. By when should the action be completed?</b></p> <p style="text-align: center;">6 months</p>
<b>3.</b>	<p><b>7. Is the FSN required to be communicated to the patient /lay user?</b></p> <p style="text-align: right;">No</p>
<b>3</b>	<p><b>8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?</b></p> <p>Choose an item.                      Choose an item.</p>

<b>4. General Information*</b>		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Provide reference and date of previous FSN if relevant
4.	3. For Updated FSN, key new information as follows: <b>N/A</b>	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to: N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	<b>Appendix A, Appendix B, Recall Notice.</b>
4.	10. Name/Signature	<b>Karla Guerrero Director, External Quality Compliance</b>

<b>Transmission of this Field Safety Notice</b>	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p>

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.



**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 is 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](http://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

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](mailto: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](mailto:CustomerNotice@masimo.com), or Fax it to 1-949-297-7575 **by «Response Date»**.

Contact Information and Authorization	Customer Name		Customer ID
		«CUSTOMER»	
→ _____			
Printed Name	Title	Signature	Date
Email Address:			