Masimo
52 Discovery
Irvine, CA 92618

Rev 1: February 2026

FSN Ref: HHE-1088 & HHE-1089B

FSCA Ref: MD26.035

Date: 03/26/2026

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.)*
Masimo Corporation, 52 Discovery, Irvine, CA 92618 customernotice@masimo.com

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Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	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.	2. Commercial name(s)
	See Appendix A
1.	3. Unique Device Identifier(s) (UDI-DI)
	See Appendix A
1.	4. Primary clinical purpose of device(s)*
	See HHE-1089B for the Radius VSM ECG Electrodes and HHE-1088 for Radius VSM Blood Pressure Cuffs
1.	5. Device Model/Catalogue/part number(s)*
	See Appendix A
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	See Appendix B
1.	8. Associated devices
	The recall notice applies to specific part numbers and lot numbers identified in this communication.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	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.	2. Hazard giving rise to the FSCA*
	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.
2.	3. Probability of problem arising Radius VSM Electrode: A false positive alarm could distract attention away from a true positive alarm resulting in unrecognized clinical deterioration and patient injury due to delaying treatment. However, hospital mitigations already implemented include the use of multi-layered alarm management strategies. Therefore, the likelihood of injury is assessed as “low.”

	Pressure cuffs: The likelihood of skin irritation or redness is “moderate”. The risk of skin irritation is dependent on the skin making contract and rubbing the rough edge of the cuff. When the cuff is applied and in place, the rough edge does not contact the skin. However, skin can contact the rough edge if the cuff slips down to contact the elbow crease or skin folds over the cuff edge.
2.	4. Predicted risk to patient/users Radius VSM Electrode: The need to manage false positive alarms may distract clinicians away from the management of true positive alarms. These are partially mitigated by existing hospital policies for multi-layered alarm management. The immediate health consequence could be that an extreme tachycardia, bradycardia, or AFib condition could be overlooked, resulting in delayed treatment. Pressure cuffs: For skin lacerations/abrasions to occur, the cuff edge would likely need to be rubbed against the skin undetected at a high rate for a short period of time (e.g., intentional attempt to cause injury) or for a prolonged time with normal arm movements. Therefore, the likelihood of skin abrasion was considered “low.”
	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). Radius VSM Electrode: Alarm fatigue resulting from repeated false positive alarms could result in delayed recognition and treatment of a true positive alarm or administration of incorrect treatment to a patient that is not experiencing true extreme bradycardia, tachycardia, or AFib. Although no patient injury has been reported for existing complaints, either scenario could result in a moderate severity injury. Pressure cuffs: A rough edge was found on some Radius VSM small and medium cuffs. If the rough edge rubs against the skin, there is possibility of skin irritation or redness. In most cases, the resulting skin irritation or redness would be self-limited and would not cause any adverse health consequences. However, individuals with frail or compromised skin, or patients with an indwelling line adjacent to the rough edge may be at greater likelihood of skin abrasion injury and/or infection. The impact of the rough edge is easily detectable and the likelihood the skin irritation progresses to skin abrasion or a laceration is lower.
2.	5. Further information to help characterize the problem Radius VSM Electrode: The conductive path used by the Radius VSM ECG electrode assemblies is dependent upon the electrode’s conductive contact to the patient’s skin and the wired connections with the electrodes to the ECG Electrode assembly connector. Poor conductive conduct by the ECG electrodes with the patient’s skin can cause incorrect detection of electrical potentials that can impact the detected ECG signals leading to the reported false alarms. Similarly, the electrical connection of the wires to the electrodes can also impact the relay of the detected electrical potentials to the ECG module impacting the detected ECG signals leading to the reported false alarms. Pressure cuffs: An investigation performed by Masimo identified Radius VSM Cuffs, no rough edge on large sized cuffs and a rough edge on the size small and medium cuffs. The investigation identified that the rough edge was likely to form during the manufacturing process to weld the PVC fabric to form the cuff. During that process, the folded side of the small and medium sized cuffs appeared to become deformed/embrittled along the folded edge. Unlike the large cuff that is welded and cut along all 4 sides, the small and medium cuffs are welded and cut along only three sides and not cut along the folded side. The lack of cutting of the folded side was found to contribute to the forming of a rough edge.

	If the rough edge makes contact with the skin, there could be skin irritation and redness, especially if the skin rubs against the rough edge. The chance of rubbing the rough edge increases based upon the orientation of the cuff – placed on the left arm vs. right arm (see Figure 1). There is no impact to the performance of the device due to the rough edge. The potential risk to health is assessed in later sections of this document.
2.	6. Background on Issue Radius VSM Electrode: Masimo received complaints related to Radius VSM devices used with its ECG feature (using ECG electrodes). Complaints received include frequent false alarms of extreme tachycardia, bradycardia, or atrial fibrillation (AFib). Customers reported the Radius VSM with the ECG feature incorrectly detected extreme bradycardia and tachycardia events and triggered an alarm on patients with a normal heart rate. In other cases, customers reported frequent false alarms incorrectly identified as AFib (e.g., false positive) or tachycardia on patient with waveforms that are not indicative of AFib or tachycardia. Customers have reported issues related to false positive alarms for extreme tachycardia, bradycardia, or AFib. This condition can occur if the conductive path of the ECG electrode is compromised, leading to poor signal detection and introduction of signal artifact. Preliminary investigation, including review of complaints, found evidence of electrodes with broken wires and poor adhesion which could result in compromised signal detection. Investigational testing confirmed the broken wires and/or poor adhesion can impact the ECG electrode's conductive path and lead to false positive alarms for extreme tachycardia, bradycardia, and AFib. Pressure cuffs: Retained samples and potentially impacted cuffs were contained and inspected at Masimo where approximately 50% of small cuffs were observed with a "rough edge" and 100% of medium cuffs were observed with a "rough edge". The lots of the cuffs inspected were manufactured between 2022 to 2025.
2.	7. Other information relevant to FSCA Radius VSM Electrode: The recommendation is to notify customers to reinforce the potential for false alarms with use of certain Radius VSM ECG electrode assemblies. Customers can reach out to Masimo for replacement, as needed. This action is being performed to mitigate potential issues related to reported false positive alarms that could cause an indirect risk to health. Pressure Cuffs: The cuff can be used on either the upper left or right arm with the cuff artery-mark aligned on the brachial artery in the middle of the inner arm. If the cuff is placed on the left arm, there is an increased chance that the rough edge can rub against elbow crease with arm movement, especially if the cuff slips down the arm. If the cuff is placed on the right arm the rough edge is exposed to the upper bicep/arm. See Figure 1 above. Therefore, if the user applies a cuff that is oversized, there is a potential for the cuff to slip down and make greater contact with the elbow crease.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☒ Return Device ☐ Destroy Device ☐ On-site device modification/inspection ☐ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
3.	2. By when the action should be completed?	April 30, 2026
3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? No	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes April 30, 2026
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☒ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None	
3	6. By when should the action be completed?	12/09/2026
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	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?	

	4. General Information*	
4.	1. FSN Type*	Initial
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
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	Masimo Corporation
	b. Address	52 Discovery Irvine, CA 92618
	c. Website address	www.masimo.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	9. List of attachments/appendices:	Appendix A, Appendix B, Recall Notice
4.	10. Name/Signature	Karla Guerrero Director, External Quality Compliance

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organizations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. 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.*

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