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.)*
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)*
	Add as Appendix if necessary.
1.	6. Software version
	Only where relevant.
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. 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.	3. Probability of problem arising
	Provide an indication (from incident data or prospective modelling) of the likelihood the problem will arise.

2.	4. Predicted risk to patient/users
	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.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	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.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.

	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 should the action be completed?	Specify where critical to patient/end user safety April 30, 2026
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required	
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 Provide further details of the action(s) identified.	
3	6. By when should the action be completed?	6 months
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? Choose an item. Choose an item.	

	4. General Information*	
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:	
	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	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:	**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 organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations 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.