



UPDATED Urgent: Medical Device Recall Notice
Rad-G® Devices (see Attachment 2 for Affected Part and Serial Numbers)

«Letter_Date»

«CUSTOMER»

«Address1»

«Address2»

«Address3»

«CITY» , «STATE» «ZIP»

«COUNTRY»

Attention: Clinical Engineering/Biomedical Department

Customer ID: «ID»

Reason for Recall:

Masimo identified certain Rad-G® devices with power issues, including powering off, power cycle loops, and powering off and on without pressing the power button. If the device powers off, it will impact the device's ability to alarm. Masimo's investigation identified an issue that can result in an unintentional change in the power state.

The Recall Notice applies to the specific Rad-G® devices with the part and Serial number(s) identified in Attachment 2. It updates the original recall notice by including additional devices that are subject to the recall. Even if you have already responded to the recall, please check Attachment 2 to determine if you are in possession of any of the additional devices subject to the recall. Masimo received a total of 865 complaints related to this issue, resulting in an occurrence rate of 3%.

Risk to Health:

If the device powers off unexpectedly, it could result in a loss of monitoring, which could potentially result in a delay in patient care because the device may fail to recognize a change in patient condition. If a change in a patient's condition is not recognized through other monitoring or other means, a deterioration of the patient's condition, including one resulting in a severe adverse outcome or death, could go undetected. Masimo received two reports of patient deaths while being monitored with Rad-G devices. Masimo has not determined whether these devices powered off unexpectedly.

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 Rad-G devices listed in Attachment 2-part number(s) and serial number(s).
- If you identify affected Rad-G® devices, please promptly remove them from use and follow the steps below.
- Contact Masimo Customer Care to request return of the affected part and serial number (s) for replacement.

Masimo's Customer Care is available Monday through Friday 6:00am -5:00pm PST for live assistance or 24 hours a day to leave a message and someone will contact you. Local contact information can be found at <https://www.mymasimo.com/contact-us/>. Complete Attachment 1, then email it to CustomerNotice@masimo.com, or Fax it to 1-949-297-7575 by «Response_Date».

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 online, by regular mail or by fax.

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,

Mathew Jimenez
SVP, Worldwide Quality & Compliance Masimo Corporation

UPDATED Attachment 1

Action to be taken:

1. Please follow the steps below .

Contact Masimo Customer Care to request replacement of the affected part and Serial number (s) and indicate which, if any, of the affected part and Serial number (s) is (are) no longer in service. If you have part numbers or Serial number not included in this communication and have questions about those parts, please contact Masimo Customer Care at customercare@masimo.com. Local contact information can be found at <https://www.mymasimo.com/contact-us/>.

Complete the bottom portion of this *Attachment*, 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 receipt of the Recall notice titled Rad-G® Devices. Select **one**.
 - a. I have contacted Masimo Customer Care and arranged for replacement of the affected part and Serial number (s).
 - b. None of the potentially affected part and Serial number (s) listed in *Attachment 2* is (are) in service at my facility.
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	Signature	Date
Email Address:		

Attachment 2

Part and Serial number (s) shipped to your facility:

Part number: «Part1», Serial number: «Lot1»

Part number: «Part2», Serial number: «Lot2»

Part number: «Part3», Serial number: «Lot3»

Part number: «Part4», Serial number: «Lot4»

Part number: «Part5», Serial number: «Lot5»

Part number: «Part6», Serial number: «Lot6»

Part number: «Part7», Serial number: «Lot7»

Part number: «Part8», Serial number: «Lot8»