



MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Customer ID: «ID»

CUSTOMER NOTICE

Rad-57® with Select Red SpO2 SET Direct-Connect Sensors (see Attachment 2 for Affected Part and SN Numbers)

«Letter_Date»

«CUSTOMER»

«Address1»

«Address2»

«Address3»

«CITY», «STATE» «ZIP»

«COUNTRY»

Attention: Clinical Engineering/Biomedical Department

Customer ID: «ID»

Reason for Customer Notice:

Masimo has decided to initiate Field Action and notify customers of the potential incompatibility of the specific combination of certain Rad-57 used with select SpO2 SET® direct-connect sensors (i.e., P/N 2053, 2054, 2256, 2257, 2643, 2644).

Masimo received complaints that Rad-57 displayed an error/fault message to replace the sensor (“RPL SEN”) or replace the cable (“RPL CBL”) when certain SpO2 SET® sensors are directly connected to the Rad-57. This error/fault message prevents the use of the direct-connect sensors with the Rad-57. Masimo’s investigation identified an incompatibility error which can occur in the connection between the specific SpO2 SET® direct-connect sensors (P/N 2053, 2054, 2256, 2257, 2643, and 2644) and the Rad-57.

Masimo received a total of 45 complaints related to Rad-57 used with select SpO2 SET® direct-connect sensors incompatibility, which resulted in an occurrence rate of 1.02%.

Please refer to **Attachment 2** for a listing of the specific Rad-57 devices shipped to «CUSTOMER» subject to this Customer Notice.

Risk to Health:

This Field Action is not being performed to reduce a risk to health. There have been no reports of injuries or adverse events associated with Rad-57. There is no risk of inaccurate monitoring or interruption of active monitoring, as the devices incompatibility will prevent the monitoring under these conditions. There is no impact on any other Masimo products. Please note that the only customers impacted are those who use SpO2 SET® direct-connect sensors (PN 2053, 2054, 2256, 2257, 2643, 2644) and a potentially impacted Rad-57 device on the serial number list.

No Impact to Other Products:

There is no impact on any other Masimo products.

Actions to be taken by Customer:

- Please assess your specific Rad-57 device and confirm the compatibility of each SpO2 SET® direct-connect sensors (i.e., P/N 2053, 2054, 2256, 2257, 2643, 2644) before putting any of them into service.
- Always pay attention to Rad-57 alerts and alarms displayed and post this customer notice as a constant reminder to confirm compatibility of Rad-57 with SpO2 SET® direct-connect sensors for those using the devices.
- Read through the customer notice and be aware of the potential issues associated with the devices.

If you confirm the incompatibility, a replacement compatible patient cable and sensor combination will be provided. For additional questions or information please contact your local Masimo Technical Services. Masimo’s Technical Services contact information by region can be found in this customer notice.

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 www.fda.gov/medwatch/report.htm , 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,

Rishi Jain VP, Quality Compliance Masimo Corporation



Attachment 1

Action to be taken:

Please follow the steps below .

- 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.
- Read through the notice to be aware of the potential issues.
- If your part numbers and serial numbers are not included in this communication and have questions about those parts, please contact Masimo Technical Services (**Attachment 3**)
- 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»**.
- On behalf of my facility, I acknowledge that I have received, read and understood this customer notice titled **Rad-57® with Select Red SpO2 SET Direct-Connect Sensors (see Attachment 2 for Affected Part and SN Numbers)** and have followed the actions listed in this notification. I am authorized to sign on behalf of my facility.

Select **one**.

- a. ☐ We have confirmed the incompatibility of the Rad-57 and the Spo2 sensor and I will contact Masimo's Technical Services to receive a compatible patient cable and sensor combination.
- b. ☐ We have confirmed that we do not have any of the affected devices serial numbers in service outlined in this letter.

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:		

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program www.fda.gov/medwatch/report.htm , by regular mail or by fax.



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Attachment 2

Part and lot code (s) shipped to your facility (:

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



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52 Discovery
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Customer ID: «ID»

Attachment 3

Technical Service Contact Information

USA	TechService-US@masimo.com
Canada	TechService-CA@masimo.com
APAC/Singapore	TechService-APAC@masimo.com
EMEA	TechService-EMEA@masimo.com
Latin America	TechService-MX@masimo.com
S. Korea	TechService-KR@masimo.com
India	TechService-IN@masimo.com
China	TechService-CN@Masimo.com
Middle East (Saudi Arabia)	TechService-SA@masimo.com
UK	TechService-UK@masimo.com
Italy	TechService-IT@masimo.com
Spain	TechService-ES@masimo.com
France	TechService-FR@masimo.com
Germany	TechService-DE@masimo.com
Switzerland	TechService-CH@masimo.com
Australia/New Zealand	TechService-ANZ@masimo.com