



MASIMO CORPORATION  
52 Discovery  
Irvine, CA 92618

**Urgent: Customer Notice**

January 29, 2024

Bound Tree Medical LLC  
PO Box 8023  
Dublin, OH 43016-2023  
United States

Attention: Quality or Risk Manager

Customer ID: BO0290\$D

Re: Rainbow Adhesive Sensor (R25 L Adult/Neonatal, R25 Adult, R20 Pediatric)

**Reason for Customer Notice:**

Masimo identified specific lots of Rainbow Adhesive Sensors that may provide readings outside of the accuracy specification for SpCO and/or SpMet readings. The extent to which the SpCO reading are inaccurate are unlikely to significantly affect patient care and as a result there are no immediate and/or long-range health consequences. The extent to which the SpMet reading may be inaccurate would most likely be undetectable and therefore, would not affect clinical practice. It is unlikely this issue would result in any adverse health outcome. No complaints alleging adverse events have been received by Masimo.

Please see Attachment 1 for actions to be completed.

**Product Affected:**

The Customer Notice applies to the specific Rainbow Adhesive Sensors with the part and lot number(s) identified in this communication. Please assess your inventory and promptly remove all sensors with part numbers and lot numbers listed below from use and inventory.

Please refer to Attachment 2 for a listing of the Rainbow Adhesive Sensor(s) shipped to Bound Tree Medical LLC subject to this Customer Notice.

**No Impact to Other Products:**

There is no impact to any other Masimo products, including the same part numbers with different lot numbers. If you have any questions regarding this Customer Notice or should you experience this issue, please contact Masimo Technical Services. Local contact information can be found at <http://service.masimo.com>.

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

**Attachment 1**



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**Action to be taken:**

1. Please follow the steps below.

To support this Customer Notice, we are requesting your cooperation by assisting us by either providing us a comprehensive list of the final consignees for the Rainbow Adhesive Sensor shipped to you from Masimo or agreeing to contact all of the consignees and providing them with a customer notice letter, which will be customized for each. You should have distribution records that identify the name, phone number (if available), and address of all end-users.

To ensure a comprehensive notification of all Rainbow Adhesive Sensor users, Masimo is requesting its distributors to complete one of two actions and indicate if you have any affected products(s) in your possession. Once you have completed sections 2 and 3 below fax or email Attachment 1 to Masimo at 1-949-297-7575 or [CustomerNotice@masimo.com](mailto:CustomerNotice@masimo.com).

2. On behalf of my facility, I acknowledge receipt of the Customer Notice titled Rainbow Adhesive Sensor (R25 L Adult/Neonatal, R25 Adult, R20 Pediatric) and have selected the applicable option(s) below.

- a. ☐ We will provide Masimo a list of our customers, contact information, and affected product(s) in the end users' possession. Masimo will contact the end-user.
- b. ☐ We will communicate to the end-users in possession of the affected product(s) and provide Masimo traceability of the communication to the end-user.

Note: should you choose this option, you will need to work with Masimo to generate the Customer Notice letter(s).

Choose one option below

- c. ☐ We have identified the affected sensor(s) at our facility and contacted Masimo Technical Service team to return the affected sensors for replacement.
- d. ☐ We have confirmed we do not have any of the affected sensors at our facility.

Note: For Masimo Technical Services, local contact information can be found at <http://service.masimo.com>.

Sign below, then email this attachment to [CustomerNotice@masimo.com](mailto:CustomerNotice@masimo.com), or fax it to 1-949-297-7575 **by February 29, 2024**.

- 3.

Contact Information & Authorization	Distributor Name	Customer ID
	Bound Tree Medical LLC	BO0290\$D
→		
Printed Name	Signature	Date
Email Address:		



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**Attachment 2**

**Part and lot number(s) shipped to your facility:**

**Part number: N/A, Lot number: N/A**

**Part number: N/A, Lot number: N/A**

**Part number: 2222, Lot number: 22FTD,**