

Urgent: Customer Notice
TC-I Reusable Tip Clip Sensor (see Attachment 2 for Affected Part and Lot Numbers)

June XX, 2023

«SOLD_TO_CUSTOMER»
«SOLD_TO_ADDRESS_1»
«SOLD_TO_ADDRESS_2»
«SOLD_TO_ADDRESS_3»
«SOLD_TO_CITY» , «SOLD_TO_COUNTRY»
«SOLD_TO_COUNTRY»

Attention: Clinical Engineering/Biomedical Department

Customer ID: «SOLD_TO_ID»

Reason for Notice:

Masimo identified TC- I Reusable Tip Clip sensors with higher than expected variability in SpO2 readings that are outside of the accuracy specification. Masimo's investigation found the TC-I sensors had higher variability with an overall Arms of 4.4% compared to the specification of 3.5% Arms.

The Customer Notice applies to the specific TC-I Reusable Tip Clip Sensor 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 TC-I Reusable Tip Clip Sensor(s) shipped to «CUSTOMER» subject to this Customer Notice.

Risk to Health:

Inaccurate readings could potentially result in a delay in care or unnecessary medical intervention. Masimo has not received any complaints alleging adverse events.

No Impact to Other Products:

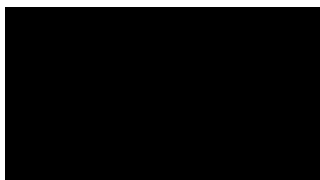
There is no impact to any other Masimo products.

Actions to be taken by Customer:

Contact Masimo Technical Services to request return of the affected part and lot number(s) for replacements and/ or if you have part numbers or lot numbers not included in this communication and have questions about those parts. Masimo's Technical Services 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 <http://service.masimo.com>. Complete Attachment 1, then email it to CustomerNotice@masimo.com, or Fax it to 1-949-297-7575 by July XX, 2023.

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,



SVP, Worldwide Quality & Compliance Masimo Corporation



Attachment 1

Action to be taken:

1. Please follow the steps below .

Contact Masimo Technical Services to request return of the affected part and lot number(s) to Masimo for replacement and indicate which, if any, of the affected part and lot number(s) is (are) no longer in service. If you have part numbers or lot numbers not included in this communication and have questions about those parts, please contact Masimo Technical Services. Local contact information can be found at <http://service.masimo.com>.

Complete the bottom portion of this *Attachment*, then email it to CustomerNotice@masimo.com or Fax it to 1-949-297-7575 **by July XX, 2023.**

2. On behalf of my facility, I acknowledge receipt of the Customer notice titled TC-I Reusable Tip Clip Sensor. Select **one**.

- a. I have contacted Masimo Technical Services and arranged for return of the affected part and lot number(s) to Masimo for replacement.
- b. None of the potentially affected part and lot 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 July XX, 2023.**

Contact Information and Authorization	Customer Name	Customer ID
	«SOLD_TO_NAME»	«SOLD_TO_ID»
→ _____		
Printed Name	Signature	Date
Email Address:		



MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Attachment 2

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

Part number: «Part number_LIST», Lot number: «Lot number_LIST»