



MASIMO CORPORATION
52 Discovery
Irvine, CA 92618

Customer ID: IN0050SI-001

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

1/13/2025

295 Hjälpmedelscentralen
Gustav Adolfs gata 40
SKÖVDE, 541 45
SWEDEN

Attention: Clinical Engineering/Biomedical Department

Customer ID: IN0050SI-001

Reason for this Notification:

We have been advised by Masimo's direct customer that the TC-I Reusable Tip Clip sensor was further distributed through a 2nd Party (Infiniti Medical AB). Infiniti Medical AB has identified your facility as being impacted by this notification.

Reason for Recall:

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 Recall 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 295 Hjälpmedelscentralen subject to this Recall 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 2/13/2025.

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



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 2/13/2025.**

2. On behalf of my facility, I acknowledge receipt of the Recall 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 **2/13/2025.**

Contact Information and Authorization	Customer Name	Customer ID
	295 Hjälpmedelscentralen	IN0050\$1-001
→ _____		
Printed Name	Signature	Date
Email Address:		



Attachment 2

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

Part number: 1794, Lot number: K16ANC,

Part number: 1895, Lot number: 14GFV, 17DCH, 17DCJ, 17DYJ, 17FAL, 17J08, 17JRE, 17KBQ, 17KBR, 17MDD, 17MPD, 17N06, 17N07, 18A26, 18A27, 18B99, 18BAA, 18CCT, 18CWV, 18CYG, 18DCB, 18EEC, 18ENJ, 18FAG, 18G1V, 18GUC, 18H3N, 18HVP, 18J32, 18JPI, 18JVL, 18K47, 18K52, 18M01, 18M02, 18NAE, 19AAA, 19AHL, 19B2G, 19BFC, 19CAC, 19CUX, 19D83, 19DGK, 19DVR, 19EAJ, 19EAK, 19F43, 19GCV, 19GSX, 19GZX, 19JEE, 19JVK, 19K42, 19K4V, 19KAM, 19KQB, 19M09, 19M11, 19M2V, 19NDD, 20A4H, 20ABN, 20BBT, 20BKJ, 20BWP, 20CRU, 20DAK, 20EQM, 20F49, 20G31, 20HFV, 20JLT, 20K2C, 20KGW, 20KQS, 20MJX, 20MST, 20NGB, 20NGD, 20NUT, 21AGX, 21AXQ, 21BJG, 21BVK, 21CMG, 21DFN, 21EXD, 21EYU, 21F6J, 21FUH, 21GFE, 21H2M, 21HCT, 21HUC, 21K4B, 21KGZ, 21MUT, 21MWW, 21NEB, 21NLV, 21NZA, 22ADM, 22BVR, 22CJN, 22CYA, 22DMJ, 22DSG, 22E72, 22E91, 22EGL, 22EQD, 22EZD, 22G68, 22K4P, E20CLS, E20FNT, E20H1G, E21DYY, E21G7M, K16JDS, K16KFD, K16KFE, K16NFF, K16NFG, K17AEV, K17CFJ, K17CFK, K17CFM,

Part number: 2503, Lot number: 18FQZ, 19D84,

82984

Part number: 4053, Lot number: 17A3A, 17AKN, 17CPV, 17DBE, 17E87, 17FAQ, 17GEV, 17J13, 17KBP, 17MDH, 18AEG, 18DCE, 18E04, 18GNZ, 18HKS, 18J35, 18JPH, 18JWM, 18K49, 18KST, 18M03, 19BFG, 19CBA, 19D87, 19EAN, 19F47, 19GCW, 19HDI, 19HTV, 19K3N, 19KAP, 19KPZ, 19M2U, 19MKM, 19NRL, 20ABM, 20C76, 20DAL, 20FUR, 20G2S, 20HFU, 20KMY, 20KUE, 20MNW, 20NGC, 21ASU, 21CBY, 21CTU, 21E09, 21EMQ, 21EYT, 21FUF, 21FUG, 21G2S, 21GAG, 21JDD, 21K09, 21NEW, 22ADL, 22APR, 22BJM, 22C29, 22D18, 22DRN, 22FHY, 22FYS, 22HYW, 22JHE, 22K65, 22NHZ, E20H1H, E21DYW, E21G2N, E21HCQ, E21HMK, E23CVQ, R17BXM,