



Safety Notice

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No. -/-	Target audience Affected users	Date 2024-01-25	Number of pages 3
Affected products TC- I reusable Tip-Clip Ear Sensor	Serial numbers / Lot identification see page 2	Software / Firmware -/-	

Dear sir or madam,

our partner, Masimo, has recalled the products marked Reusable TC-I-Tip-Clip-Sensor.

- 04227.4 - MASIMO® SpO2 Rainbow ear clip sensor Adult >30 kg, 15pol (Masimo Art. No. 2503 M-LNCS TC- I reusable Tip-Clip Ear Sensor, 3ft.)
- 04228.3 - MASIMO® SpO2 ear clip sensor Adult >30 kg, 9pol (Masimo Art. No. 1895 LNCS TC-I, Tip-Clip EAR, Reusable Sensor)

The customer notification has the following content:

Reason for Notice:

Masimo identified TC- I Reusable Tip Clip sensors with variability higher than expected 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 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.

Please check the sensors in stock and in use and contact your local sales and service center. These sensors will be replaced free of charge on return.



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

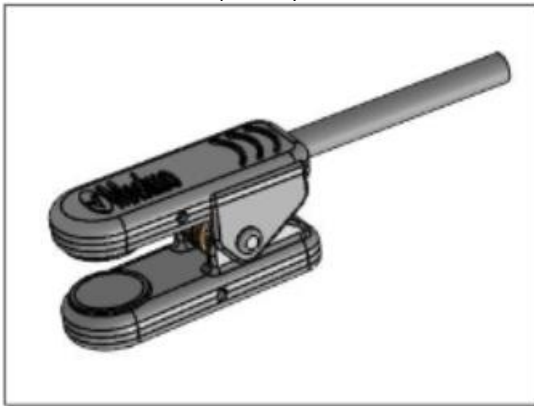
04227.4 - MASIMO® SpO2 Rainbow ear clip sensor Adult >30 kg, 15pol

21FFY, E21DXT

04228.3 - MASIMO® SpO2 ear clip sensor Adult >30 kg, 9pol

N/A

Affected sensor (white)



Improved sensor (black)





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Contact person of the distributor corpuls® (for questions):

Daniel Rampp,
Vice President, Customer Support
Head of Customer Support

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We thank for your understanding and apologize for any inconvenience this may cause. Questions concerning this matter will be answered by your authorised corpuls® sales and service centre.

With kind regards
GS Elektromedizinische Geräte G. Stemple GmbH

Klaus Stemple
Dipl.-Ing., Electrical engineering and Information technology
CEO/CTO
R&D, Product Safety