



FSCA Ref: SAGQI-1023

FSN_with acknowledgment form_TC-I Reusable Tip Clip Sensor_CAPA-SAGQI-1023_EN.docx

Field Safety Notice (FSN)
TC-I Reusable Tip Clip Sensor
manufactured by
Masimo Corporation

distributed by

SCHILLER AG, Altgasse 68 CH-6341 Baar, Switzerland
www.schiller.ch

SRN: CH-MF-000012722 / CHRN: CHRN-MF-20000372

Date: 12.03.2024

Attention: SCHILLER authorized distributors and their customers

A problem related to higher-than-expected variability in SpO2 readings.

This notice is intended to inform you about:

- what the problem is and under what circumstances it can occur.
- the actions that you as a distributor/customer can take to minimize the effect of the problem.
- the actions planned by Masimo to correct the problem.

We kindly ask that you read this notice carefully and send us written acknowledgement by 2024-04-30 that you have read and understood the contents of this notice. Written acknowledgement can be sent to SCHILLER AG via the contact details listed below.

If you need any further information concerning this FSN, please do not hesitate to contact the SCHILLER AG Vigilance Team: vigilance@schiller.ch

For technical support, please contact your local distributor.

SCHILLER AG apologizes for any inconveniences caused by this problem.

Sincerely,

Stefan Bigler
Head of Regulatory Affairs
vigilance@schiller.ch
T: +41 41 766 42 42



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1. INFORMATION ON AFFECTED DEVICES	
COMMERCIAL NAME(S):	Masimo TC-I Reusable Tip Clip Sensor
PRIMARY CLINICAL PURPOSE OF DEVICE(S)*	The TC-I reusable sensor is indicated for either “spotcheck” or continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (measured by an SpO2 sensor) for use with adult and pediatric patients, who are well or poorly perfused in hospitals, hospital- type facilities, mobile, and home environments.
MODEL/CATALOGUE/ REF NUMBER(S):	Masimo Ref / SAG Ref: (1) 1895 / 2.100582 (2) 2503 / 2.100649 (3) 4053 / 2.101166
AFFECTED SERIAL OR LOT NUMBER RANGE:	LOT numbers affected: (1) 17N06, 18B99, 18CWV, 18CYG, 18FAG, 18H3N, 18K47, 19CUX, 19DVR, 19EAJ, 19GSX, 19JVK, 19KQB, 19MII, 19NDD, 20ABN, 20CRU, 20EQM, 20G8F, 20JLT, 20NGD, 21AXQ, 21CMG, 21EFA, 21EYU, 21FUH, 21NLV, 22E72, 22HSC, 22JGE, 22K4N, 23CER, E21G7M (2) 19D84, 19HMB, 20FMM, 21FFY (3) 19F47, 20G2S, 20HFU, 20NGC
UNIQUE DEVICE IDENTIFIER(S) (UDI-DI):	(1) 00843997000048 (2) 00843997003230 (1) 00843997009904
DEVICE TYPE:	Pulse Oximeter
2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)	
BACKGROUND INFORMATION AND PROBLEM DESCRIPTION	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.
HAZARD GIVING RISE TO THE FSCA	Inaccurate readings could potentially result in a delay in care or unnecessary medical intervention. Neither Masimo nor SCHILLER AG have received any complaints alleging adverse events
PREDICTED RISK TO PATIENT/USERS	There are no health consequences (injuries or illnesses) (both immediate and long-term) that would be expected to result from Use of or Exposure to the affected devices (including known off label uses).



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3. TYPE OF ACTION TO MITIGATE THE RISK	
ACTION TO BE TAKEN BY THE DISTRIBUTOR / IMPORTER	<ol style="list-style-type: none"> 1) Send this FSN to all identified USERS. 2) Send the signed ANNEX Ia – Initial Distributor / Importer Reply Form including a list of all USER(s) back to SCHILLER AG by 30. April 2024 as confirmation that the content of this notice was read and understood and that this Field Safety Notice was distributed to all USER(s). 3) Contact the USER(s) to arrange the replacement of the USER's device(s). 4) Send the replacement device(s) to the USER(s). 5) Send the USER's device(s) to SCHILLER AG 6) Send the signed ANNEX Ib – Final Distributor/Importer Reply Form back to SCHILLER AG by 26. June 2024 as confirmation that all defined actions for IMPORTER / DISTRIBUTOR have been completed.
ACTION TO BE TAKEN BY THE USER	<ol style="list-style-type: none"> 1) Wait until your local distributor contacts you to arrange the replacement of your device(s). 2) Send your device(s) to your local distributor after having received the replacement device(s). 3) Send ANNEX II – Customer Reply Form back to your authorized distributor as confirmation that your affected device(s) have been replaced.
DATE FOR COMPLETION:	26. June 2024
IS THE FSN REQUIRED TO BE COMMUNICATED TO THE PATIENT / LAY USER?	No
LIST OF ATTACHMENTS	ANNEX Ia – Initial Distributor / Importer Reply Form ANNEX Ib - Final Distributor / Importer Reply Form ANNEX II - Customer Reply Form
TECHNICAL SUPPORT	For technical support, please contact your local distributor.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organisations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. *

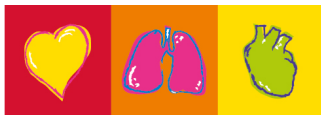
Contact person of manufacturer:

Stefan Bigler

Head of Regulatory Affairs

vigilance@schiller.ch

T: +41 41 766 42 42



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FSN_with acknowledgment form_TC-I Reusable Tip Clip Sensor_CAPA-SAGQI-1023_EN.docx

ANNEX Ia – Initial Distributor / Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-1023
FSN Date*	01.30.2024
Product/ Device name*	TC-I Reusable Tip Clip Sensor

2. Manufacturer Details	
Company Name	SCHILLER AG
SRN	CH-MF-000012722
CHRN	CHRN-MF-20000372
Address	Altgasse 68 6341 Baar, Switzerland
Contact Name	Stefan Bigler
Email	vigilance@schiller.ch
Telephone Number	+41 41 766 42 42

3. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

4. Distributors/Importers (Tick all that apply)		
<input type="checkbox"/>	*I confirm the receipt of this Field Safety Notice and that I read and understood its content.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	I checked my stock and quarantined inventory.	Distributor/Importer to enter quantity or enter N/A
<input type="checkbox"/>	* I have identified all customers that received or may have received this device and informed all customers about this FSN.	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	*I attached the completed device list	Distributor/Importer to complete or enter N/A
<input type="checkbox"/>	Neither I nor any of my customers have any affected devices in inventory. (In this case ANNEX Ib must not be completed)	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign here
Date *		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



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ANNEX Ib – Final Distributor / Importer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-1023
FSN Date*	01.30.2024
Product/ Device name*	TC-I Reusable Tip Clip Sensor

5. Manufacturer Details	
Company Name	SCHILLER AG
SRN	CH-MF-000012722
CHRN	CHRN-MF-20000372
Address	Altgasse 68 6341 Baar, Switzerland
Contact Name	Stefan Bigler
Email	vigilance@schiller.ch
Telephone Number	+41 41 766 42 42

2. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Distributors/Importers (Tick all that apply)	
<input type="checkbox"/> *I have carried out all the actions for DISTRIBUTOR / IMPORTER as requested by this FSN.	Note Qty., Lot/Serial Number(s), Date of completion
<input type="checkbox"/> *I have received the completed reply form from all identified customers.	
<input type="checkbox"/> I returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number, Date Returned
<input type="checkbox"/> I destroyed affected devices.	Add quantity, Lot/Serial Number, Date destroyed
Print Name *	Distributor/Importer print name here
Signature *	Distributor/Importer sign Here
Date *	

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

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ANNEX II - Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SAGQI-1023
FSN Date*	01.30.2024
Product/ Device name*	TC-I Reusable Tip Clip Sensor

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation	
<input type="checkbox"/> *I confirm the receipt of this Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
<input type="checkbox"/> *I have identified all affected devices	Note quantity, Lot/Serial Number(s)
<input type="checkbox"/> *The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
<input type="checkbox"/> *I have carried out the actions for USER as requested by this FSN.	Note Qty., Lot/Serial Number(s), Date of completion
<input type="checkbox"/> I have returned affected device(s)	Note Qty., Lot/Serial Number(s), Date of return of all returned devices.
<input type="checkbox"/> I have destroyed affected device(s)	Note Qty., Lot/Serial Number(s), Date of destruction of all destroyed devices.
<input type="checkbox"/> I sold my device(s)	Note device serial number(s) and contact details of the new owner.
<input type="checkbox"/> I do not have any affected devices.	Customer to complete or enter N/A
Print Name*	Customer print name here
Signature*	Customer sign here
Date*	

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.