

URGENT PRODUCT CORRECTION NOTICE

July 16, 2024

Dear Valued McKesson Customer:

Masimo Corporation has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Customer Notice regarding specific lots of their LNCS Disposable Sensors. This notice has been issued because Masimo identified certain part numbers and lots manufactured between March 2024 through the end of May 2024 not being compatible with older versions of Masimo technology boards used in both Masimo monitors and OEM monitors. The affected sensors cannot be authenticated by certain older versions of Masimo technology board preventing their use, whereas use on newer versions of Masimo technology boards is not impacted. Affected product first shipped March 1, 2024.

McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For clinical inquiries, please contact Masimo's Technical Services at TechSupport-US@masimo.com.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS#	MFG: Calalog#	Description	Affected Lot(s)
533883	1859 🗙	SENSOR, ADHSV ADLT (20/BX)	24DT6; 24DV5; 24DV6; 24EP9
795614	2318	SENSOR, SPO2 PED ADH (20/BX)	24DT5
772506	2329	SENSOR, OXIMETER NEO/ADLT (20/BX)	24DR5; 24DU4; 24DU7; 24CP2; 24EM5; 24CM1

McKesson Customer Instructions:

- Immediately discontinue use of any product matching the affected items and lot numbers listed in the item 1.) table. If you have no products matching the affected items and lot numbers, no further action is needed.
- A copy of the Urgent Customer Notice from Masimo has been included for reference. 2.)
- 3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at (866) 871-0270. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
 - Please note: Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected product lot numbers are listed in the item table. Once the product is returned, credit will be issued to you.
 - Please place a new order for replacement product if there is an immediate need.
- If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a 4.) copy of this notification and request that they return the affected product directly to you.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our McKesson Medical-Surgical Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

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July 16, 2024

McKesson Medical-Surgical Inc.

Product Correction Reply Form: RC-2024-154

Masimo LNCS Disposable Sensors

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at (866) 871-0270 should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account: 20037573 District: 22510000 CARELINC MEDICAL EQUIP & SUPP

ATTN: RISK MANAGEMENT 89 54TH ST SW STE 1 GRAND RAPIDS, MI 49548-5503

☐ I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return.

Ohy	Unit of Measure	MMS#	MFG Catalog#	Description
		533883	1859	SENSOR, ADHSV ADLT (20/BX)
		795614	2318	SENSOR, SPO2 PED ADH (20/BX)
		772506	2329	SENSOR, OXIMETER NEO/ADLT (20/BX)

^{*}Return Affected lot numbers only

* Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected lot numbers are listed on the McKesson customer letter.

If you are on a McKesson truck route, a delivery professional will pick up the affected products, otherwise you will receive UPS return label(s) via email or fax.

☐ I am on a McKesson truck route, please schedule a delivery professional pick up.	
Please send my UPS/Return label by Fax or Email. Number of UPS Parcels to be returned:	

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

See instructions on the reverse side of this form to access McKesson Medical-Surgical's online product ordering system, "SupplyManager", for a fillable form.

Instructions for the McKesson Medical-Surgical online product ordering system – "SupplyManager", to access and download a "fillable" PDF reply form.

- 1) It is important to download the correct reply form for the specific recall you are responding to.
 - a. Reply forms have a specific designation, example: RC-202X-XXX.
 - "202X" is the recall year, and "XXX" is the 3-digit unique numeric identifier for the recall.
- 2) Go to https://mms.mckesson.com/ and log in to "SupplyManager", with your username and password.
- 3) On the home page, under 'Essential Tasks' click 'Your Account.' Under 'Resources' a support link titled "Product Recalls" can be found on the right side.
- 4) Click on the hyperlink "Product Recalls" (this will open a listing of recalls for the last 3 months).



- 5) On the recalls list page, locate the "Find" box.
 - a. From the drop-down options, select one of the following: "Keyword", "McKesson Item #" or "Manufacturer".
 - b. Enter a Keyword, McKesson Item #, or Manufacturer name in the Find box and click "Find".



- c. A list of issued recalls will be made visible for you to select from.
- 6) Click on the blue hyperlink, found under the heading "Recall Notice," for the notice details you want to access.

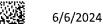
Manufacturer Recall Notice Issued

- 7) The PDF customer documents associated with the notice will be displayed, this includes the reply form to download and complete for your response.
- 8) Click on the hyperlink(s) to open the Customer Document(s). Save/Download this document to your computer. Once the documents are saved, close out the document window.
- 9) Submit completed reply form to MMSRecalls@McKesson.com.
- 10) If you wish to view additional recalls, return to the home recall page by clicking the blue "View All Recalls" button at the upper right corner of the page above the blue alert banner.

Customer ID: MC0080\$D

Urgent: Customer Notice

LNCS Disposable Sensors (see Attachment 2 for Affected Part and Lot Numbers)



McKesson Medical-Surgical PO Box 4059 Danville, IL 61834-4059 United States

Attention: Clinical Engineering/Biomedical Department

Customer ID: MC0080\$D

Reason for Customer Notice:

Masimo identified certain part numbers and lots of LNCS Disposable Sensors manufactured between March 2024 through the end of May 2024 not being compatible with older versions of Masimo technology boards used in both Masimo monitors and OEM monitors. The affected sensors cannot be authenticated by certain older versions of Masimo technology boards preventing their use, whereas use on newer versions of Masimo technology boards is not impacted.

The Urgent Customer Notice applies to the specific LNCS Disposable Sensor part numbers and lot number(s) identified in this communication.

Please refer to Attachment 2 for a listing of the LNCS Disposable Sensors shipped to McKesson Medical-Surgical subject to this Customer Notice.

Risk to Health:

There are no health consequences associated with this issue. The issue may render impacted sensors unusable when connected to older versions of Masimo technology boards.

The issue has been addressed and currently manufactured sensors are not impacted. If the impacted LNCS Disposable Sensors are connected to newer versions of Masimo technology boards and provide SpO2 and pulse rate values, they can be used as labeled. If the impacted LNCS disposable sensors are connected to older versions of Masimo technology boards and do not provide readings or result in an error message such as "Replace Sensor", please place the sensor(s) aside and follow the steps defined in the "Actions to be taken by Customer" section of this notice.

No impact to Other Products:

There is no impact on any other Masimo products.

Actions to be taken by Customer:

- Please assess your inventory to identify if you have impacted LNCS disposable sensors which are not able to provide SpO2 and pulse rate values listed in Attachment 2-part number(s) and lot number(s), then
- Contact Masimo Technical Services to request return of the affected part and lot number (s) for replacement.

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. US customers may use TechSupport-US@masimo.com to request return authorization (RMA) and replacements.

Complete Attachment 1, then email it to CustomerNotice@masimo.com, or Fax it to 1-949-297-7575 by 7/6/2024.

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