



Customer Advisory Notice

PRODUCT: Nova StatStrip® Lactate Hospital Meter

Customer Advisory Notice: 01-26SS

DATE: July 2026

IMPORTANT CUSTOMER ADVISORY / FIELD CORRECTION NOTICE

Nova StatStrip® Lactate Strip Performance

Dear Nova StatStrip® customer,

As part of Nova Biomedical's ongoing commitment to product quality and customer support, we are issuing this Customer Advisory / Field Correction Notice to inform you of specific StatStrip Lactate Test Strips that have been identified as not meeting established performance expectations.

Issue Description:

During routine quality monitoring, Nova Biomedical identified that the StatStrip Lactate Test Strip lots listed below may produce QC and/or linearity results outside the established acceptance criteria. This notice applies only to the identified StatStrip Lactate Test Strip lots and does not indicate a problem with the performance of the StatStrip meter itself. Based on Nova Biomedical's investigation to date, the issue has been observed during QC and linearity testing of the affected strip lots. The StatStrip Lactate system incorporates built-in quality control mechanisms designed to detect abnormal system performance before patient test results are relied upon. Users should continue to follow all QC and linearity procedures described in the Instructions for Use (IFU) Manual.

Affected Strip Lots:

Part Number	Affected Lot Number(s)
47486	2626054249 & 2626055249
61440	2626055249

Nova Biomedical, 200 Prospect Street, Waltham, MA 02454

This information is intended for use by Nova Biomedical customers and may contain information that is privileged and confidential. If you are not the intended recipient, you are hereby notified that unauthorized dissemination of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately at (800)545-6682.

Potential Clinical Impact

Nova Biomedical's investigation determined that the affected strip lots may produce QC and/or linearity results that fall outside established acceptance criteria. The issue is expected to be detected through routine QC and linearity verification procedures performed in accordance with the IFU. If QC or linearity results are outside acceptable limits, users should follow their established troubleshooting procedures and should not use the affected strip lot for patient testing until QC requirements are met.

Testing performed during Nova Biomedical's investigation demonstrated acceptable accuracy and precision for blood sample testing, and Nova Biomedical has received no reports of patient injury, death, or adverse health consequences associated with this issue. Nova Biomedical has not identified evidence of patient harm associated with the affected strip lots.

Meter Functionality:

Nova Biomedical's investigation indicates that this issue is limited to the affected QC strip lots identified in this notice. It does not indicate a problem with the Nova StatStrip meter. Customers may continue to use Nova Biomedical meter(s) and non-affected lactate strip lots in accordance with the applicable Instructions for Use and established facility procedures.

Replacement and Acknowledgement:

Nova Biomedical is coordinating replacement of affected StatStrip Lactate Test Strip inventory. Please follow the actions outlined below to document the quantity of affected product in your possession, discontinue use of affected lots, and return the acknowledgement form so replacement product can be provided efficiently.

Customer Actions Requested:

Upon receipt of this notice, please take the following action:

1. Identify and segregate any inventory and discontinue use of affected lactate test strip lots listed above.
2. Complete and return the acknowledgement form to Novameters@novabio.com (customers in North America), EU-QA@novabio.com (customers in Europe or affiliated nations in the European Union (Iceland, Nordics, etc)), or intlservice@novabio.com (all other international customers) so Nova Biomedical can confirm receipt of this notice and support replacement coordination.
3. Record the quantity of affected inventory on hand and the quantity discarded.

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4. Dispose any inventory of the affected lactate test strip lots in accordance with your facility's standard disposal procedures. If any affected product has been transferred to another department, laboratory, or facility, provide them with a copy of this notice and notify Nova Biomedical.
5. Continue to use unaffected strip lots in accordance with the Instructions for Use and established quality control procedures.

Frequently Asked Questions

What should I do if I previously used one of the affected strip lots?

If acceptable QC requirements were met prior to testing, no additional action is recommended at this time. Customers who have experienced QC or linearity failures should continue to follow their facility's established investigation procedures and the Instructions for Use.

Are patient results affected?

Nova Biomedical's investigation has identified the issue during QC and linearity testing of the affected strip lots. Testing performed during the investigation demonstrated acceptable accuracy and precision for blood sample testing, and Nova Biomedical has not identified evidence of patient harm associated with this issue.

Is the StatStrip Lactate Meter affected?

No. Nova Biomedical's investigation indicates that the issue is limited to the affected strip lots identified in this notice and does not indicate a malfunction of the StatStrip Lactate Meter.

If you have questions regarding this notice, please contact Nova Biomedical Technical Support at 1 (800) 545-6682 (USA) or at (800) 263-5999 (Canada). For customers outside of the USA or Canada, please contact your authorized Nova Biomedical distributor. Nova Biomedical appreciates your prompt attention to this advisory and your continued partnership. We apologize for any inconvenience and are available to support you through the replacement process.

CUSTOMER ACKNOWLEDGEMENT FORM

Nova StatStrip® Lactate Strip Customer Advisory / Field Correction Notice

Response is Required

Customer / Facility Name:	
Customer Account Number, if applicable:	
Address:	
Contact Name / Title:	
Phone / Email:	

Inventory Review and Replacement Information

Part Number	Affected Lot Number	Quantity on Hand	Quantity Discarded	Comments
47486	2626054249			
47486	2626055249			
61440	2626055249			
Have any complaints been reported for the affected product?				NO
Have any adverse events been associated with the affected product?				NO

If yes, please explain:

Questions:

☐ Please have Customer Service contact me (if applicable).

Please return the completed form to:

Nova Biomedical

(Customers in North America) Novameters@novabio.com

(Customers in Europe or affiliated nations in the European Union (Iceland, Nordics, etc))

EU-QA@novabio.com

(All other International Customers) intlservice@novabio.com

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