



Customer Advisory Notice

PRODUCT: Nova StatStrip® (Gen 2) Glucose and Glucose/β-Ketone Hospital Meter Systems

Customer Advisory Notice: 02-26NG-INTL

DATE: July 2026

URGENT FIELD SAFETY NOTICE

**Nova StatStrip® (Gen 2) Glucose and Glucose/β-Ketone
Hospital Meter Systems**

Patient ID Scanning Issue Notification

Dear Nova StatStrip® customer,

As part of Nova Biomedical's ongoing commitment to product quality and customer support, Nova Biomedical is issuing this urgent field safety notice due to a high-priority software-related operational issue for the StatStrip (Gen 2) Glucose and Glucose/β-Ketone Hospital Meter Systems that may affect patient identification workflow management. This issue affects StatStrip (Gen 2) Glucose and Glucose/β-Ketone Hospital Meter Systems operating on all versions of firmware and does not impact the analytical performance of glucose measurements.

To date, Nova has received several reports from customers indicating that when scanning patient ID barcodes, prior patient information may remain on the meter screen, which if accepted, may lead to a patient result being assigned to the incorrect patient. While the observed occurrence rate is low relative to the number of devices in the field, the potential for patient misidentification is considered a serious safety concern, and Nova is taking appropriate corrective actions.

There have been no reports of serious adverse events because of this issue.

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.

Affected Devices

Nova Part Number	Product Description
63683	Kit Meter Connectivity StatStrip 2.0 Glu/Ket
63685	Kit Meter Connectivity Glu 2.0
63726	Kit Meter Japan StatStrip 2.0 Glu/Ket
63910	Kit Meter StatStrip 186 Glu/Ket MOL-L 2.0
66429	Kit Meter Next Gen 2.0 Hospital Glu/Ket Rilibäk
66739	Meter Kit Packaging, Multipack

Customer Actions

Until a permanent resolution can be provided for this issue, Nova is providing the following recommendations to end users:

- Verify the patient information displayed on the meter exactly matches the scanned patient identification after **every** patient barcode scan and before accepting the patient's record or result.
- If the displayed patient information does not match the scanned patient identification, discontinue testing with the meter, and notify your administrator.
- Complete and return the acknowledgement form to the appropriate e-mail address provided below so Nova Biomedical can confirm receipt of this notice.
 - 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

Corrective Actions to be Taken by Nova Biomedical

Nova is actively working on a planned firmware update to address this issue. As a precautionary measure, Nova has implemented a shipment hold on all StatStrip (Gen 2) Glucose and Glucose/β-Ketone Hospital Meter Systems while corrective actions are being developed and validated.

We are allocating and dedicating significant resources to extended and extensive internal testing to ensure this issue is reliably addressed. Efforts are underway for the development and validation of the firmware update to address this issue, and Nova will communicate availability as soon as validation activities are completed.

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Nova is prioritizing the review and investigation of this issue to take appropriate action, including regulatory notifications as warranted.

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.

Thank you for your continued partnership.

Sincerely,



Julie MacKenzie
VP, Clinical Business
Nova Biomedical



Autumn Collasius
SVP, Quality & Regulatory
Nova Biomedical

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CUSTOMER ACKNOWLEDGMENT FORM

Nova StatStrip® (Gen 2) Glucose and Glucose/β-Ketone Hospital Meter System Urgent Field Safety Notice 02-26NG-INTL

Response is Required

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

Acknowledgment of Receipt and Required Actions	
☐	I acknowledge that our facility has received and reviewed Customer Advisory Notice 02-26NG.
☐	I confirm that applicable personnel have been informed of the need to verify the patient information displayed on the meter after every patient barcode scan and before accepting the patient record or result.
☐	I confirm that users have been instructed to discontinue testing with the meter and notify the appropriate administrator if the displayed patient information does not match the scanned patient identification.
☐	I confirm that this notice has been distributed to all applicable departments, locations, and users within our facility, as appropriate.

Product Information	
Affected Product	Nova StatStrip® (Gen 2) Glucose & Glucose/Ketone Hospital Meter
Have any complaints been reported for the affected product?	Yes / No
Have any adverse events been associated with the affected product?	Yes / No

If yes, please explain:

Return Instructions: Please return the completed acknowledgment form to:

- Customers in North America: Novameters@novabio.com
- Customers in Europe or affiliated nations or the European Union (Iceland, Nordics, etc.):
EU-QA@novabio.com
- All other International Customers: Intlservice@novabio.com

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