

UPDATE to
URGENT FIELD CORRECTION NOTICE

FCN 01-24, Revision B

DATE: December 12, 2024

PRODUCT: StatStrip Glucose and Glucose/Ketone Hospital Meter Systems

Models Affected by Part Number (PN):

PN 63683 StatStrip Glucose/Ketone Hospital Meter (CE)
PN 63685 StatStrip Glucose Hospital Meter (K232075)
PN 63910 StatStrip Glucose/Ketone (mmol/L) Hospital Meter (CE)

SUBJECT:

This letter is an update to Nova Biomedical Corporation's November 19, 2024, Field Correction Notice to provide additional details on the affected meters and to address verification and remediation of historical test results. Nova Biomedical Corporation has recently become aware of a potential risk of transmitting incorrect glucose patient test results to a healthcare system's data management system (DMS).

Nova Biomedical received two (2) complaints from U.S. based customers in which incorrect glucose patient test results were transmitted erroneously to the site's DMS. The complainant confirmed that 53 incorrect results were transmitted over a 24-day period and estimated that approximately 100 patient records may have been impacted by this issue. Based upon the information reported to Nova, there were no adverse events reported due to delay of therapy or incorrect therapy.

SOFTWARE VERSION AFFECTED:

The software versions listed below are impacted:

- All versions from v0.0.13.10 to v0.0.13.44 inclusive.

IDENTIFIED ISSUE:

The potential risk of transmitting incorrect glucose patient test results to a healthcare system's DMS.

This issue may impact healthcare sites using a WiFi connection to transmit glucose test results to a DMS. The issue occurs when an operator navigates to the "Review Results" screen, to review previous historical glucose test results, while the meter is still in the process of transmitting the current glucose test result to the DMS, typically a 1-5 second delay after completion of a test. Please note, this issue may affect the historical glucose test results within your DMS prior to your meters being updated to v.0.0.13.45 software. The ability to verify and remediate historical glucose test results is DMS-dependent and likely not possible.

Ketone results would also be impacted by this software defect, however, Nova Biomedical Corporation confirmed that no Glucose/Ketone meters had been operational at the time this issue was identified and the corrective software subsequently released (see Manufacturer Correction below). Therefore, this issue does not impact historical ketone test results in your DMS.

POTENTIAL RISK:

Incorrect glucose patient results may lead to a delay of patient therapy or possible incorrect therapy.

MANUFACTURER CORRECTION:

The potential software risk described in this notification has been corrected and validated through the release of a new software version (v0.0.13.45 and above) for the StatStrip Glucose and Glucose/Ketone Hospital Meter Systems. The new software release eliminates the potential risk of transmitting incorrect glucose and/or ketone patient test results to a healthcare system's DMS.

Nova Biomedical or your authorized Nova Biomedical representative will schedule a no charge update of your StatStrip Glucose Hospital Meter System software to V0.0.13.45 or above. A representative will contact you shortly to schedule this update.

WHAT TO DO UNTIL I RECEIVE MY SOFTWARE UPDATE:

All current Nova StatStrip customers that have gone "Live" with their new meters recently received a meter software update (v.0.0.13.45 or above) from Nova Biomedical to eliminate the potential risk described above.

All remaining customers that have been shipped StatStrip meters impacted by this field correction, will have their meter software updated by Nova Biomedical or your local dealer prior to going "Live" with your new meters. You do not have to take any action at this time, a Nova Biomedical representative or your local distributor will perform the update and document completion of the update during the implementation process.

INTERNAL HEALTHCARE FACILITY COMMUNICATION:

This Field Correction Notice should be distributed to all those within your organization who need to be aware of this issue. Please notify other parties affiliated with your organization, which are affected by this notice. Please maintain awareness of this notice until the issue has been corrected with a scheduled software update.

If your organization or healthcare facility has distributed or transferred your StatStrip meters to another facility, you are instructed to forward this Urgent Field Correction Notice to the additional facility and to contact Nova Biomedical Technical Support at 1-800-545-6682, or outside of N. America contact your authorized Nova Biomedical subsidiary or distributor to ensure that Nova properly updates the firmware on the meters that have been distributed or transferred as part of this field correction.

If your organization or healthcare facility is aware of a similar incorrect data transfer occurrence within your facility, in the U.S. contact Nova Biomedical Technical Support at 1-800-545-6682, or outside of N. America contact your authorized Nova Biomedical subsidiary or distributor to ensure the incident is properly reported to the appropriate regulatory authority(s). Alternatively, within the U.S., you may report the incident directly to the U.S. Food and Drug Administration through the FDA's MedWatch online portal by clicking on the following link: [MedWatch Voluntary Report](#).

QUESTIONS:

If you have any questions on the contents of this notice, would like to discuss other risk mitigation options, or require assistance with implementing any of the recommended actions above, in the U.S. contact Nova Biomedical Technical Support at 1-800-545-6682, or outside of N. America contact your authorized Nova Biomedical subsidiary or distributor.

We apologize for this inconvenience and thank you for your support of Nova StatStrip Hospital Meter System products.

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