



Field Correction Notice

URGENT FIELD CORRECTION NOTICE

FCN 01-24

DATE: November 19, 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:

Nova Biomedical Corporation has recently become aware of a potential risk of transmitting erroneous glucose patient test results to a healthcare system's data management system.

Nova Biomedical received two (2) complaints from U.S. based customers in which erroneous glucose patient test results were transmitted erroneously to the site's data management system. 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 versions listed below are impacted:

- v0.0.13.41
- v0.0.13.42
- v0.0.13.43
- v0.0.13.44

IDENTIFIED ISSUE:

The potential risk of transmitting erroneous glucose patient test results to a healthcare system's data management system.

POTENTIAL RISK:

Erroneous 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 erroneous glucose patient test results to a healthcare system's data management system.

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 received this communication in error, please notify us immediately at (800) 545-6682.

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 erroneous 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.

Nova Biomedical Corporation
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USA