

URGENT MEDICAL DEVICE CORRECTION: NOVA STATSTRIP GEN 2 GLUCOSE HOSPITAL METER SYSTEMS

Applicable to: All locations using Nova StatStrip (Gen 2) Glucose Hospital Meter Systems

SUMMARY

Nova Biomedical has initiated an urgent **medical device recall** due to a high-priority software-related operational issue affecting StatStrip (Gen 2) Glucose Hospital Meter Systems.

To date, Nova has received 24 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 an accurate glucose result being assigned to the incorrect patient. Note, this issue does not impact the accuracy of the glucose result, but rather patient identification.

This issue has not been reported at OSUWMC, however, it is important that testing personnel are aware of this potential issue.

ACTION NEEDED

Until a permanent software correction is available:

- After every patient barcode scan, verify that the patient information displayed on the meter **exactly matches the scanned patient identification before accepting the patient result.**
- If the displayed patient information does not match the scanned patient identification:
 - **Do not accept** or transmit the result.
 - **Stop** using that meter.
 - **Contact** Point-of-Care Testing immediately.
- Continue to follow all standard patient identification and point-of-care testing procedures.

Please share this information with all applicable staff and providers who use Nova StatStrip glucose meter testing.

FOR QUESTIONS OR CONCERNS:

The POC Team is here to support you during the transition.

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