



Customer Information Bulletin

PRODUCT: Nova StatStrip Glucose Hospital and Xpress 2 Hospital Meter

CIB NO: 06-24SS

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Nova StatStrip Glucose Hospital Meter System Sani Wipe Approval for Cleaning and Disinfection

Dear Nova StatStrip Glucose Hospital Meter customer,

Nova Biomedical has updated the cleaning and disinfection recommendations for the StatStrip Glucose Hospital meters. Please disseminate the contents of this bulletin to your staff as needed. This bulletin should be used as a supplement to the information contained within the Instructions for Use manual, as appropriate. Updated Instructions for Use manuals will be made available as quickly as possible.

Cleaning and Disinfecting the Meter

For Technical Support in the USA dial (800)-545-6682. Outside the USA, contact your local Nova dealer.

The StatStrip Glucose Hospital Meter should be cleaned and disinfected after each patient use to minimize the risk of transmission of blood-borne pathogens between patients and healthcare professionals.

Healthcare professionals and others should follow Good Laboratory Practice guidelines and these important safety instructions.

Healthcare professionals should ensure they are wearing protective gloves when disinfecting the meter and should sanitize their hands following approved guidelines after handling the meter.

Acceptable Cleaning and Disinfecting Materials

Nova Biomedical recommends the use of Clorox Healthcare® Bleach Germicidal Wipes, EPA Registration #67619-12, or any disinfectant product with EPA Registration #67619-12, and Super Sani Disposable Wipes (Sani Wipes) EPA Registration #9480-4.

The disinfectants were validated separately; therefore, only one disinfectant should be used on the device as the effect of using more than one disinfectant interchangeably has not been evaluated.

The StatStrip Glucose Hospital Meter cleaning and disinfection procedure was validated a total of 10,950 times to simulate a 3-year use life of 10 patient tests per day 365 days per year.

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.

Meter Cleaning and Disinfection Procedure

Clean and disinfect after each patient use following this protocol to help ensure effective cleaning and disinfection. Cleaning is not the same as disinfecting. Disinfecting means to kill or prevent the growth of disease carrying microorganisms.

Prepare

Make sure the test strip is removed from the meter. Lay the meter on a flat surface prior to cleaning and disinfecting the meter.

WARNING: To ensure proper disinfection, it is important to clean the meter (Step 1) prior to disinfecting the meter (Step 2).

1. Clean the Meter.

- Remove a fresh germicidal wipe from the canister.
- Wipe the external surface of the meter thoroughly with a fresh germicidal disinfecting wipe. Discard the used wipe into an approved waste container.

2. Disinfect the Meter.

- Using a new, fresh germicidal wipe, thoroughly wipe the surface of the meter (top, bottom, left, and right sides) for example, a minimum of 3 times horizontally and 3 times vertically, avoiding the bar code scanner and electrical connector.
- Gently wipe the surface area of the test strip port making sure that no fluid enters the port.



3. Observe surface contact time.

Ensure the meter surface stays wet for 1 minute (Clorox Wipes) or for 2 minutes (Super Sani Wipes) then allow to air dry for an additional 1 minute.

4. Dispose of wipe and gloves.

- Dispose of used wipe and gloves in an approved waste container.

5. Sanitize hands.

- Sanitize your hands thoroughly following approved guidelines and put on a fresh set of protective gloves before proceeding to perform testing on the next patient.

Additional Information

WARNING: Do not allow liquid to enter the strip port connector or allow pooling of liquid on the touch screen. If liquid does get into the strip port or connector, immediately dry the components with a dry cloth or gauze.

WARNING: Do not spray the meter directly with solutions as this could cause the solution to enter the case and damage the electronic components.

WARNING: Do not immerse the meter or hold the meter under running water.

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WARNING: *Cleaning and disinfection may in rare cases damage the meter. Damage may include plastic housing cracks, cloudiness or frosting of the display, response issues with the display, battery compartment fluid leakage, or test port damage. Signs of meter performance deterioration may include failure to recover proper control solution results or the inability to perform a blood glucose test. If you observe damage due to cleaning and disinfection, stop using the meter and contact Nova Technical Support at 800-545-6682.*

If you have any questions on the contents of this bulletin, in the United States please contact Nova Biomedical Technical Support at 800-545-6682, in Canada contact Nova Biomedical Technical Support at 800-263-5999, outside of Canada contact your local Nova Biomedical distributor.

Thank you for your continued support of Nova products.

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