Nova StatStrip Xpress® 2 Glucose Hospital Meter System Quick Reference Guide

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Refer to the StatStrip Xpress 2 Glucose Hospital Meter System Instructions for Use Manual and Package Inserts for complete instructions for use, indications, precautions, and limitations of the system.

Unit of Measure Disclaimer

The StatStrip Xpress 2 Glucose Hospital Meter System is factory set to report glucose results in mg/dL or mmol/L and can not be changed. Separate Result screens are shown in the Quick Reference Guide for each unit of measure.

Intended Use

The StatStrip Xpress 2 Glucose Hospital Meter System is intended for point-of-care, in vitro diagnostic, multiple-patient use for the quantitative determination of glucose in capillary finger stick, venous whole blood, arterial whole blood, neonate arterial whole blood, and neonate heel stick specimens throughout

all hospital and all professional healthcare settings, including patients receiving intensive medical intervention/therapy.
The system should only be used with single-use, auto-disabling lancing devices when performing a capillary finger stick or neonate heel stick.
It is not intended for use with neonate cord blood specimens.
It is not intended for the screening or diagnosis of diabetes mellitus but is indicated for use in determining dysglycemia.

CLIA Waived

CLIA Complexity: This StatStrip Xpress 2 Glucose Hospital Meter System is WAIVED under the Clinical Laboratory Improvements Amendments of 1988 (CLIA) and all applicable state and local laws must be met. Facilities performing this test must have a Certificate of Waiver and must follow the manufacturer's instructions for performing the test. If a laboratory modifies the test instructions, the test will no longer be considered waived.

Capillary Precautions

- Caution should be exercised when testing capillary whole blood due to potential pre-analytical variability in capillary specimen collection.
- A capillary whole blood specimen relies upon an adequate, non-compromised capillary blood flow. The healthcare provider must be aware that a capillary whole blood specimen glucose result may not always be the same as an arterial or a venous whole blood glucose result, especially when the patient's condition is rapidly changing.
- If a capillary whole blood glucose result is not consistent with a patient's clinical signs and symptoms, glucose testing should be repeated with either an arterial or venous specimen on the StatStrip Xpress 2 Glucose Hospital Meter System.
- When performing a capillary heel stick glucose test on a neonate, caution should be exercised to ensure adequate

blood flow to the heel. Healthcare facilities should consider unswaddling the neonate, massaging and/or warming the heel prior to specimen collection.

Limitations

- The system has not been evaluated for use with neonate venous blood.
- Blood source - Use only whole blood. Do not use serum or plasma.
- Temperature and humidity extremes - Test results may be inaccurate when test strips are stored outside of the storage and handling conditions.
- Altitudes above 15,000 feet (4572 meters) above sea level have not been evaluated.
- Specimens - Only fresh whole blood or whole blood collected in lithium heparin collection devices should be used for arterial and venous specimens.

- Fluoride, EDTA, Sodium, and Ammonium blood collection devices should not be used for arterial and venous specimens.

General Precautions

- Prior to use, read the Instructions for Use Manual.
- DO NOT reuse test strips. Test strips should be disposed after a single use.
- Discard used test strips according to local regulations.
- Remove the test strip from the vial only when ready to test.
- Use of the system outside of traditional healthcare settings(e.g., ambulance services) is limited to the following ambient temperature range: 41-104°F (5-40°C). Outside of this range, the system will generate an E-2 Temperature Error code and a blood glucose result will not be obtained.

- Do not use the test strip if the expiration date has passed, for this may cause inaccurate results.
- Do not tamper with the test strip.
- If test result is higher or lower than expected, follow institutional policy or run a control solution test to confirm test strip performance.
    1. If control solution result is out of range, remove test strip vial from point of use and repeat control solution test with new test strip vial.
    2. If control solution test is within expected range, repeat patient test.
    3. If patient test result is higher or lower than expected, perform glucose test on alternate method and consult healthcare professional.

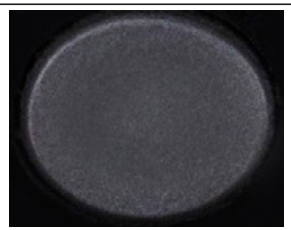
Analyzing a Patient Sample

1. Insert a test strip into the meter.

A blood drop will display.


Left Arrow


Right Arrow


MODE

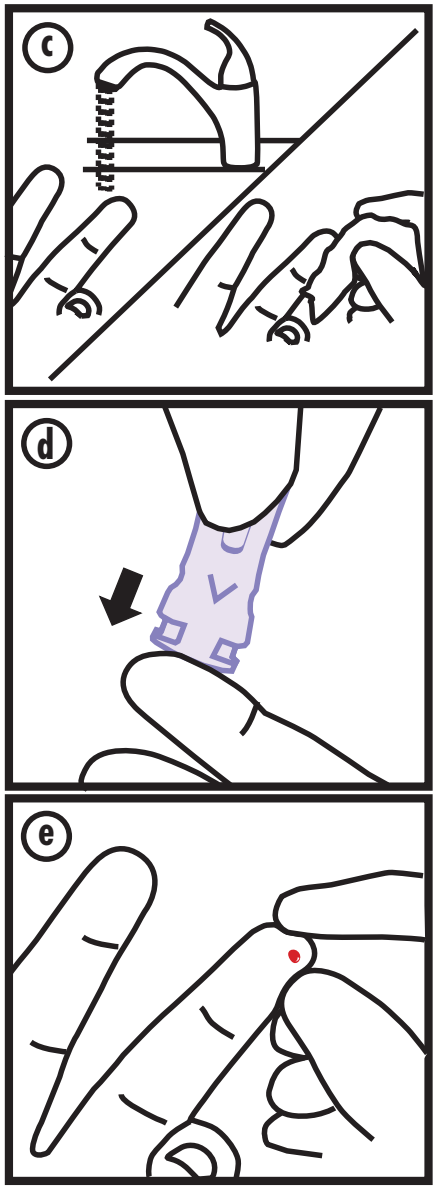
2. Prepare the Puncture Site.

a. Wash patient's hand with water then dry thoroughly. Alternatively, use alcohol pads to clean area; dry thoroughly after cleaning.

b. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.

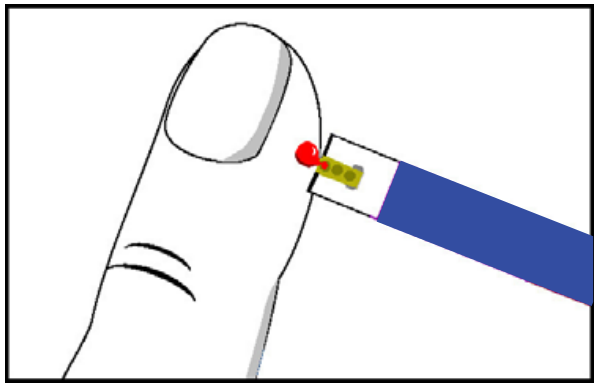
c. Use a Safety Lancet to puncture the finger.

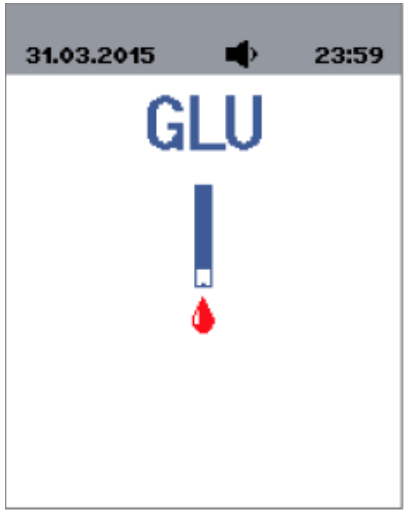
d. Squeeze the finger to form a drop of blood. Wipe away the first drop of blood. Then squeeze the finger again to form a second drop of blood.



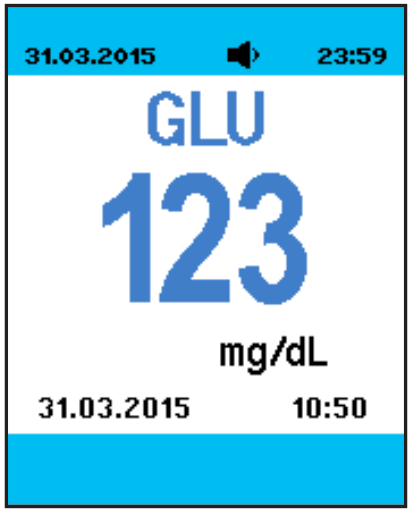
3. Add Blood to Test Strip.

When the blood drop appears, touch the end of the test strip to the blood drop until the test strip fills and the meter beeps.

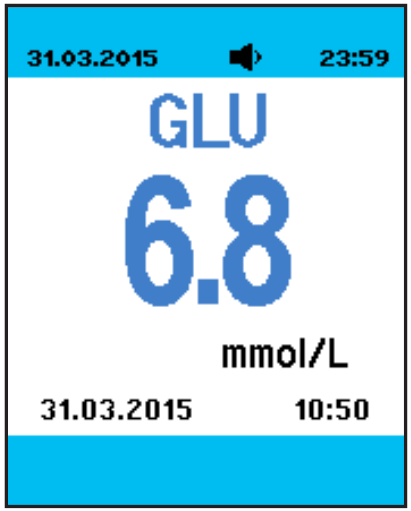




The Glucose result is available on-screen in 6 seconds.



Results in mg/dL



Results in mmol/L

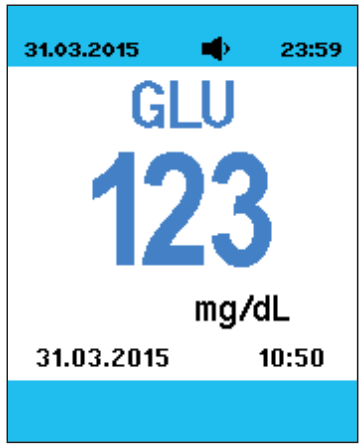
Analyzing a Quality Control Solution

1. Insert a test strip into the meter. Verify that all segments of the screen display. If the display is incomplete, discontinue use for diagnostic testing. Then a flashing blood drop will display.

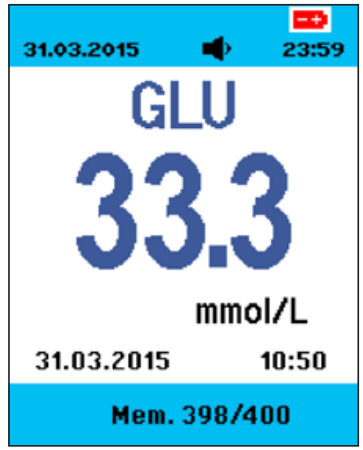
2. Identify the sample as a Control; use the Left or Right button to find the desired control level: QC1, QC2, or QC3.

3. Touch the end of the test strip to a drop of control solution until the test strip fills and the meter beeps.

4. Glucose quality control test results are available on-screen in 6 seconds.



Results in mg/dL



Results in mmol/L

Cleaning and Disinfecting the Meter

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

The StatStrip Xpress 2 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 wash their hands thoroughly with soap and water 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 may be used.

The StatStrip Xpress 2 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.

Meter Cleaning and Disinfection Procedure

Clean and disinfect after each patient use by following this protocol to help ensure effective cleaning and disinfection. Cleaning is not the same as disinfecting. Cleaning is intended to remove protein, visible blood, bodily fluids and soils from the external surfaces. 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 bleach wipe. Discard the used wipe into an appropriate biohazard container.
2. **Disinfect the Meter.**
   - Using a new, fresh germicidal bleach wipe, thoroughly

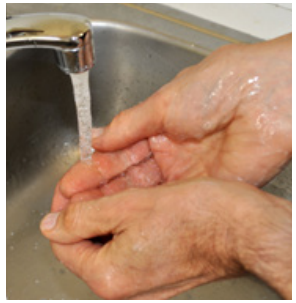
wipe the surface of the meter (top, bottom, left, and right sides) a minimum of 3 times horizontally followed by 3 times vertically avoiding the bar code scanner and electrical connector.

- 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 and is allowed to air dry for an additional 1 minute.

4. **Dispose of wipe and gloves.**
   - Dispose of used wipe and gloves in a standard biohazard container.

5. **Wash and sanitize hands.**
   - Wash your hands thoroughly with soap and water, 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 LCD 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.*

WARNING: *Cleaning and disinfection may in rare cases damage the meter. Damage may include plastic housing cracks, cloudiness or frosting of the LCD 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.*

Error Codes

E0 Software Error: Error detected. Repeat the test. If the error persists, remove and reseat the battery. If the error continues, call Technical Support.

E1 System Hardware Error: Error detected. Repeat the test. If the error persists, call Technical Support.

E2 Operating Temperature Error: Error means no blood glucose result. Move the meter to an area where the temperature is acceptable (41-104°F or 5-40°C), allow meter to adjust to the temperature. Repeat the test.

E3 Used Strip Error: Test strip is defective or used. Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

E4 Short Sample Error: An insufficient sample (control or blood) has been placed on the test strip. Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

E5 Strip Not Recognized Error: Defective test strip. Repeat the test with a new test strip. If the error persists, repeat using alternate test strip vial or alternate method.

E8 Bad Strip Error: Defective test strip. Repeat the test with a new test strip. If the error persists, repeat using an alternate test strip vial or alternate method.

E9 Bad Sample Error: Error detected with sample. Repeat the test with a new test strip. If the error persists, repeat the test using an alternate test strip vial or alternate method.

Technical Assistance

For technical assistance, call Nova Biomedical Technical Services at

U.S.A.: 1-800-545-NOVA 1-781-894-0800

FAX: 1-781-894-0585 Web: www.novabiomedical.com

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℞ Only IVD

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