IVD CE

Nova StatStrip Xpress®
Glucose Hospital Meter
Instructions for Use Manual

nova® biomedical

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Symbols

The following are symbols that are used in this manual, on insert sheets, and on the meter.

IVD *In vitro* diagnostic medical device

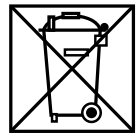
EC REP Authorized Representative in the European Community

CE Product fulfills the requirements of Directive 98/79 EC (IVDD)

 Caution, consult accompanying documents

 Consult instructions for use

 Biological risk

 Electronic Waste

REF Catalog number

 Temperature limitation

 Upper Limit of Temperature

 Manufactured by

About This Manual

This manual is for the Nova Biomedical StatStrip Xpress™ Glucose Hospital Meter.

Unit of Measure Information

The unit of measure of the StatStrip Xpress Glucose Hospital Meter is factory set to the standards in the country of use. The Meter either reports glucose results in mg/dL, REF 43404, or mmol/L, REF 44321, and can not be changed. Separate Result screens and specifications are shown in the Instructions for Use Manual for each unit of measure.

Throughout this manual:

NOTES *provide important or helpful operating information.*

CAUTIONS *provide information that is important for instrument protection.*

WARNINGS *provide information that is important for user protection or about risk for inaccurate results.*

Safety

Personnel operating this meter must be proficient in the operating and maintenance procedures of the meter. The following safety procedures must be followed.

1. Read the safety and operating instructions before operating the meter.
2. Retain the safety and operating instructions for future reference.
3. Observe all warnings on the meter and in the operating instructions.
4. Follow all operating and use instructions.
5. Place the meter away from heat sources.
6. The meter should be cleaned only as recommended by the manufacturer.
7. The meter should be serviced by qualified service personnel.

Safety

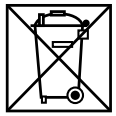
Electrical Safety

1. Battery powered: 3-volt coin battery

Chemical and Biological Safety

1. Observe all precautionary information printed on the original solution containers.
2. Operate the meter in the appropriate environment.
3. Dispose of all waste solutions according to standard hospital procedures.

Disposal of Used Batteries for customers in Europe:

- This symbol  on the battery label indicates that the battery provided with the meter should not be treated as household waste. To ensure the used battery is treated properly, remove the used battery from the meter and hand over the used battery to the

applicable collection point for the recycling of electrical and electronic equipment.

Disposal of Used Meters for customers in Europe:

- The meter may become infectious during the course of use. Discard in accordance with local regulations for biohazardous waste.

Environmental

- The operating temperature range for Meter operation: 59˚F to 104˚F (15˚C to 40˚C)
- The relative humidity range for Meter operation: 10% to 90% non-condensing
- The maximum altitude for Meter operation: Up to 15,000 feet (4572 meters)

Dimensions:

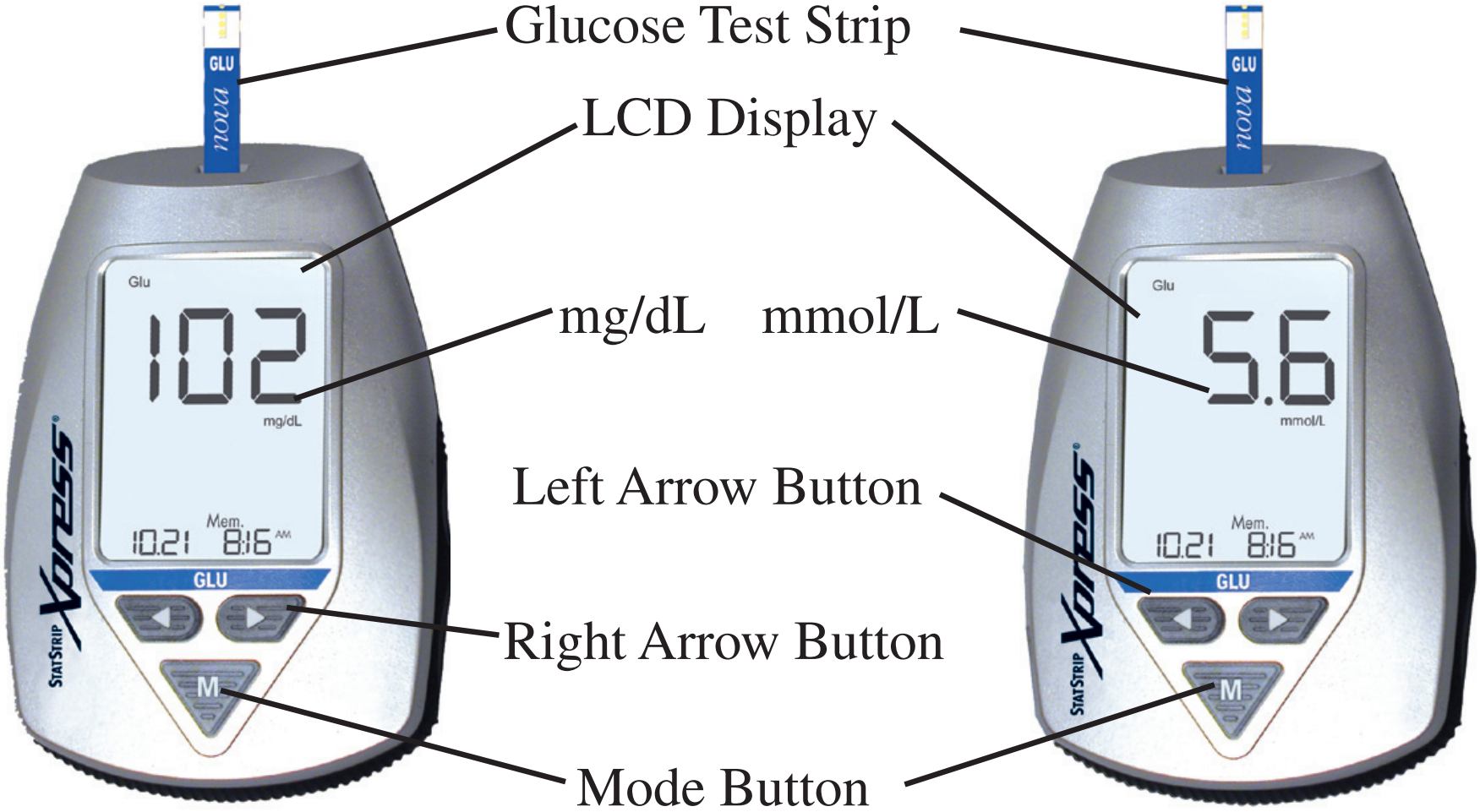
Height: 91.4mm (3.6in)
Width: 58.4mm (2.3in)
Depth: 22.9mm (0.9in)

Weight:

75 g (2.65 oz)

Intended Use

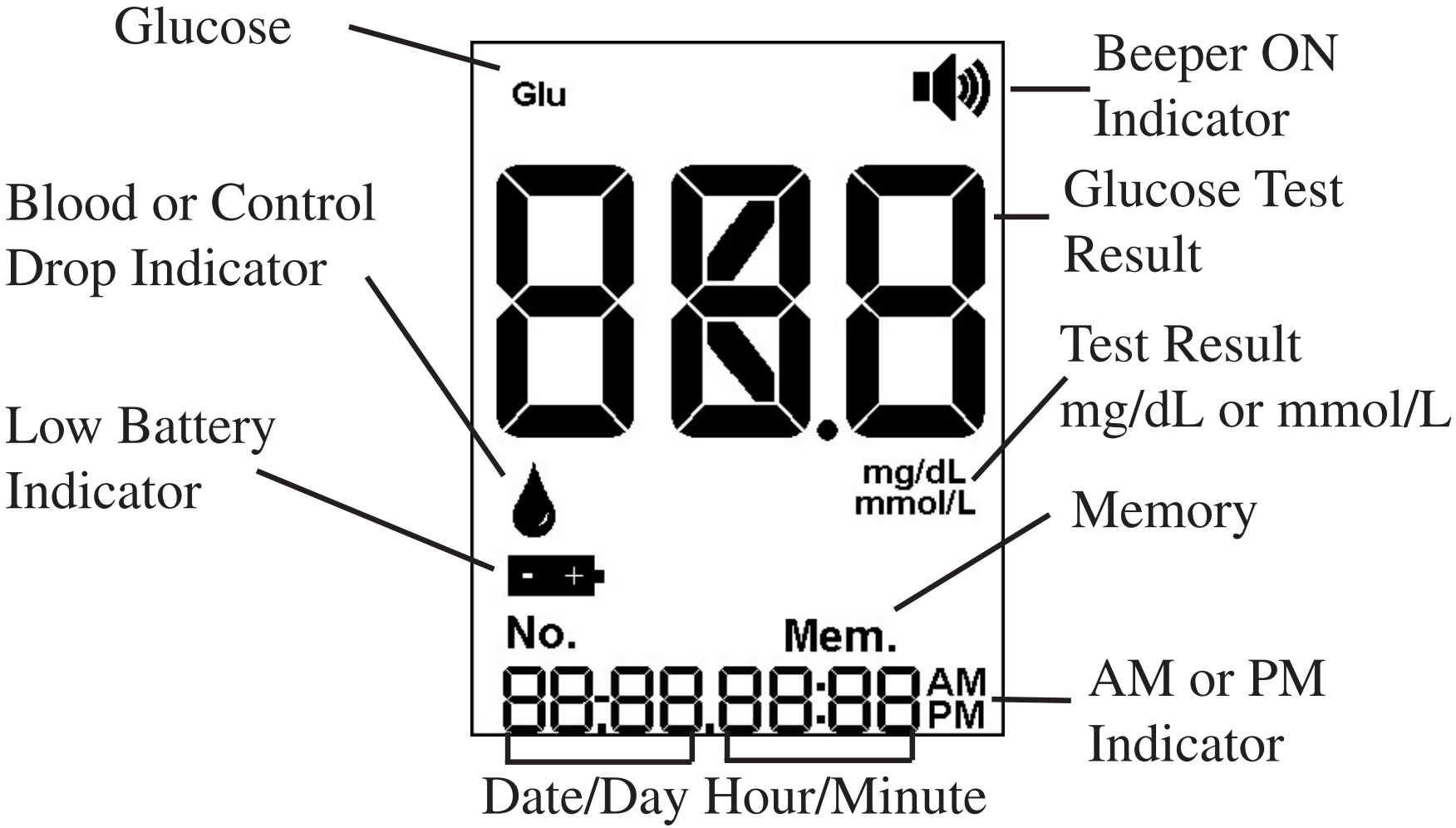
The Nova StatStrip Xpress Glucose Hospital Meter System is intended for *in vitro* diagnostic use by health care professionals and for point-of-care usage in the quantitative determination of Glucose (Glu) in capillary, venous, and arterial whole blood and neonatal capillary whole blood. It is not for diagnosis of or screening for diabetes.



Result in mg/dL

Result in mmol/L

Nova StatStrip Xpress Glucose Hospital Meter



Nova StatStrip Xpress Glucose Hospital Meter Screen

CLIA Complexity

This test is WAIVED for capillary, venous, and arterial whole blood and neonatal capillary whole blood under the Clinical Laboratory Improvements Amendments of 1988 (CLIA). Laboratories with a Certificate of CLIA waiver can perform this test in a waived setting 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. (Refer to Appendix A.8, Results of CLIA Waiver Study.)

This manual provides all necessary instructions for the routine operation and maintenance of the Nova StatStrip Xpress Glucose Hospital Meter. Please read this manual carefully. It has been prepared to help you attain optimum performance from your Meter.

Introduction

WARNING: Healthcare professionals and others using this system on multiple patients should be aware that all products or objects that come into contact with human blood should be handled as if capable of transmitting viral diseases, even after cleaning.

Precaution:

- Capillary blood glucose testing may not be appropriate for persons with decreased peripheral blood flow, as it may not reflect the true physiological state. Examples include, but are not limited to, severe hypotension, shock, hyperosmolar-hyperglycemia (with or without ketosis) and severe dehydration.

This section introduces the meter and covers requirements, tests performed, procedural limitations, clinical utility, and sample handling.

Introduction

- Prior to use, read the StatStrip Glucose Meter Instructions for Use Manual.
- DO NOT reuse test strips. Strips are designed to be disposed after a single use.
- Discard used test strips according to local regulations.
- Use only the Nova StatStrip Glucose Test Strips for testing with the Nova StatStrip Glucose Meter.
- If test result is higher or lower than expected, run a control solution test.
- Remove the test strip from the vial only when ready to test.
- 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.

Introduction

Additional Information for Healthcare Professionals

- The Nova StatStrip Glucose Test Strips are calibrated against plasma.
- The Nova StatStrip Glucose Test Strips are used for whole blood testing only.

Introduction

The Nova StatStrip Xpress Glucose Hospital Meter is a hand-held, battery-powered, *in vitro* diagnostic laboratory instrument that works in conjunction with Nova Biomedical glucose electrochemical test strips to measure glucose in a whole blood sample, a Quality Control (QC) solution, linearity, or proficiency solutions. The meter can store up to 400 patient and/or quality control test results. The user can review all stored test results on screen. Functions and data selection are accomplished by 3 push buttons. The meter has a built-in beeper for audible alerts and prompts.

Introduction

Clinical Utility

The Nova StatStrip Xpress Glucose Hospital Meter System is intended for *in vitro* diagnostic use by health care professionals and for Point-Of-Care usage for the quantitative measurement of glucose in capillary, venous, arterial, and neonate whole blood. It is indicated for use in a clinical setting by health care professionals as an aid to monitor the effectiveness of diabetes control.

The Sample

- Capillary, venous, arterial, and neonate whole blood
- Plasma calibrated patient test results
- Sample size 1.2 µL
- Anticoagulants: sodium, lithium, and ammonium heparin

Interfering Substances

Glucose Interferences:

The Nova StatStrip Xpress Glucose Hospital Meter exhibits **no** interference from the following substances up to the following concentration levels:

Substances	Conc mg/dL	(mmol/L)	Substances	Conc mg/dL	(mmol/L)
Acetaminophen	10.0	(0.66)	D(+) Maltose	240.0	(6.66)
Ascorbic Acid	10.0	(0.57)	D(+) Maltotetraose	240.0	(3.6)
Bilirubin	15.0	(0.26)	D(+) Maltotetriose	240.0	(4.76)
Cholesterol	500.0	(12.9)	Methyl-Dopa	1.0	(0.042)
Creatinine	6.0	(0.53)	Oxygen	All Conc	
Dopamine	10.0	(0.53)	Salicylate	30.0	(1.87)
Ephedrine	0.9	(0.055)	Tetracycline	30.0	(0.62)
D(+) Galactose	350.0	(19.4)	Tolazamide	15.0	(0.48)
Hematocrit (RBC)	65%		Tolbutamide	45.0	(1.67)
Ibuprofen	48.0	(2.33)	Triglycerides	750.0	(8.78)
L-Dopa	100.0	(5.07)	Uric Acid	20.0	(1.05)

Operation Overview

- To perform a test, the operator inserts a test strip into the test strip port. Touch the end of the strip to a drop of blood, QC solution, or linearity solution. The results are obtained in 6 seconds.
- Prior to analysis, the operator may designate the test sample as a quality control sample (level C1, C2, or C3).
- Test results are automatically stored into non-volatile memory.
- The operator can recall and review all stored test results.
- There are automatic electronic function checks to verify proper meter operation.
- The meter stores up to 400 patient, quality control, linearity, and proficiency test data.

- A coin-size battery provides power to operate the meter. The battery provides sufficient power to operate for approximately 600 tests. A low-battery warning on the meter display alerts the operator to change the battery. An auto sleep feature conserves power when the meter is not in use.

Meter Sleep/Wakeup

The LCD display is turned off to conserve battery power (sleep mode) after one minute of no activity. Keep-awake activities includes:

- Pressing a button
- Inserting a test strip

If the meter goes into sleep mode, the following conditions should be expected:

- If blanking occurs when a Patient Result screen is displaying, the result is automatically saved.
- If the currently displayed screen is a Setup screen, any unconfirmed input data or menu selection are discarded prior to blanking.

Wakeup

To wake the meter, one of the following can be done:

- Press any button.
- Insert a strip.

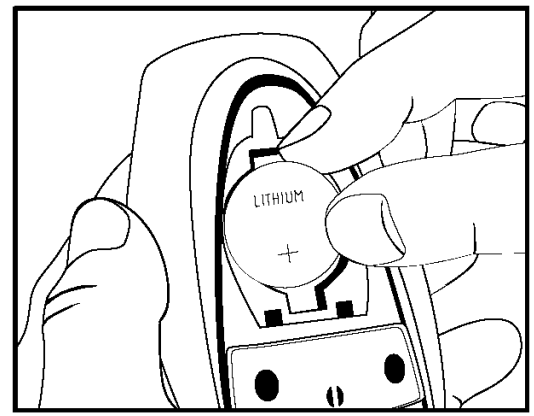
Setup

This section describes how to setup the Nova StatStrip Xpress Glucose Hospital Meter. The operator can set the meter for local time and date, have the beeper On or Off, enable the sample counter, and set the date display format.

Installing the Battery (Replacing)

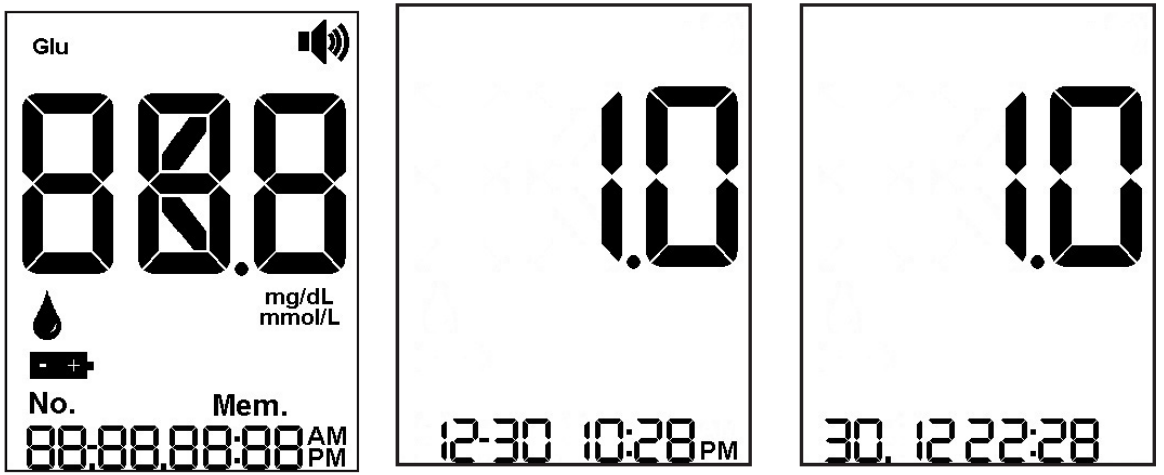
The meter is powered by a single 3V coin cell battery, 2450. Install/Replace the battery as follows:

1. Remove the back battery cover on the meter.
2. Install the coin cell battery with the + side facing up. (If replacing the battery, remove the used battery and replace with a new one.)



3. Replace the battery cover. All segments flash 3 times. The software version and the default date and time will appear for 3 seconds then the screen will go blank.

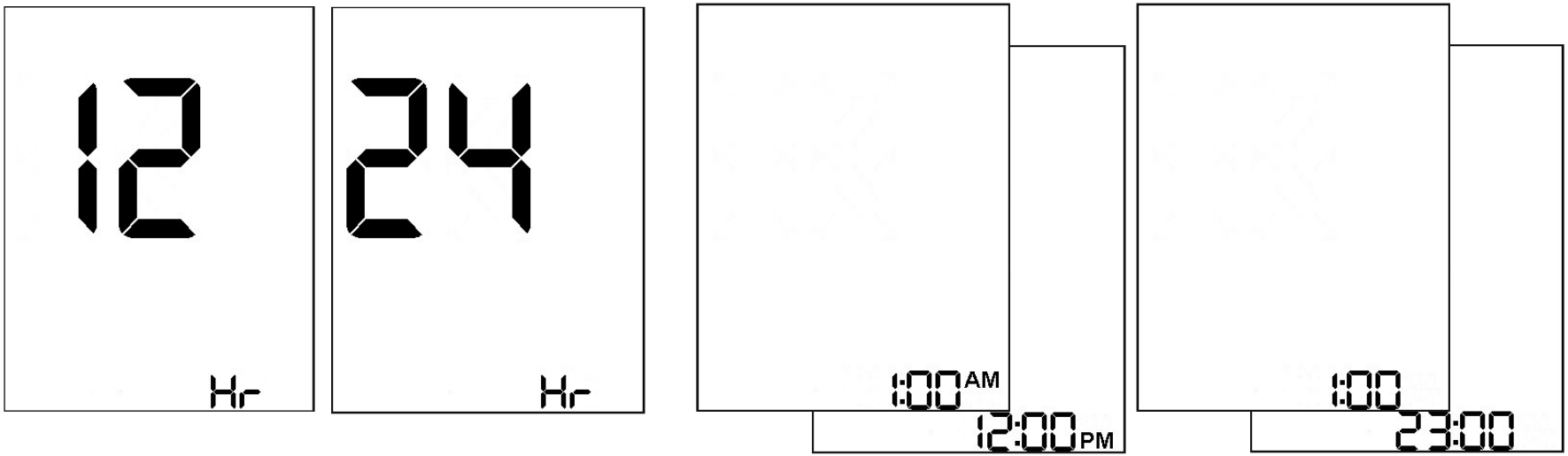
CAUTION: *Upon installing the battery, the meter software version is displayed for 3 seconds. Software versions may be numeric (example 5.0); therefore, please exercise caution to ensure the software version is not reported as a glucose result.*



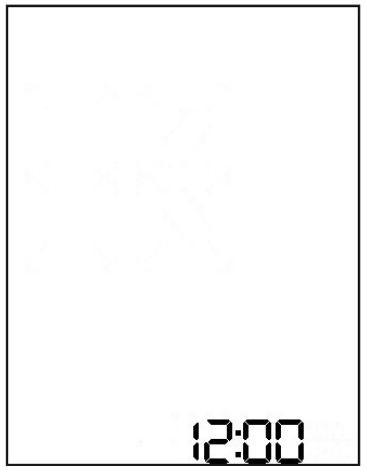
4. Go to setup to configure the meter.

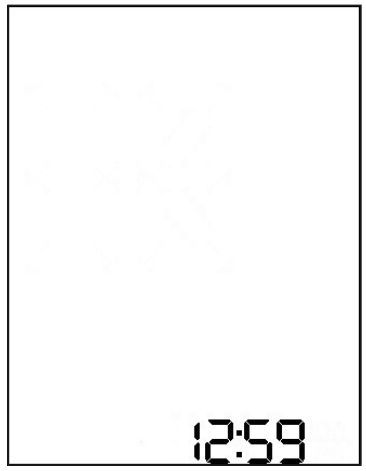
Set the Time

1. Press the MODE  button for longer than 3 seconds. The meter if in Sleep Mode wakes up and enters the SETUP Mode.



2. Select the hour (flashing) format: either 12 Hr or 24 Hr. Press the Right/Left Arrow  buttons to toggle between the 2 time format options.
3. Press the MODE  button to accept the Hour Format.
4. The meter displays the current time or the default time with the hour digits flashing.
5. Press the Right/Left Arrow  buttons to scroll from 1AM to 12PM (for 12 Hr Clock) or 0 to 23 (for 24 Hr Clock).
6. Press the MODE  button to accept the displayed Hour choice.
7. Next set the minutes (digits flashing). Press the Right/Left Arrow  buttons to scroll from 00 to 59 minutes.



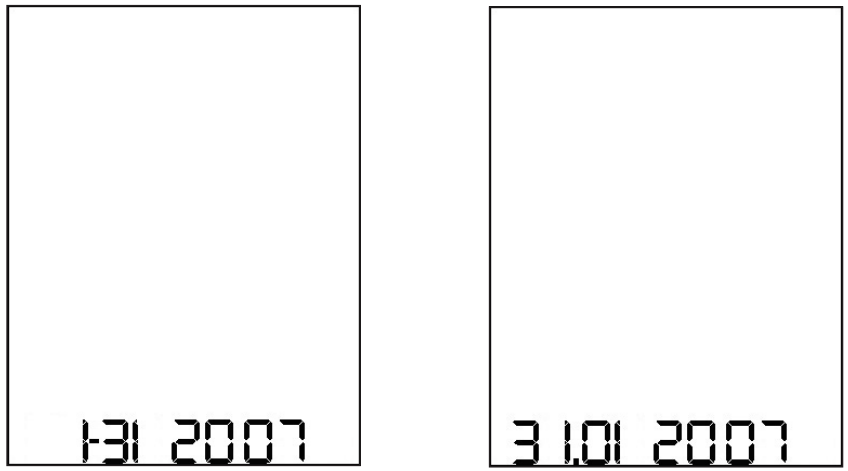


8. Press the MODE 

button to accept the displayed Minutes choice.

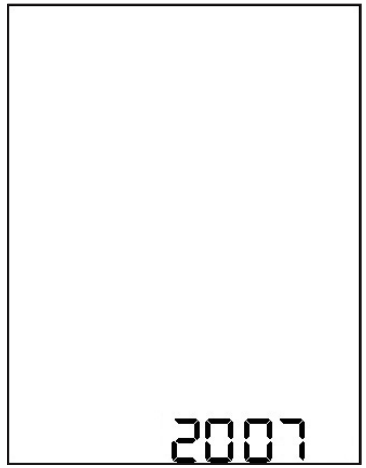
Set Date Format

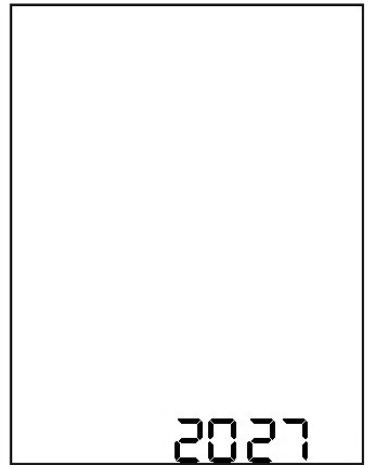
1. Next set the date format. The display is 1-31 2007 or 31.01.2007.
2. You can choose to have the date displayed as DD.MM or MM-DD. Press the Right/Left Arrow buttons to toggle between DD.MM or MM-DD.



3. Press the MODE button to accept the displayed Date Format.

4. The year should be flashing. Press the Right/Left Arrow buttons to select the current year.



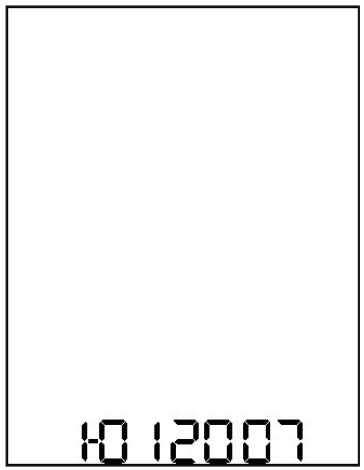


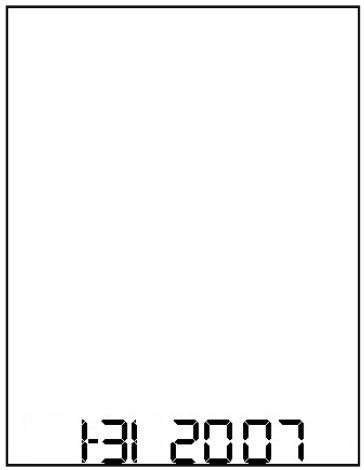
5. Press the MODE button to accept the displayed Year.

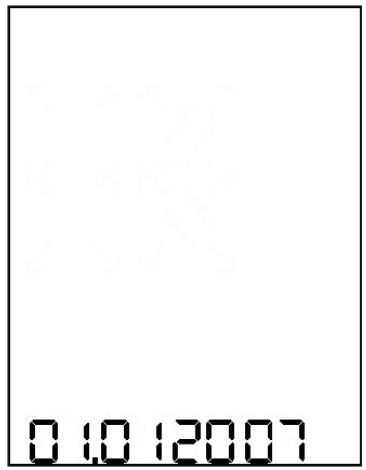
6. The month should be flashing. Press the Right/ Left Arrow buttons to scroll through the 12 months (1 to 12).

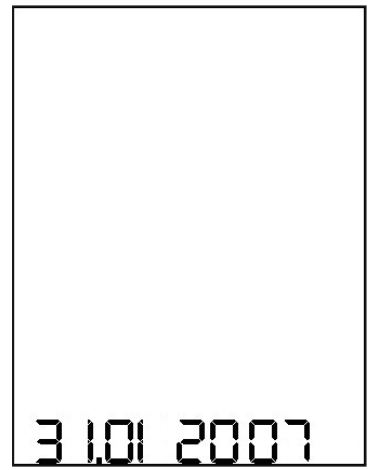
7. Press the MODE button to accept the displayed Month.

8. The day should be flashing. Press the Right/Left Arrow buttons to scroll through the days of the month.





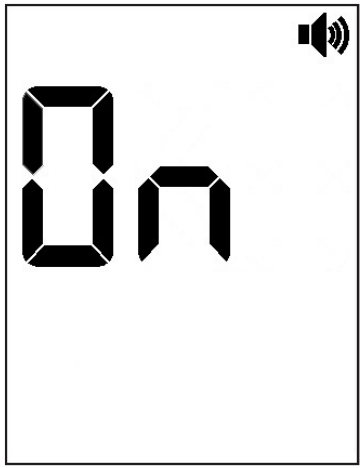




9. Press the MODE button to scroll the displayed Day.

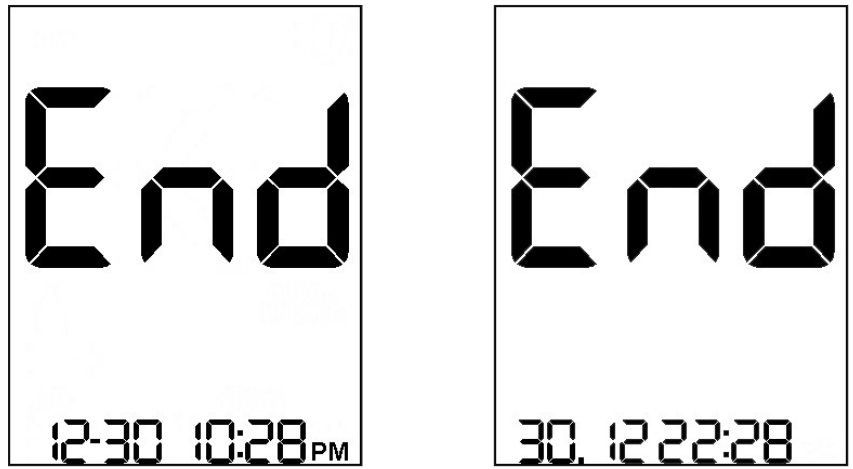
Beeper On or Off

1. Press the Right/Left Arrow buttons to toggle between Beeper ON or OFF (flashing).



2. Press the MODE button to accept the displayed ON or OFF.

End is displayed with the entered date and time. Press the Mode button for 1.5 seconds to exit Setup or the meter will time out in 1 minute.



Testing: QC/Linearity/Proficiency/Blood Samples

This section describes how to run QC (Quality Control), Linearity Solution, Proficiency Solution, and blood samples.

When to Perform a QC Test

The Nova StatStrip Xpress Glucose Hospital Meter includes several quality control mechanisms that detect errors due to system failures and operator performance. External controls materials are available from Nova Biomedical for verifying the integrity of the Nova StatStrip Xpress Glucose Hospital Meter. These StatStrip Glucose Control Solutions consist of 3 levels of ready-to-use liquid controls. They are formulated at clinically relevant levels. The controls can be used as part of a laboratory quality control program. Run the controls according to the procedure in Section 2.3 Quality Control Test.

Testing a Quality Control Solution

StatStrip Glucose Control Solution

Read the StatStrip Glucose Control Solution package insert sheet for complete instructions, indications, precautions, and limitations of the system.

Only the Nova StatStrip Glucose Control Solutions are recommended for use with the Nova StatStrip Xpress Glucose Meter and the Nova StatStrip Glucose Test Strips. Ranges for the Nova StatStrip Xpress Glucose Meter using other commercially available glucose controls have not been established and may give erroneous results. Run 2 different levels of the StatStrip Glucose Control Solutions during each 24 hours of testing prior to testing of patient specimens and under the following circumstances:

Testing a Quality Control Solution

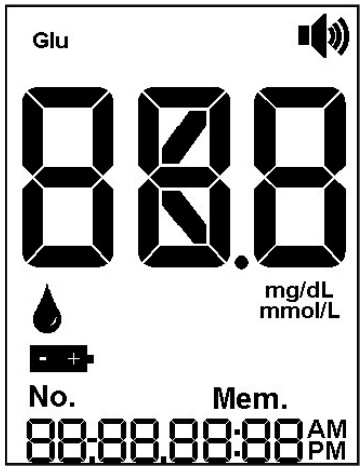
- Each new operator
- Before using the StatStrip Meter for the first time
- If a patient test has been repeated and the blood glucose results are still lower or higher than expected
- If there are other indications that the system is not working properly
- Whenever problems (storage, operator, instrument) are identified or anytime there is a concern the accuracy of the meter may have been affected by rough handling (such as dropping the meter).
- As required by the institution's quality control policy or local regulatory requirements

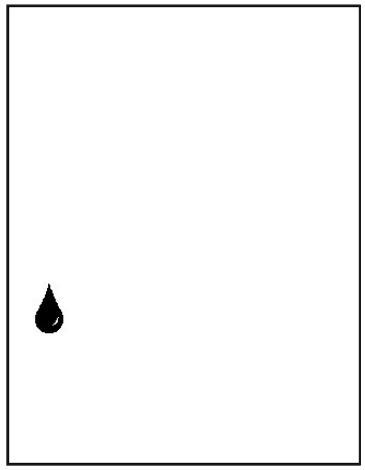
Testing a Quality Control Solution

Good Laboratory Practice principles suggest that external controls must be run whenever the laboratory director has any question about the test system integrity or operator technique. This section describes how to run QC (Quality Control), Linearity Solution, Proficiency Solution, and blood samples.

Testing 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.

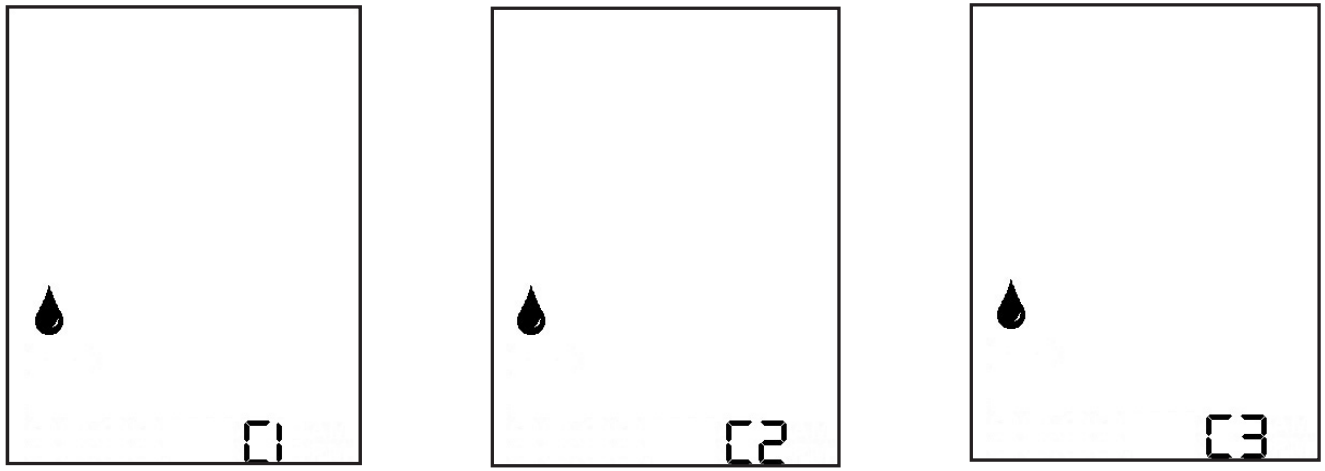




NOTE: *If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.*

Testing a Quality Control Solution

2. Identify the sample as a Control; use the Left or Right button to find the desired control level: C1, C2, or C3.



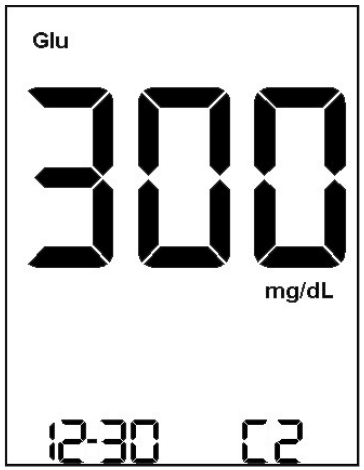
3. Touch the end of the test strip to a drop of control solution until the test strip fills and the meter beeps.

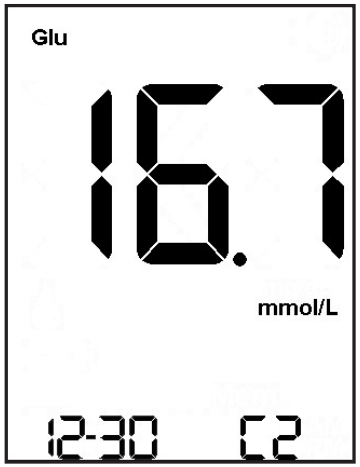
NOTE: *A quick beep sounds when sufficient control solution has been added to the test strip.*

Testing a Quality Control Solution

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

Result Displayed in **mg/dL**





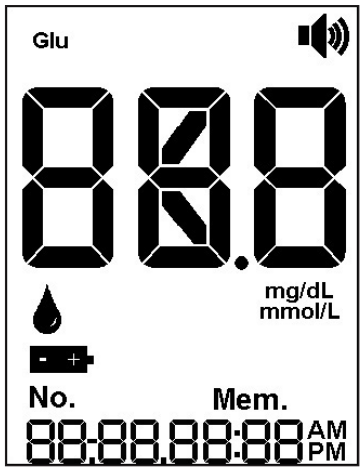
Result Displayed in **mmol/L**

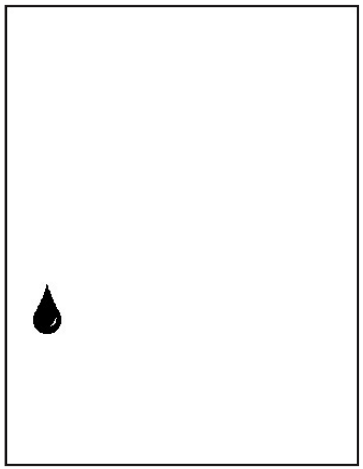
5. There is one long beep when the results are ready. There are 3 short beeps if test results are outside the measurement range of the test strip.

Testing a Blood Sample

NOTE: *Do not test patient samples until control solution test results are within expected range.*

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.

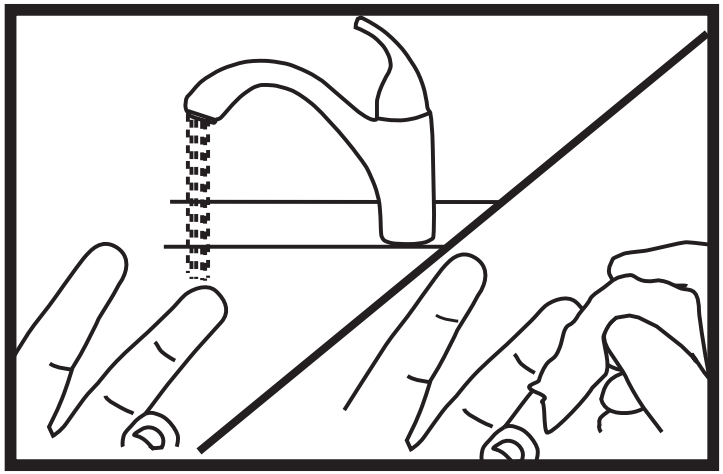




NOTE: *If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.*

Testing a Blood Sample

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

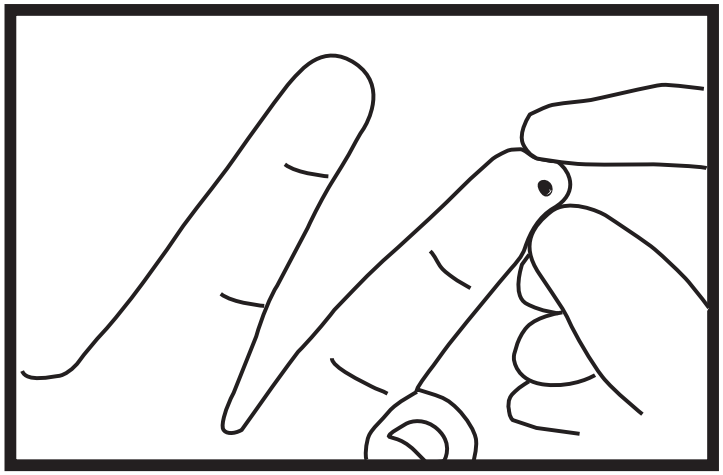


3. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.

4. Use a lancet to puncture the finger.

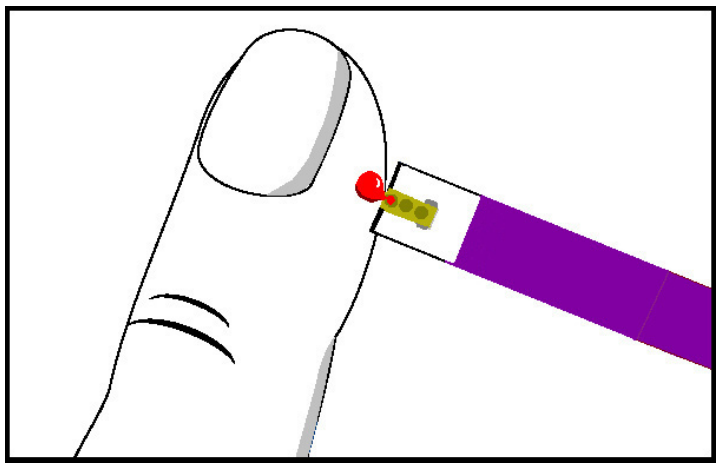
Testing a Blood Sample

5. Squeeze the finger to form a drop of blood.

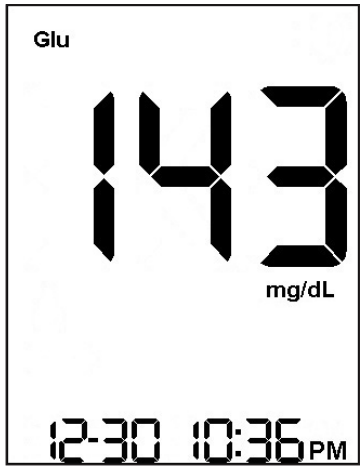


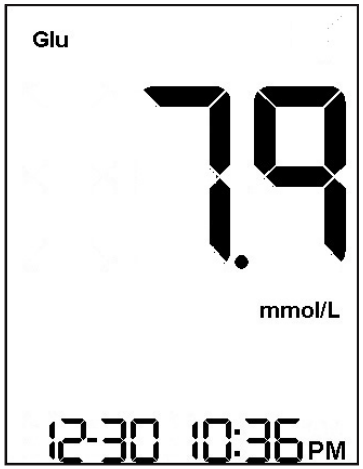
6. When the blood drop appears, touch the end of the test strip to the blood drop until the test strip fills and the meter beeps.

7. Glucose test results are available on-screen in 6 seconds.



Testing a Blood Sample



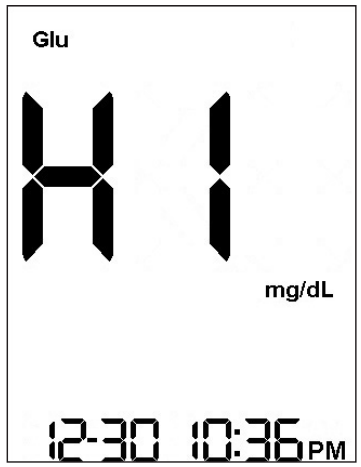


Result in mg/dL Result in mmol/L

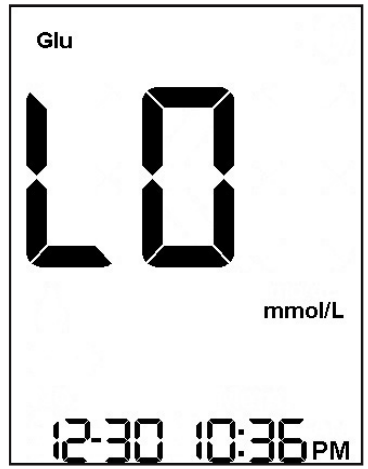
8. There is one long beep when the results are ready. There are 3 short beeps if test results are outside the range of the test strip.

Testing a Blood Sample

If result is LO (less than the measurement range) or Hi (greater than the measurement range) repeat the test.



HI in mg/dL



LO in mmol/L

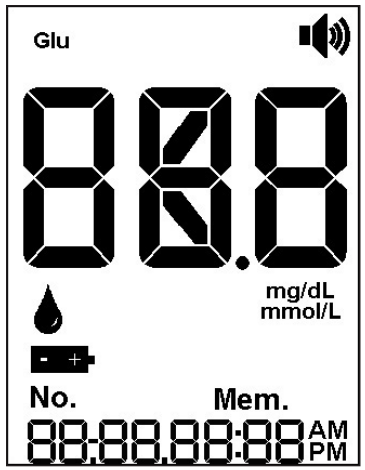
NOTE: *Test results are automatically saved. If no activity for 1 minute, the meter will time-out: screen goes blank.*

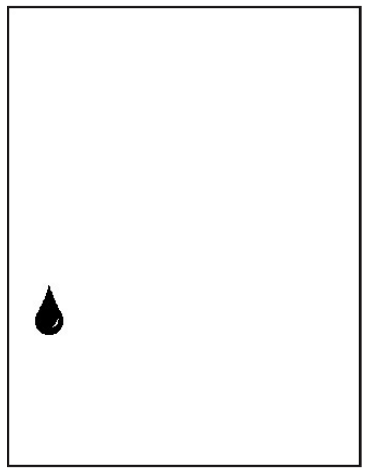
Testing a Linearity/Proficiency Solution

For CLIA Moderate Settings only: This section describes how to perform Linearity tests with the StatStrip Xpress Glucose Hospital Meter. There are 5 levels in the StatStrip Glucose Linearity kit.

Refer to the StatStrip Linearity Kit package insert sheet for complete instructions, indications, precautions, and limitations of the system.

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.





Testing a Linearity/Proficiency Solution

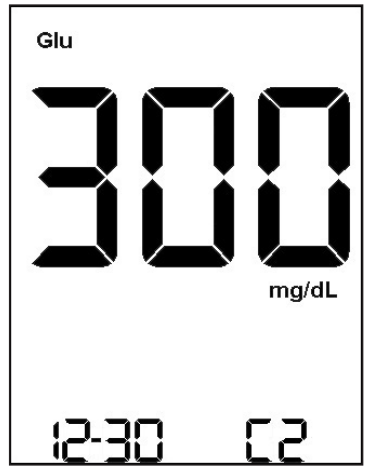
2. Touch the end of the test strip to a drop of linearity solution or proficiency solution until the test strip fills and the meter beeps.

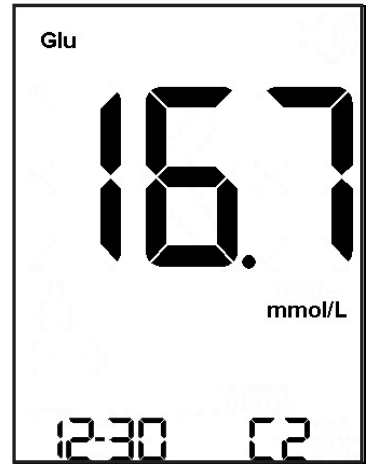
NOTE: *LinearitylProficiency test results are stored in memory as a blood sample.*

NOTE: *A quick beep sounds when sufficient linearity/ proficiency solution has been added to the test strip.*

3. Linearity or proficiency test results are available on-screen in 6 seconds.

Testing a Linearity/Proficiency Solution





Result in mg/dL Result in mmol/L

4. There is one long beep when the results are ready. There are 3 short beeps if test results are outside the measurement range of the test strip.

Reviewing Test Results

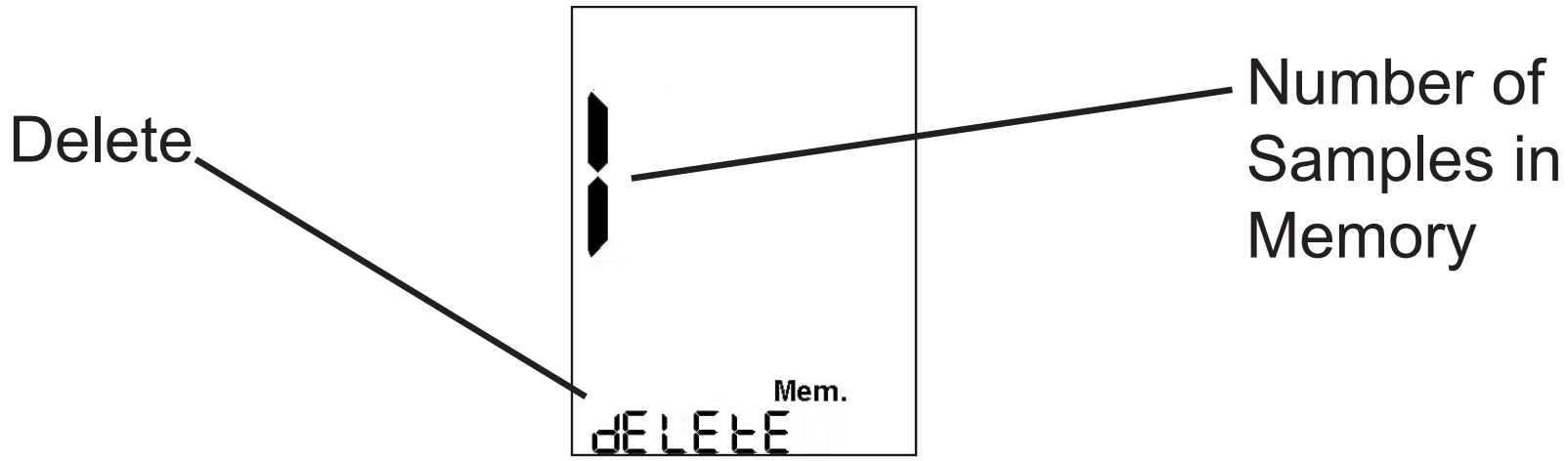
The meter is able to store up to 400 test results.

1. To review test results, press the Mode button once for less than 3 seconds.
2. If there are no results in memory, the screen displays - - - on the mem (memory) screen.
   If there are tests saved, the most recent test is displayed first.
3. Press the left arrow button to scroll backward thru results. Press the right arrow button to scroll forward thru results.
4. If you scroll past the first or last stored result, the screen displays END.
5. After 400 test results, the new result will override the oldest result in memory.

Deleting Stored Test Results

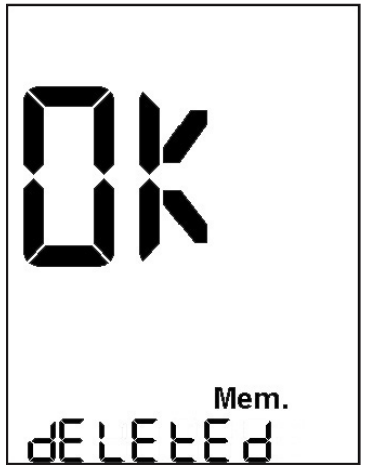
You can delete all stored test and QC results. Proceed as follows to delete all results:

1. Press the Mode button once to display the number of stored test results.
2. Press the Right and Left arrow button simultaneously for longer than 3 seconds.
3. The screen displays the number of samples in memory with delete flashing at the bottom of the screen.



Deleting Stored Test Results

4. When the Screen displays dELEtE (flashing), press the left and right buttons simultaneously for greater than 3 seconds. All results are deleted. The screen will display OK and dELEtEd as shown below.
5. To exit without deleting results. press the MODE button once.



Troubleshooting

This section describes Battery status, Error Codes, and Actions for the Nova StatStrip Xpress Glucose Hospital Meter.

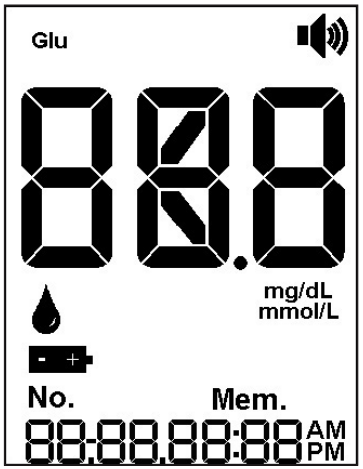
Battery Check

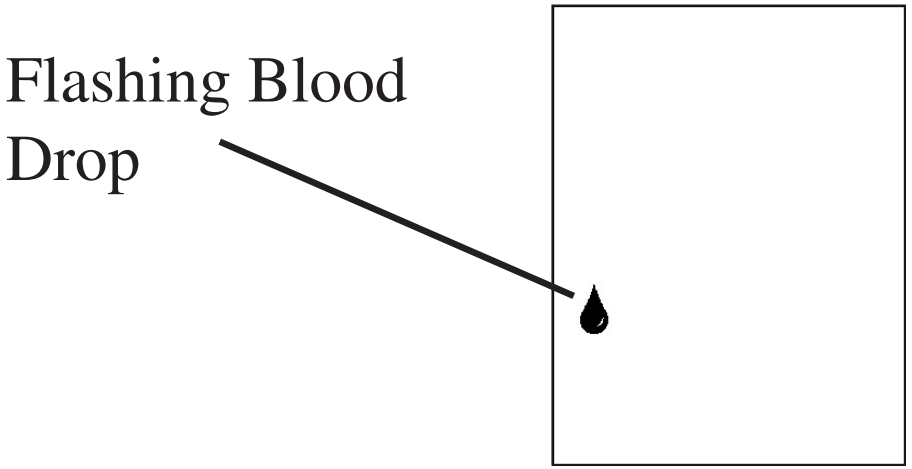
The battery provides sufficient power to operate for approximately 600 tests. A battery low warning will alert the user to replace the battery. Test results are stored in non-volatile memory to prevent test result loss.

Troubleshooting

How to view the battery status of the meter:

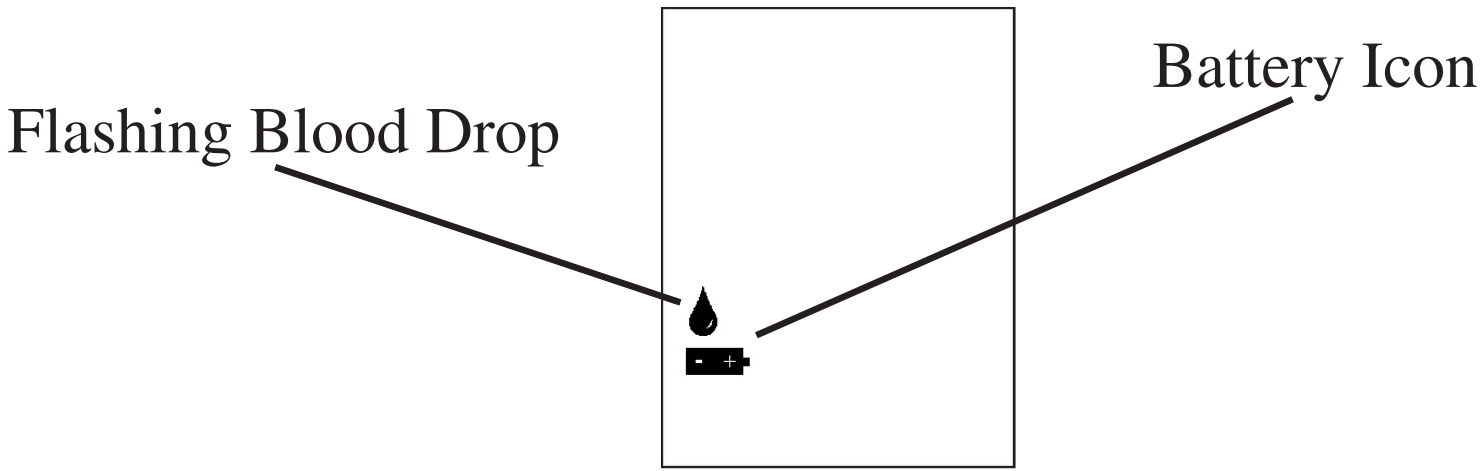
- Insert a test strip to the meter when it is turned off.
- All segments will display for 2 seconds.
- **Battery is OK:** a flashing blood drop appears at the lower left corner of the screen.
  Continue with testing as usual.



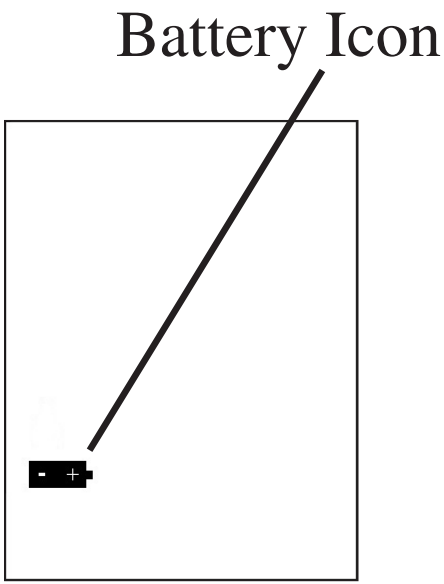


Troubleshooting

- **Battery is Low:** a flashing blood drop and battery icon appear at the lower left corner of the screen: battery charge sufficient for up to 10 tests. Continue with testing as usual. Battery icon remains on the screen.



- **Battery is very Low:** battery icon at the lower left corner of the screen: battery charge insufficient for testing.
  Meter will not operate and battery icon disappears when the test strip is removed. Replace the battery.



CAUTION: *Attempts to perform glucose testing with a low battery could result in the software rebooting. Upon rebooting, the software version is displayed for 3 seconds. Software versions may be numeric (example 5.0); therefore, please exercise caution to ensure the software version is not reported as a glucose result.*

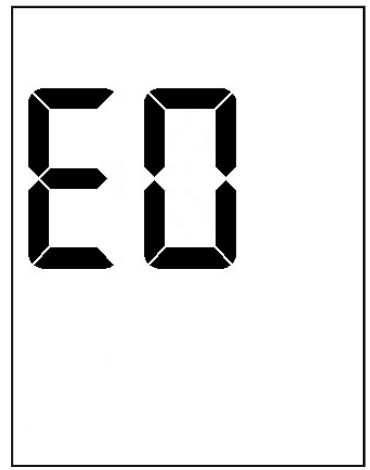
Error Codes

There are 8 Error Codes to inform you of problems with the meter. This section provides action procedures when these Error Codes are displayed. The error code displays after the test strip is inserted and the all segments screen displays for 2 seconds. If the beeper is enabled, there are also 3 quick beeps. Then the Error Code is displayed on the screen.

E0 Software Error

A software error has been detected.

Action: Perform the test again. If you get the same error again, remove and reseat the battery. If the error continues, call Nova Technical Support.

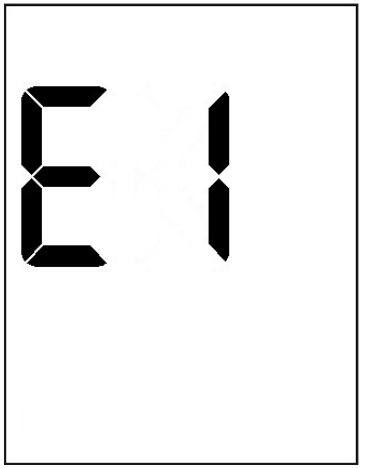


Troubleshooting

E1 System Hardware Error

A system hardware error has been detected.

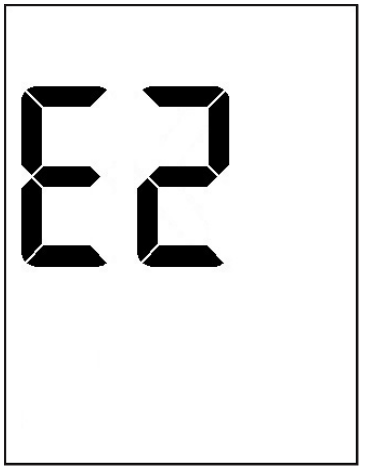
Action: Perform the test again. If you get the same error, call Nova Technical Support.



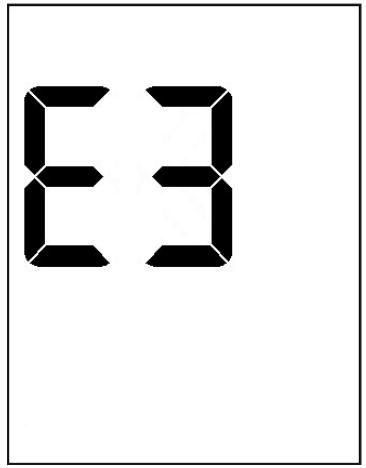
E2 Operating Temperature Error

The Meter temperature is outside of the range for testing.

Action: Move the meter to an area where the temperature is acceptable (59°-104°F or 15°-40°C), allow meter to adjust to the temperature. Repeat the test.



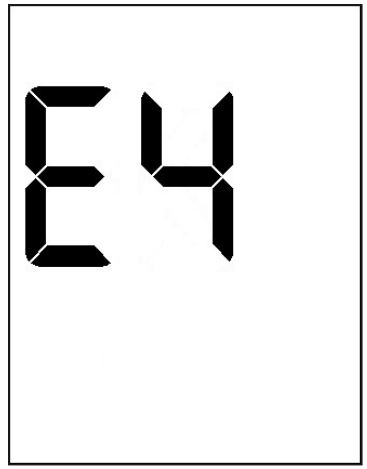
E3 Used Strip Error



The test strip was previously used.

Action: 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



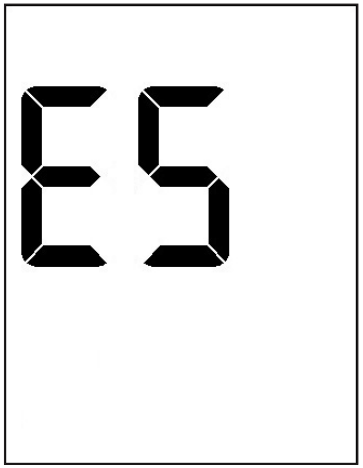
An insufficient sample volume (Control or blood) was drawn into the test strip.

Action: 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

The test strip is not recognized.

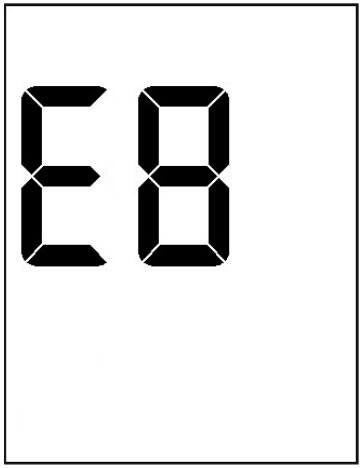
Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.



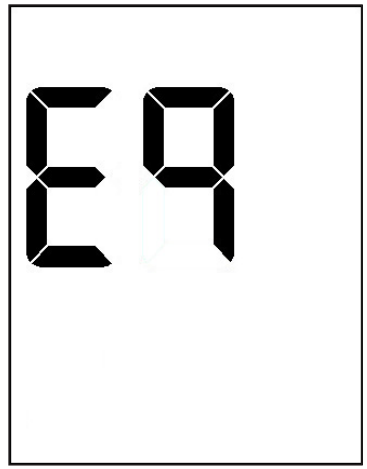
E8 Bad Strip Error

The test strip is defective or bad.

Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.



E9 Bad Sample Error



A problem was detected with the sample.

Action: Repeat the test with a new test strip. If the error persists, perform the test using an alternate test strip vial or alternate method.

Appendix

The Appendix includes solution and reagent specifications, accuracy and precision, consumable list, reference information, and warranty.

Appendix

A.1 Specifications

Tests Measured	Blood Glucose (referred to Plasma Values)
Glucose Methodology	Enzyme, Amperometric
Glucose Test Results	mg/dL, mmol/L
Sample Type	Whole blood
Glucose Test Range	10 to 600 mg/dL 0.6 to 33.3 mmol/L
Test Time	6 seconds
Test Strip Volumes	1.2 µL
Memory storage	400 Tests
Battery Life (nominal)	600 Tests
Battery Type	2450 3V coin cell
Data Cable	Serial or USB

Appendix

Operating Ranges:	
Temperature	59° to 104°F (15° to 40°C)
Humidity	10% to 90% relative humidity
Altitude	15,000 ft (4572 meters)
Hematocrit	20% to 65%
Weight	2.65 oz (75 g)
Size	3.6x2.3x0.9 in(91.4x58.4x22.9 mm)

A.2 Reference Values

Each laboratory should establish and maintain its own reference value. The value given here should be used only as a guide.

Fasting Glucose[1]	65 - 95 mg/dL (3.6 - 5.3 mmol/L)

1. Burtis, Carl A. and Ashwood, Edward R., ed. 1994. *Tietz Textbook of Clinical Chemistry.* Philadelphia, PA: W. B. Saunders Co.

Appendix

A.3 Glucose Methodology

The glucose measurement is based on the following methodology:

1. Glucose + Enzymes(oxidized form) ——>
   Gluconic Acid + Enzymes(reduced form)

2. Enzymes(reduced form) + Ferricyanide —>
   Enzymes(oxidized form) + Ferrocyanide

3. Ferrocyanide $\xrightarrow[\text{Electrode}]{-e^-}$ Ferricyanide

The current generated at the electrode is proportional to the glucose concentration of the sample.

Appendix

A.4 Quality Control Solution

QC Solutions	**Levels 1, 2, 3**
Linearity Solutions	**Levels 1, 2, 3, 4, 5**

A.5 Chemistry Measurement

The typical imprecision for glucose both for within-run and day-to-day

Glucose Levels (mg/dL)	Glucose Levels (mmol/L)	CV%
50	2.8	8%
150	8.3	6%
400	22.2	4%
600	33.3	4%

Appendix

A.6 Ordering Information

Supplies and parts for the Nova StatStrip Xpress Glucose Hospital Meter are available from Nova Biomedical.

DESCRIPTION	REF
Instructions for Use Manual	43306
Quick Reference Guide	44398
StatStrip Xpress Glucose Meter (mg/dL)	43404
StatStrip Xpress Glucose Meter (mmol/L)	44321
StatStrip Glucose Test Strips (1800), 72 vials, 50 per vial	42214
Glucose Control Solution, Level 1	41741
Glucose Control Solution, Level 2	41742
Glucose Control Solution, Level 3	41743
Linearity Solution, Levels 1-5	42173
Battery (DL2450)	41221

A.7 Cleaning and Care

The meters should never be immersed in any cleaning agent. Always apply the cleaning agent to a soft cloth to wipe the meter surface. Once complete, immediately dry thoroughly. When cleaning the meter, please follow the guidelines listed below:

- Dilute Bleach. A 10% solution of household bleach (Sodium Hypochlorite) may be used.
- 70% Isopropyl (rubbing) Alcohol may be used.
- Commercial surface decontamination preparations that are approved for use by your facility can be used. Apply to a small test area first to ensure surface finish integrity.
- Avoid harsh solvents such as benzene and strong acids.

Appendix

CAUTION: ***DO NOT*** *immerse the meter or hold the meter under running water.* ***DO NOT*** *spray the meter with a disinfectant solution.*

CAUTION: *Do Not attempt to open the meter to make any repairs. Your warranty and all claims will be void! Only Nova Biomedical authorized service personnel can repair the meter. Call Nova Biomedical or an authorized dealer if the meter needs to be repaired or checked.*

Appendix

A.8 Results of CLIA Waiver Study

Clinical Site descriptions:

A clinical study was conducted at 4 sites located in 2 regions of the United States. Three sites in Florida (Site1: Medical Surgical unit; Site2: Cardiac, Pediatric, Oncology unit; and Site3: Progressive care unit), and Northeast region (Site4: Nova Biomedical, Waltham, MA). There were a total of 24 operators distributed as follows; site1 through site 4 had 3, 4, 5, and 12 operators, respectively. The study involved running 525 specimens (110 subjects; 196 venous; 15 spiked samples; 171 arterial; and 33 low capillary samples) across over 15 days by untrained intended operators. In addition, 100 neonatal capillary samples (including 3 spiked samples) were collected from the St. Louis Children's hospital, St. Louis, MO, and compared to Vitros (Johnson & Johnson).

Results of CLIA Waiver Study (continued)

The comparative methods used were Dade RxLfor venous and arterial whole blood and Yellow Springs Instrument (YSI) model 2300 STAT Plus for capillary whole blood. Discarded whole blood samples ran by hospital personnel and then immediately centrifuged by a health care professional to obtain a plasma sample to be analyzed on a central laboratory chemistry analyzer (Dade RxL).

The study was intended to demonstrate that after reading only the test instructions, untrained intended operators were able to easily perform glucose measurements with the Nova StatStrip Xpress that were as accurate as those obtained by trained operators using the comparative methods. The criteria for success for accuracy required that at least 95% of the results fall within the allowable total error (ATE) zone, defined as ± 15 mg/dL of the comparative method for glucose levels ≤75 mg/dL and within ± 15% for glucose levels > 75 mg/dL.

Results of CLIA Waiver Study (continued)

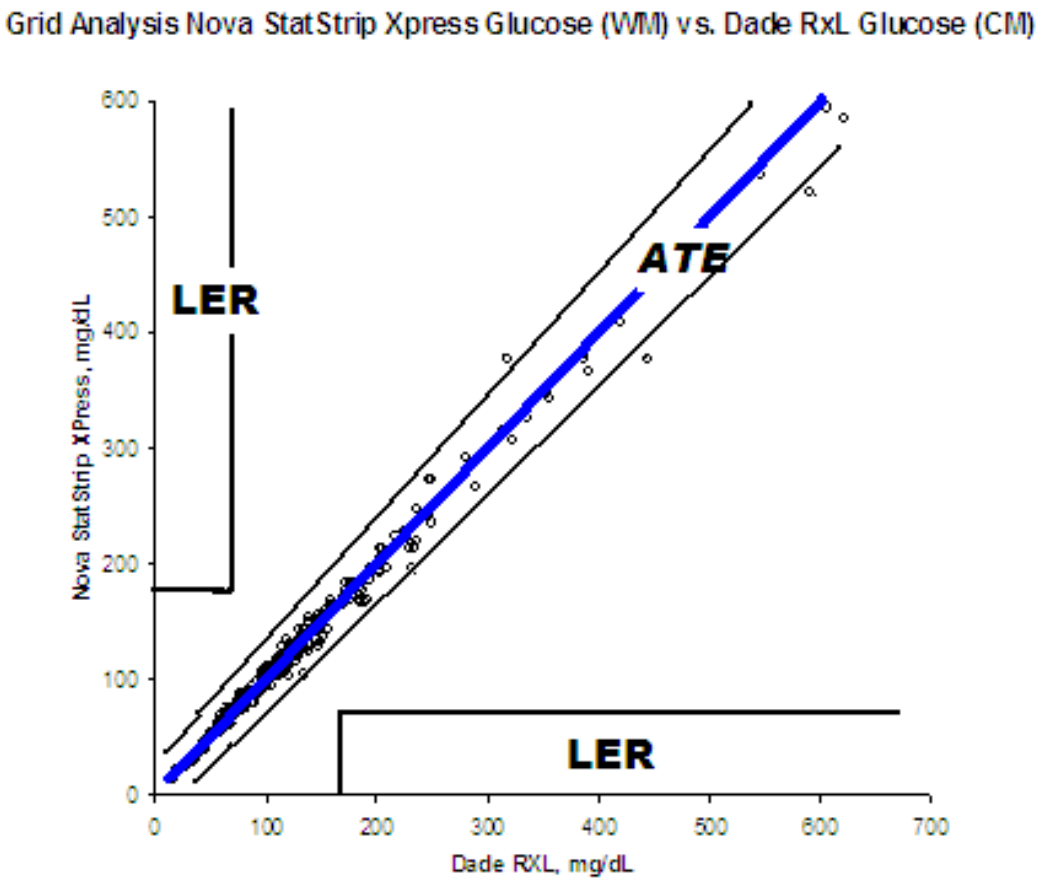
The results of the study for venous and arterial samples were following:

Range of Dade values (mg/dL)	Total number of samples	Number of samples within of ATE	Percent of samples within of ATE
17 to 97	169	169	100%
97.1 to 114	56	56	100%
114.1 to 622	142	138	97.2%
17 to 622	367	363	98.9%

The percentage of the arterial and venous samples over the entire range that fall within the ATE zone was 98.9% (363/367) with a lower one-sided 95% confidence bound of 97.6%. In the study, none samples were in the LER zone (0% with an upper bound of 95% confidence interval of 0.7%).

Results of CLIA Waiver Study (continued)

The scatter plot of the study results for arterial and venous samples with ATE and LER zones is presented by the figure below:



Results of CLIA Waiver Study (continued)

The descriptive statistics of the differences between Dade glucose and Nova StatStrip results of arterial and venous samples are presented by the table below:

Range of Dade values (mg/dL)	Average Difference	2.5th percentile of relative differences	97.5th percentile of relative differences
17 to 75	-0.45 mg/dL	-7.7 mg/dL	6.7 mg/dL
75.1 to 97	-0.1 %	-11.5 %	11.38 %
97.1 to 114	0.95 %	-10.55 %	9.65 %
114.1 to 622	-1.56%	-14.52 %	10.87 %

Results of CLIA Waiver Study (continued)

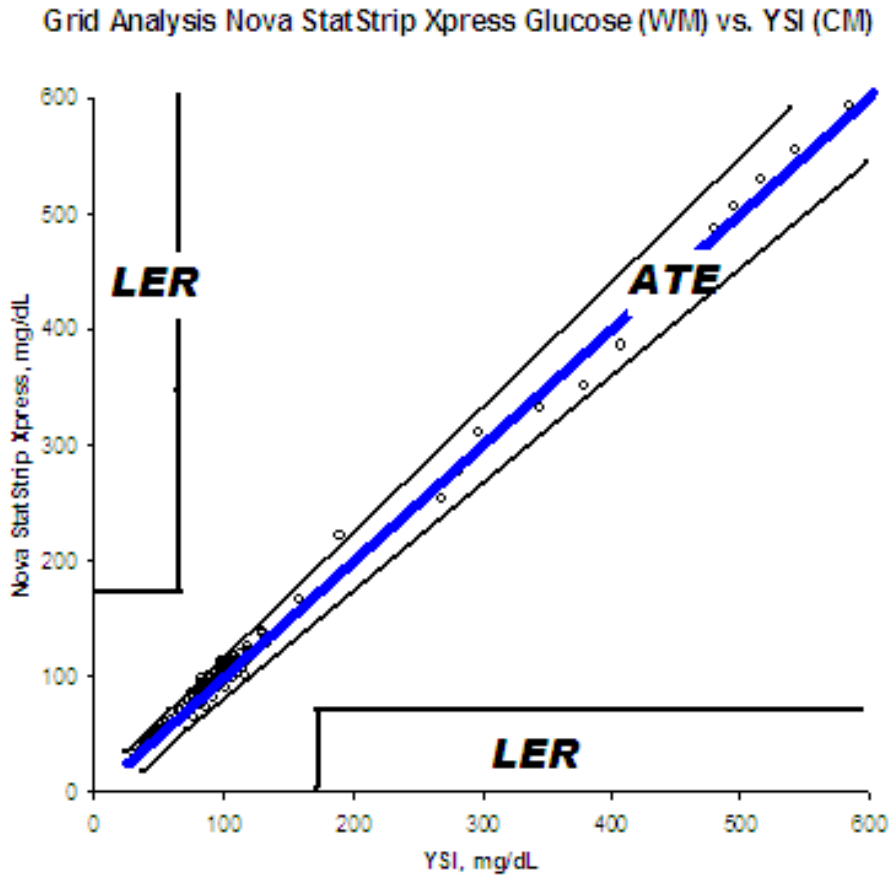
The results of the study for capillary samples were following:

Range of YSI values (mg/dL)	Total number of samples	Number of samples within of ATE	Percent of samples within of ATE
<75	32	32	100%
75 - 97	51	48	94.1%
97.1 to 114	48	47	97.9%
> 114	27	26	96.3%
Total	158	153	96.8%

Results of CLIA Waiver Study (continued)

The percentage of the capillary samples over the entire range that fall within the ATE zone was 96.8% (153/158) with a lower one-sided 95% confidence bound of 93.6%. In the study, no samples were in the LER zone (0% with an upper bound of 95% confidence interval of 1.7%).

The scatter plot of the study results for capillary samples with ATE and LER zones is presented by the figure:



Results of CLIA Waiver Study (continued)

The descriptive statistics of the differences between YSI glucose and Nova StatStrip results of capillary samples are presented by the table below:

Range of Dade values (mg/dL)	Average Difference	2.5th percentile of relative differences	97.5th percentile of relative differences
31 to 75	1.49 mg/dL	-3 mg/dL*	5.8 mg/dL
75.1 to 97	1.36 %	-15.77 %	13.81 %
97.1 to 114	1.55 %	-10.9 %	11.89 %
114.1 to 585	-0.39%	-14.53 %*	10.14 %

*Due to small sample size, the minimum was used.

Results of CLIA Waiver Study (continued)

Please note that the upper one-sided 95% confidence bound for capillary was 1.7% due to small sample size.

The results of the study for neonatal capillary samples were following:

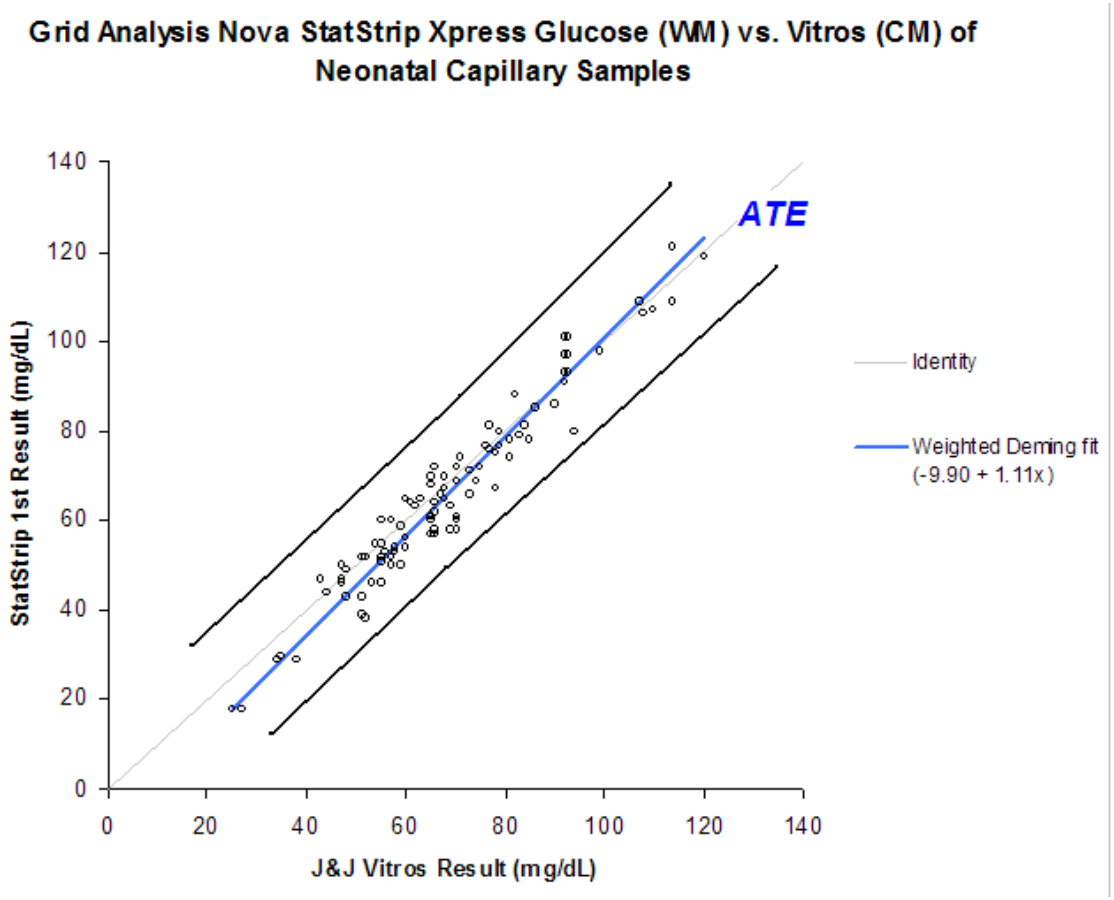
Range of Vitros values (mg/dL)	Total number of samples	Number of samples within of ATE	Percent of samples within of ATE
<75	65	65	100%
75 - 97	24	24	100%
97.1 to 114	7	7	100%
> 114	4	4	100%
Total	100	100	100%

Results of CLIA Waiver Study (continued)

The percentage of the neonatal capillary samples over the entire range that fall within the ATE zone was 100% (100/100) with a lower one-sided 95% confidence bound (score method) of 97.4%. In the study, no samples were in the LER zone (0% with an upper one-sided 95% confidence bound of 2.6%).

Results of CLIA Waiver Study (continued)

The scatter plot of the study results for neonatal capillary samples with ATE and LER zones is presented by the figure:



The descriptive statistics of the differences between Vitros (Johnson & Johnson) glucose and Nova StatStrip results of neonatal capillary samples are presented by the next table:

Results of CLIA Waiver Study (continued)

Range of Dade values (mg/dL)	Average Difference	2.5th percentile of relative differences	97.5th percentile of relative differences
18 to 75	-3 mg/dL	-12.75 mg/dL	5 mg/dL
75.1 to 97	-1.3 %	-14.9 %*	9.1 %
97.1 to 114	-0.4 %	-4.4 %*	6.1 %**
114.1 to 396	-1.1 %	-3.6 %*	2.2 %**

* Due to small sample size, the minimum was used.
** Due to small sample size, the maximum was used.
Please note that the upper one-sided 95% confidence bound for neonatal capillary samples was 2.6% due to small sample size.

Warranty

Subject to the exclusions and upon the conditions specified below, Nova Biomedical or the authorized Nova Biomedical distributor warrants that he will correct free of all charges including labor, either by repair, or at his election, by replacement, any part of an instrument which fails after delivery to the customer because of defective material or workmanship. This warranty does not include normal wear from use and excludes: (A) Service or parts required for repair of damage caused by accident, neglect, misuse, altering the Nova equipment, unfavorable environmental conditions, electric current fluctuations, work performed by any party other than an authorized Nova representative or any force of nature; (B) Work which, in the sole and exclusive opinion of Nova, is impractical to perform because of location, alterations in the Nova equipment or connection of the Nova equipment to any other device; (C) Specification changes; (D) Service required to parts in the system contacted or otherwise affected by expendables or reagents not manufactured by Nova which cause shortened life, erratic behavior, damage or poor analytical performance; (E) Service required because of problems, which, in the sole and exclusive opinion of Nova, have been caused by any unauthorized third party; or (F) Instrument refurbishing for cosmetic purposes. All parts replaced under the original warranty will be warranted only until the end of the original instrument warranty. All requests for

warranty replacement must be received by Nova or their authorized distributor within thirty (30) days after the component failure. Nova Biomedical reserves the right to change, alter, modify or improve any of its instruments without any obligation to make corresponding changes to any instrument previously sold or shipped. All service will be rendered during Nova's principal hours of operation. Contact Nova for specific information.

The following exceptions apply:

- Consumable items, including quality control solutions, are warranted to be free of defects until the end of the expiration date or 90 days after the date opened. Glucose Test Strips are warranted to be free of defects until the end of the expiration date or 180 days after the date opened. The item must be placed into service prior to the expiration date printed on the packaging.
- Freight is paid by the customer.

This warranty is invalid under the following conditions:

1. The date printed on the package label has been exceeded.
2. Non-Nova Biomedical reagents or controls are used, as follows: Nova Biomedical will not be responsible for any warranty on Nova StatStrip Xpress Glucose Hospital Meter if used in conjunction with and are adversely affected by reagents, controls, or other material not manufactured by Nova but which contact or affect such parts.

Warranty

THE FOREGOING OBLIGATIONS ARE IN LIEU OF ALL OTHER OBLIGATIONS AND LIABILITIES INCLUDING NEGLIGENCE AND ALL WARRANTIES, OF MERCHANTABILITY OR OTHERWISE, EXPRESSED OR IMPLIED IN FACT BY LAW AND STATE OUR ENTIRE AND EXCLUSIVE LIABILITY AND BUYER'S EXCLUSIVE REMEDY FOR ANY CLAIM OF DAMAGES IN CONNECTION WITH THE SALE OR FURNISHING OF GOODS OR PARTS, THEIR DESIGN, SUITABILITY FOR USE, INSTALLATION OR OPERATION. NOVA BIOMEDICAL WILL IN NO EVENT BE LIABLE FOR ANY SPECIAL OR CONSEQUENTIAL DAMAGES WHATSOEVER, AND OUR LIABILITY UNDER NO CIRCUMSTANCES WILL EXCEED THE CONTRACT PRICE FOR THE GOODS FOR WHICH THE LIABILITY IS CLAIMED.

EC REP **Authorized Representative**

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Aston Lane South, Runcorn
Cheshire, WA7 3FY UK

Telephone: + 44 1928 704040
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