For Export Only

IVD CE


# Nova StatStrip® Xpress-i Glucose and ß-Ketone Hospital Meter Instructions for Use Manual

nova® biomedical

# Table of Contents

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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

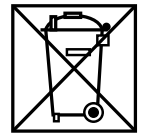
EC REP — Authorized Representative in the European Community

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-i Glucose and ß-Ketone Hospital Meter.

***Unit of Measure Disclaimer***

The StatStrip Xpress-i Glucose and ß-Ketone Hospital Meter is factory set to report glucose results in mg/dL or mmol/L and ketone results in mmol/L.

***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

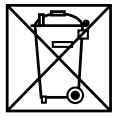
## *Electrical Safety*

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.

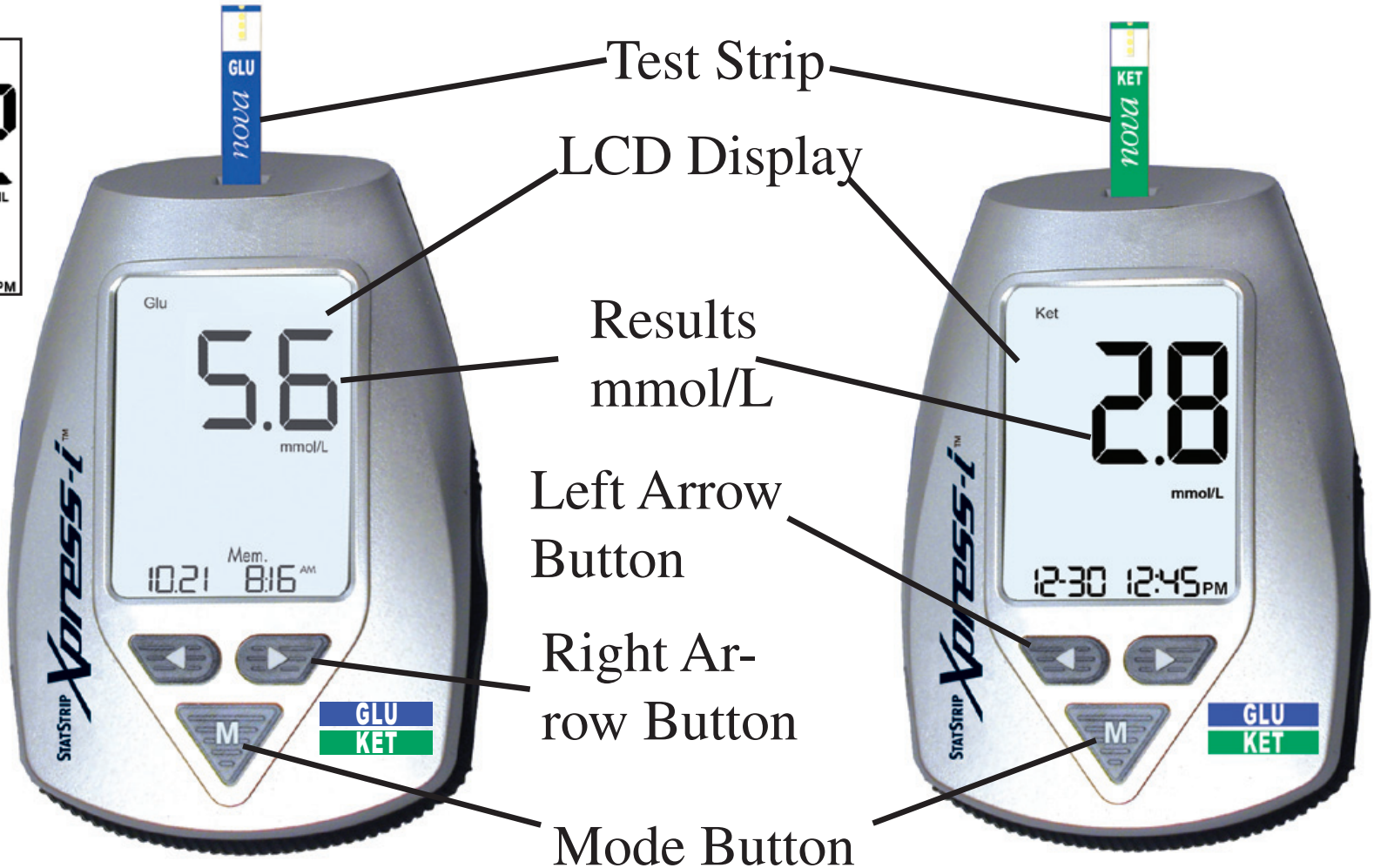
***Disposal of Used Meters for customers in Europe:***

- 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: 5˚C to 40˚C (41˚F to 104˚F)
- 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)

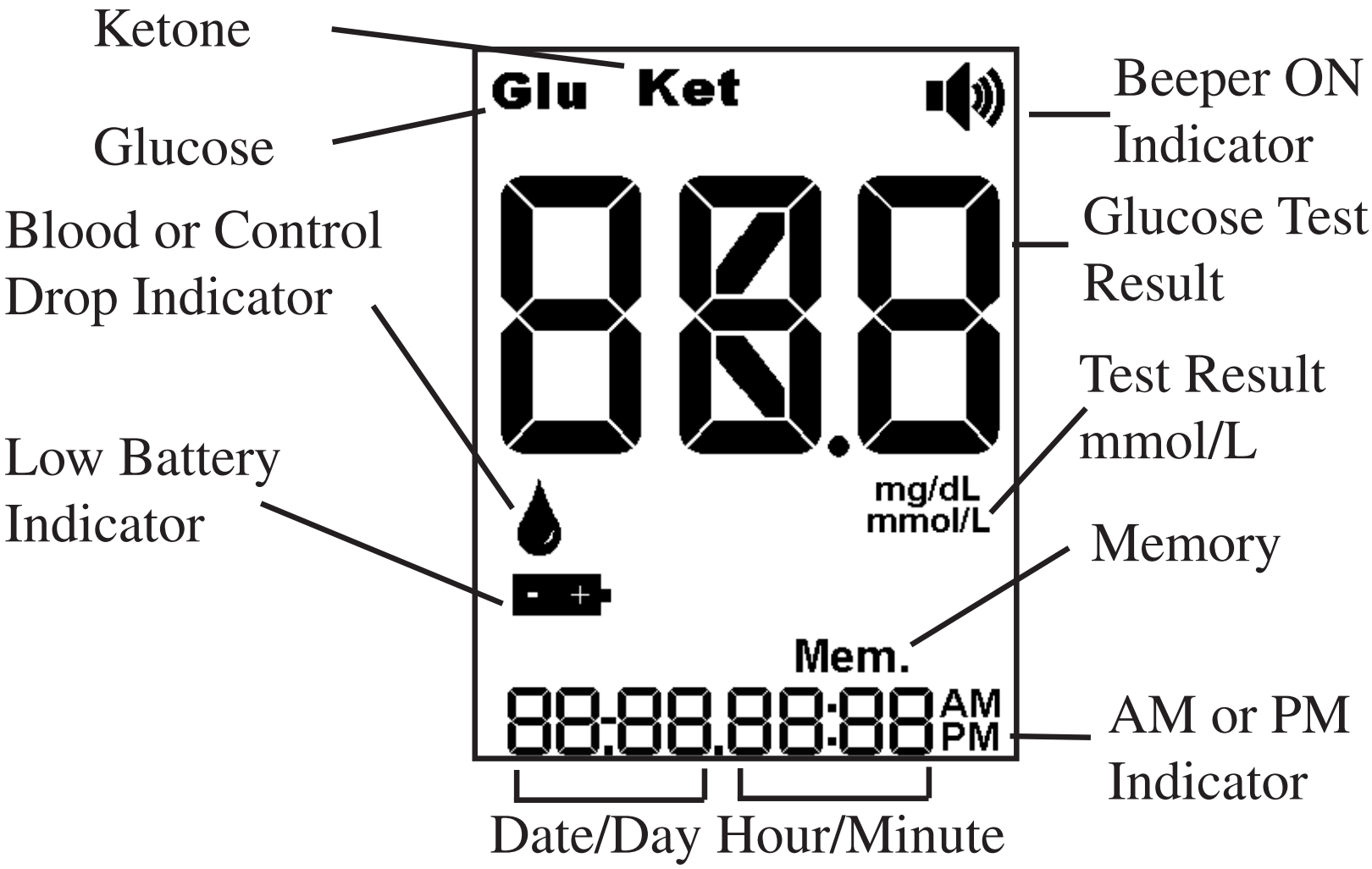

Results
mg/dL




Glucose Result

Ketone Result

***Nova StatStrip Xpress-i Glucose and ß-Ketone Hospital Meter***




***Nova StatStrip Xpress-i Glucose and β-Ketone Hospital Meter Screen***

***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-i Glucose and ß-Ketone Hospital Meter System is intended for *in vitro* diagnostic use by health care professionals and for point-of-care usage in the quantitative measurement of Glucose (Glu) in fresh capillary, venous, arterial, and neonate whole blood and the quantitative determination of ß-Ketone (Ket) in fresh capillary and venous whole blood samples. It is not for diagnosis or screening for diabetes. It is intended for **Export Only**.

# Introduction

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

***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.***

***CAUTION:*** *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.*

# Introduction

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

The Nova StatStrip Xpress-i Glucose and ß-Ketone Hospital Meter is a hand-held, battery-powered, *in vitro* diagnostic laboratory instrument that works in conjunction with Nova Biomedical electrochemical test strips to measure glucose and ketone 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 measurement of glucose is used in the monitoring of carbohydrate metabolism disturbances including diabetes mellitus, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Ref. 1. Burtis, Carl A. and Ashwood, Edward R., ed. 1999. *Tietz Textbook of Clinical Chemistry.* Philadelphia, PA: W. B. Saunders Co.

## The Sample

- Whole blood
- Plasma calibrated patient test results
- Sample size 1.2 µL

## Interfering Substances

### *Glucose Interferences:*

The Nova StatStrip Xpress-i Glucose and ß-Ketone Hospital Meter exhibits **no** interference for glucose 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) |

# Introduction

***Ketone Interferences:***

The Nova StatStrip Xpress-i Glucose and ß-Ketone Hospital Meter exhibits **no** interference for ß-Ketone from the following substances up to the following concentration levels:

| Substances | Concentration mg/dL | (mmol/L) | Substances | Concentration mg/dL | (mmol/L) |
|---|---|---|---|---|---|
| Acetaminophen | 20.0 | (1.32) | Ibuprofen | 48 | (2.33) |
| Acetone | 10 | (1.72) | L-Dopa | 10 | (0.51) |
| Aceteactate | 10 | (0.93) | Methyl-Dopa | 1 | (0.042) |
| Ascorbic Acid | 20 | (1.14) | N-Acetyl-L-Cysteine | 10 | (0.61) |
| Bilirubin | 10 | (0.18) | Tetracycline | 30 | (0.62) |
| Captopril | 10 | (0.46) | Tolazamide | 15 | (0.48) |
| Cholesterol | 500 | (12.9) | Tolbutamide | 45 | (1.67) |
| Creatinine | 6 | (0.53) | Triglycerides | 75 | (0.88) |
| Dopamine | 10 | (0.53) | Salicylate | 30 | (1.87) |
| Ephedrine | 0.9 | (0.035) | Uric Acid | 20 | (1.05) |
| Glucose | 900 | (50.0) | | | |

## 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 for glucose and 10 seconds for ketone.
- 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.

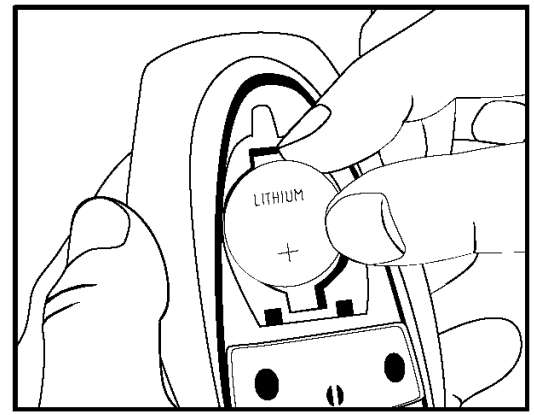
# Setup

This section describes how to setup the Nova StatStrip Xpress-i Glucose and ß-Ketone 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.

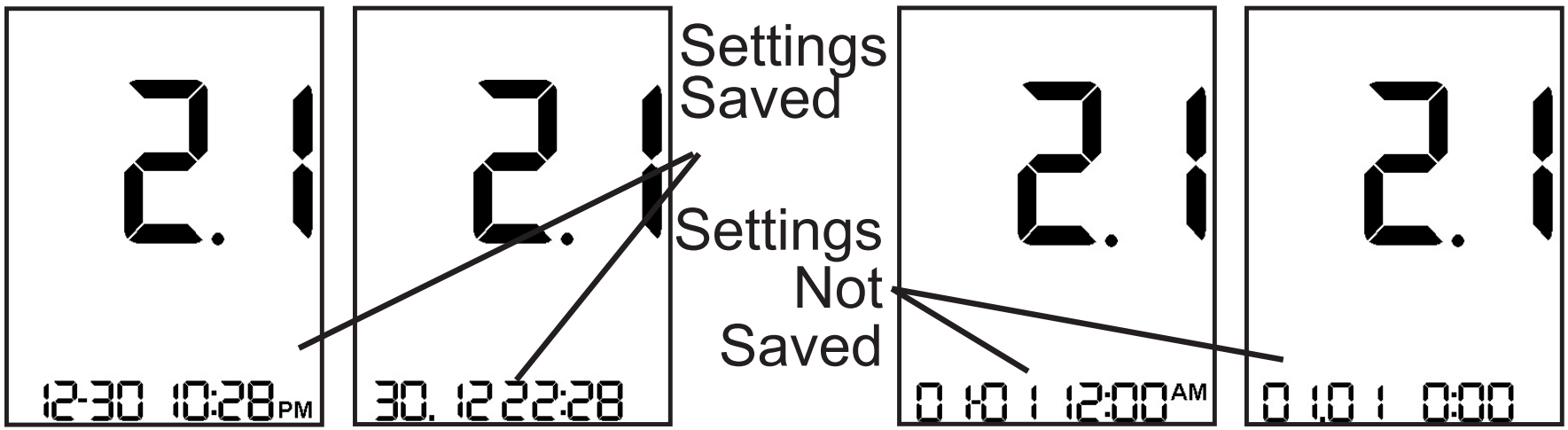
## Installing the Battery (Replacing)

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 current date and time will appear for 3 seconds then the screen will go blank.
4. If this is the initial installation, go to setup.
   If this is a battery replacement and the battery was replaced successfully within the time limit (30 seconds), all setup settings will be saved.

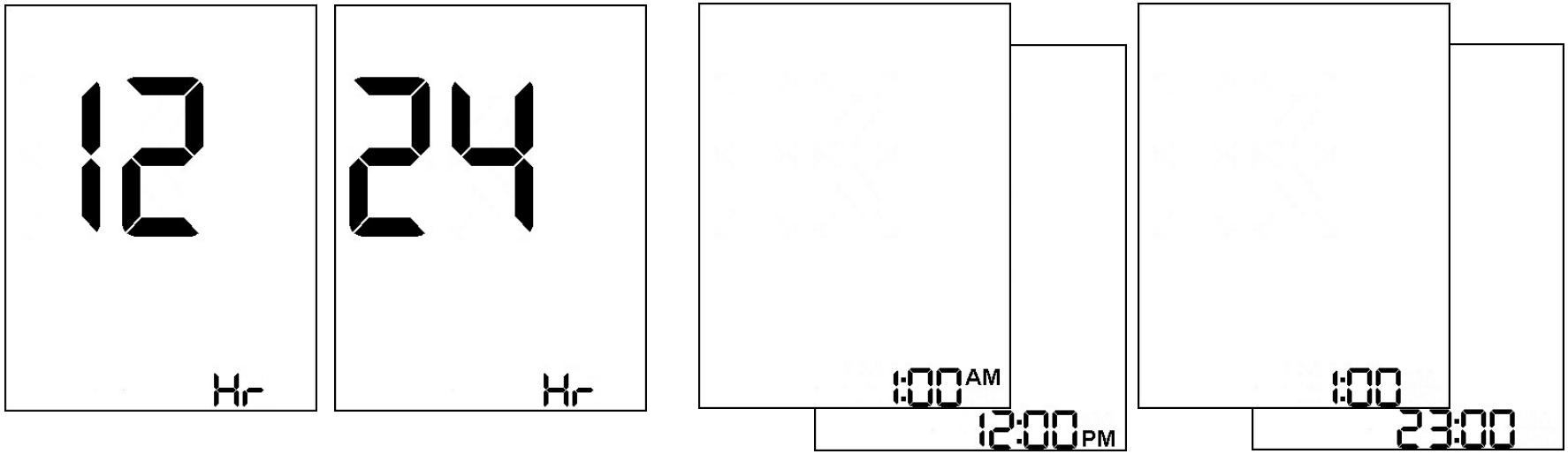


If this is a battery replacement and the battery was not replaced within the time limit (30 seconds), the time and date settings may be lost. The software version and the default date and time will appear for 3 seconds. Go to setup to configure the meter.

## 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.

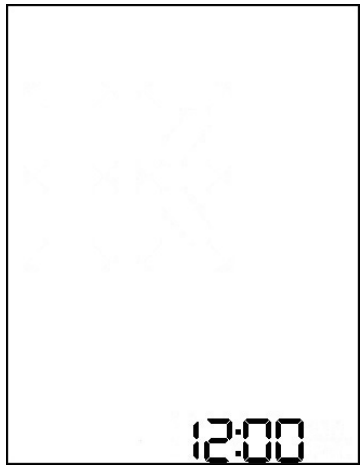
# Setup

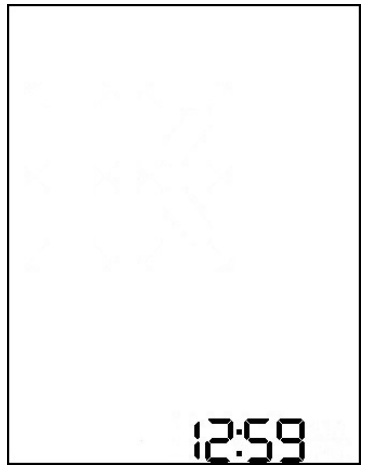



3. Press the MODE button to accept the Hour Format.
4. The meter displays the current time or the default time with the hour digits flashing.
5. Press the Right/Left Arrow buttons to scroll from 1AM to 12PM (for 12 Hr Clock) or 0 to 23 (for 24 Hr Clock).
6. Press the MODE button to accept the displayed Hour choice.

# Setup

7. Next set the minutes (digits flashing). Press the Right/Left Arrow  buttons to scroll from 00 to 59 minutes.



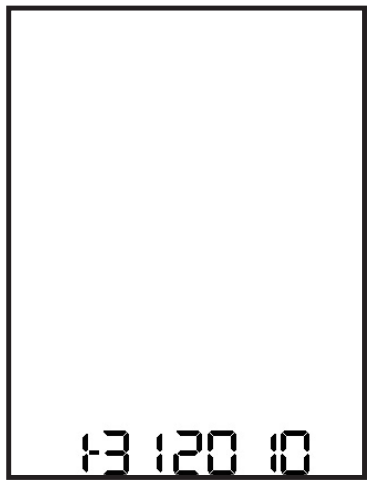



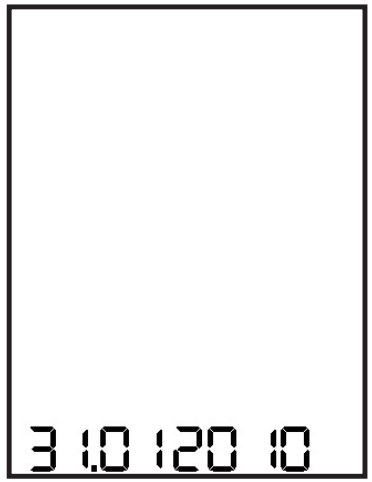

8. Press the MODE 

button to accept the displayed Minutes choice.

## Set Date Format

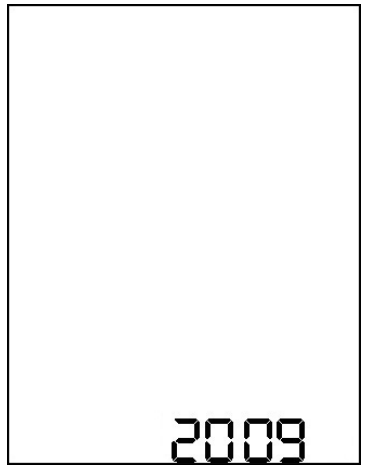
1. Next set the date format. The display is 1-31 2010 or 31.01.2010.
2. You can choose to have the date displayed as DD.MM or MM-DD. Press the Right/Left Arrow   buttons to toggle between DD.MM or MM-DD.

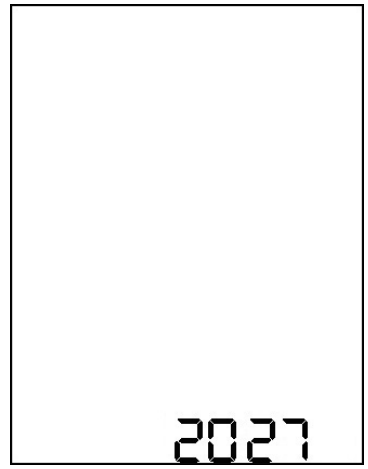



3. Press the MODE  button to accept the displayed Date Format.

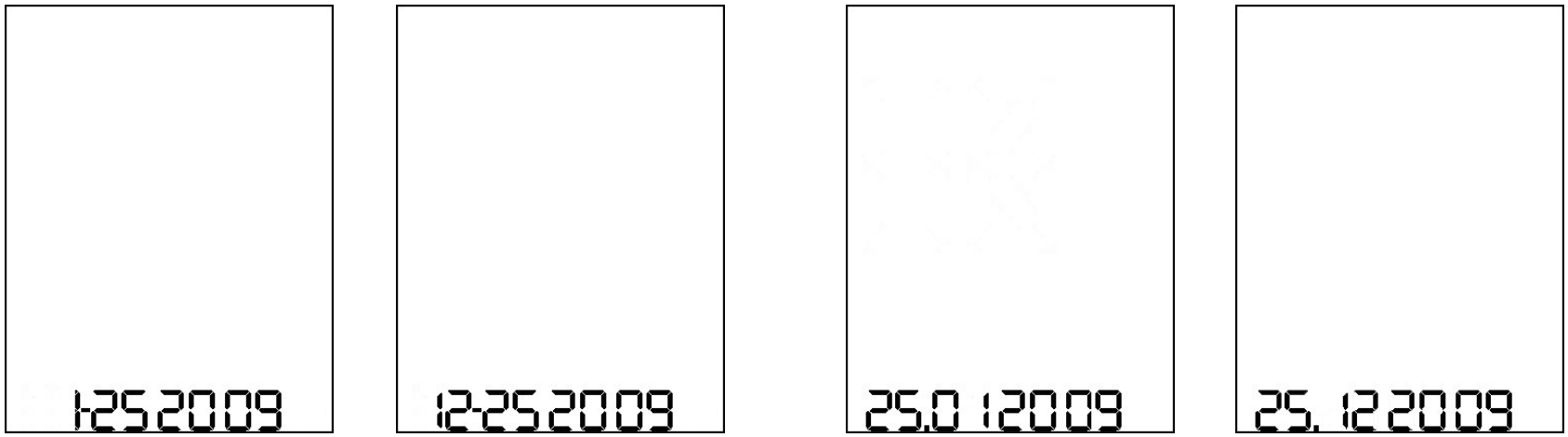
4. The year should be flashing. Press the Right/Left Arrow buttons to select the current year.



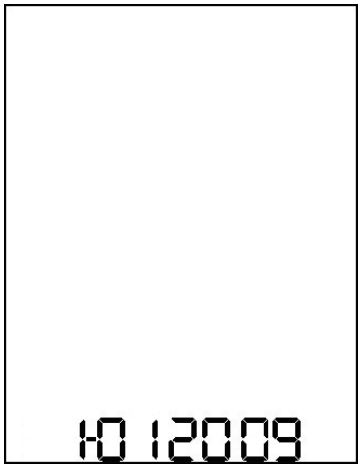

5. Press the MODE button to accept the displayed Year.

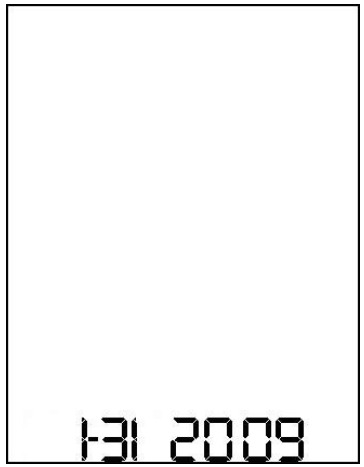
6. The month should be flashing. Press the Right/ Left Arrow buttons to scroll through the 12 months (1 to 12).

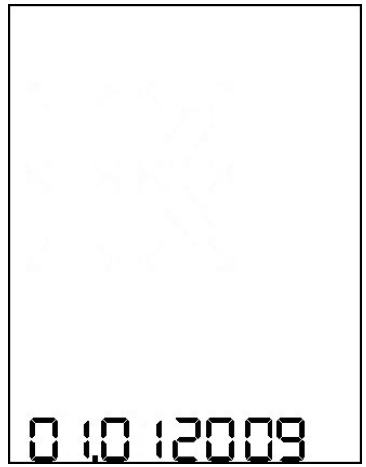


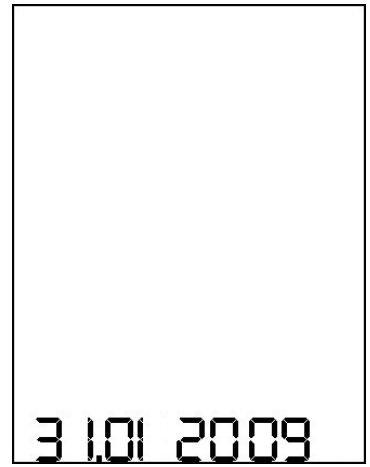

7. Press the MODE button to accept the displayed Month.

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





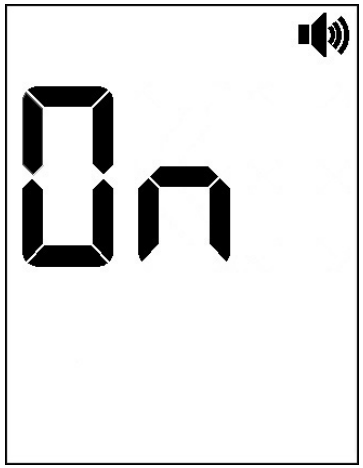





9. Press the MODE button to scroll the displayed Day.

## Beeper On or Off

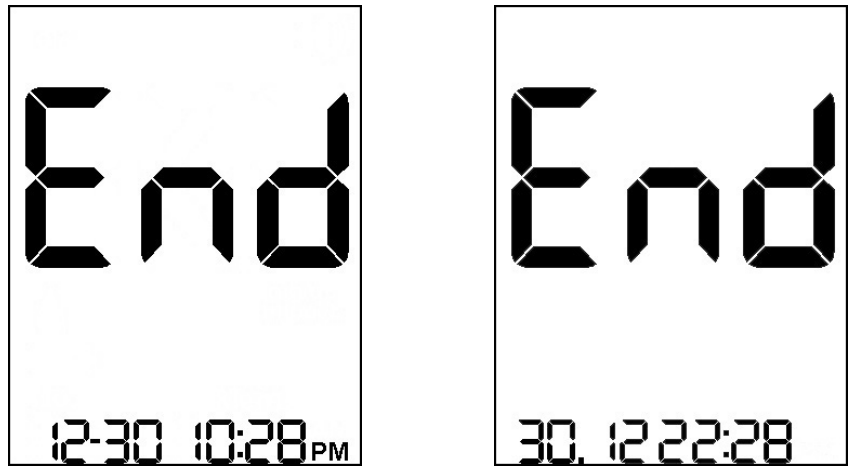
1. Press the Right/Left Arrow buttons to toggle between Beeper ON or OFF (flashing).





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.

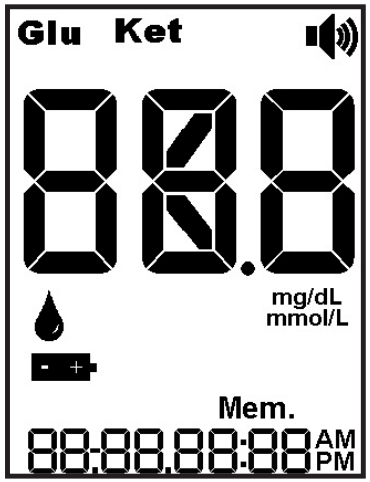


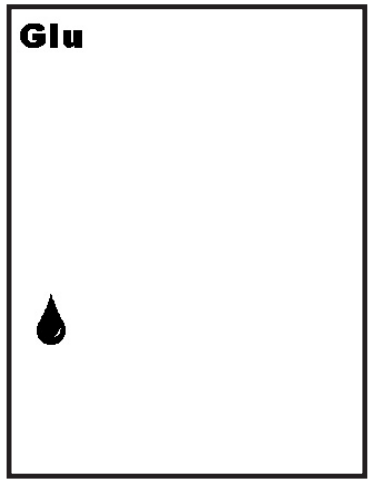
## Testing Glucose: QC/Linearity/Proficiency/Blood Samples

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

## Testing a Glucose Quality Control Solution

1. Insert a glucose test strip into the meter. All segments of the screen will display for 2 seconds. Then a flashing blood drop will display.

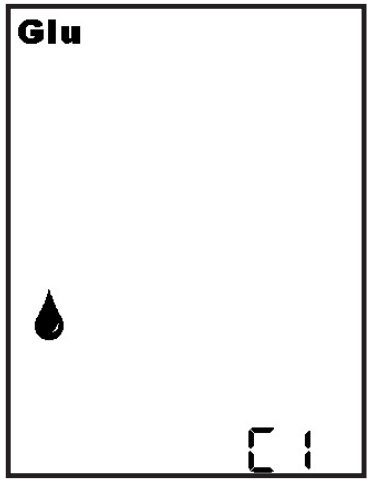


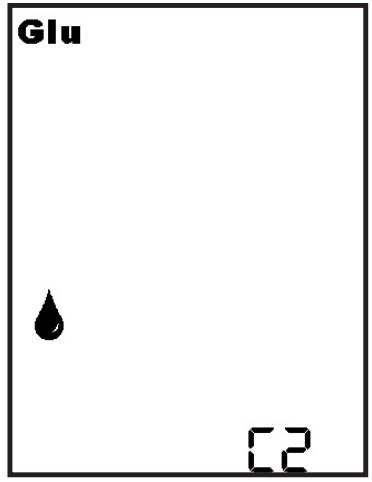



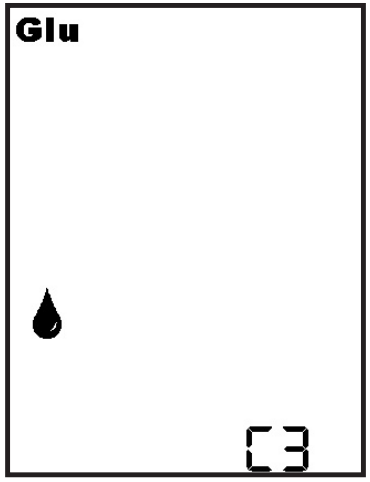

***NOTE:*** *If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.*

## Testing a Glucose 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.



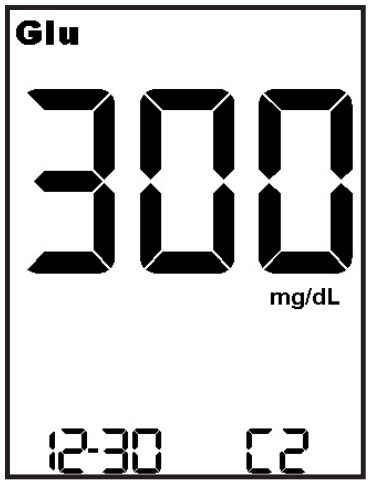

3. Touch the end of the test strip to a drop of control solution until the test strip fills and the meter beeps.

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

## Testing a Glucose Quality Control Solution

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

Result Displayed in **mg/dL**





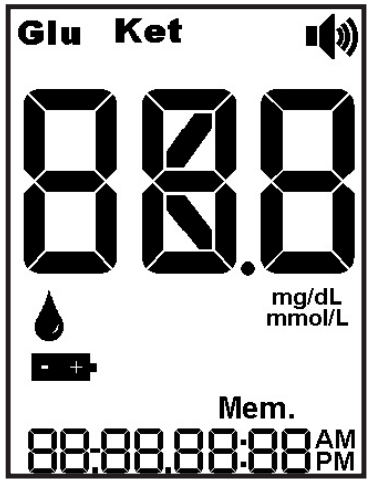
Result Displayed in **mmol/L**

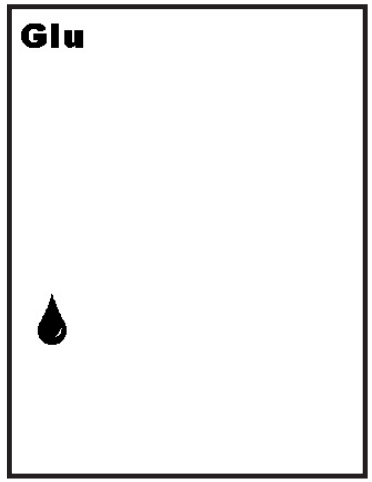
5. There is one long beep when the results are ready. There are 3 short beeps if test results are outside the measurement range of the test strip.

# Testing a Glucose Blood Sample

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

1. Insert a glucose test strip into the meter. All segments of screen will display for 2 seconds. Then a flashing blood drop will display.

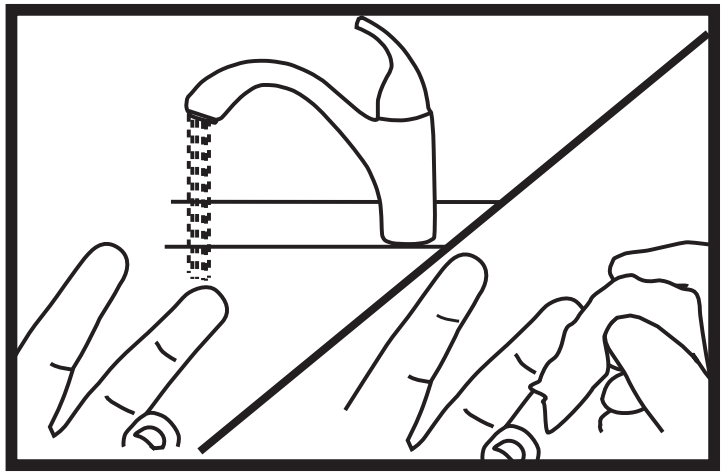



***NOTE:*** *If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.*

# Testing a Glucose Blood Sample

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

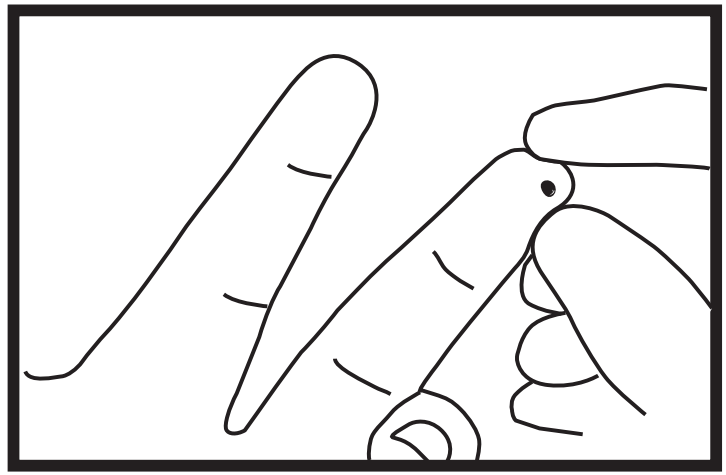


3. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.

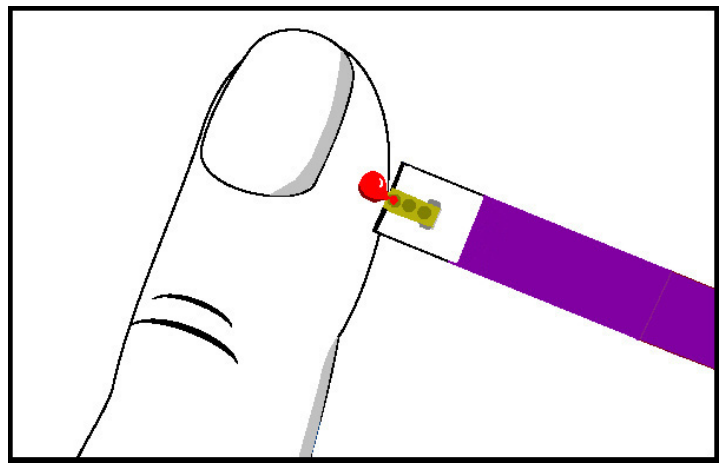
4. Use a lancet to puncture the finger.

# Testing a Glucose Blood Sample

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

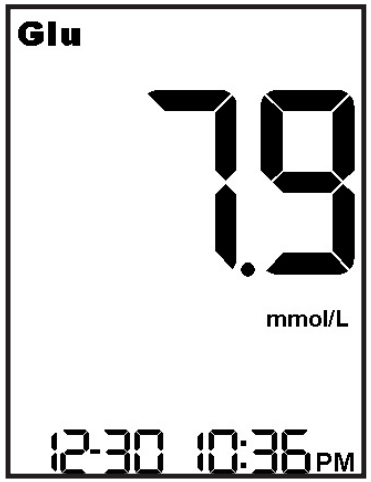


6. When the blood drop appears, touch the end of the test strip to the blood drop until the test strip fills and the meter beeps.



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

# Testing a Glucose Blood Sample

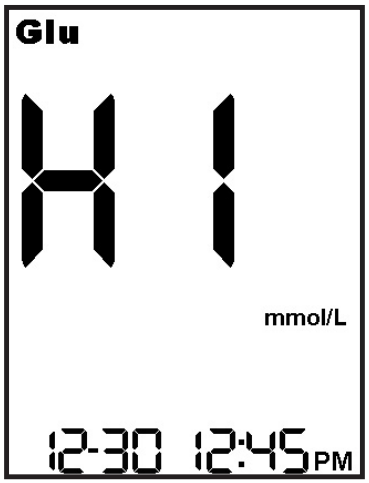




Result in mg/dL Result in mmol/L

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.

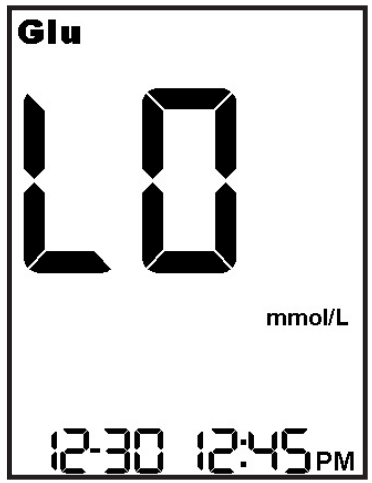
## Testing a Glucose Blood Sample

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




Glucose High
>600mg/dL
>33.3 mmol/L

HI Result



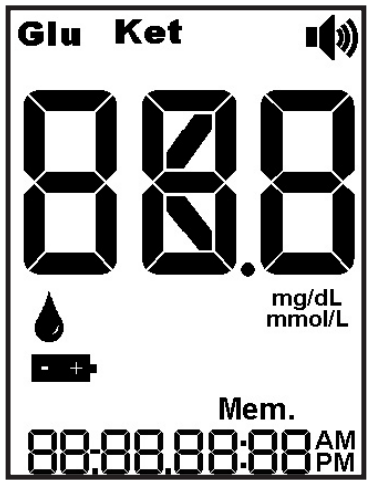

Glucose Low
<10mg/dL
<0.6 mmol/L

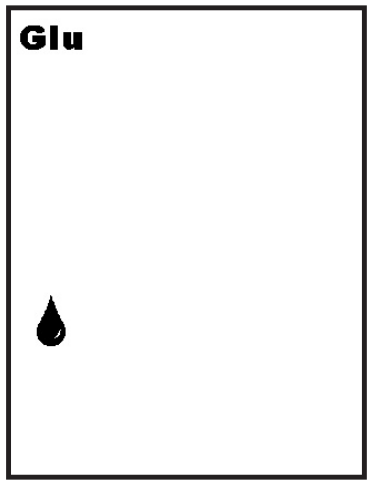
LO Result

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

## Testing a Glucose Linearity/Proficiency Solution

1. Insert a glucose test strip into the meter. All segments of screen will display for 2 seconds. 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.*

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.

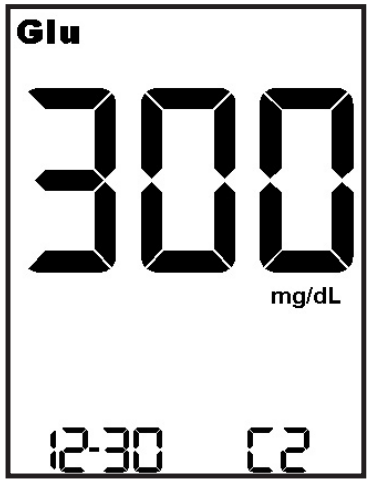
## Testing a Glucose Linearity/Proficiency Solution

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

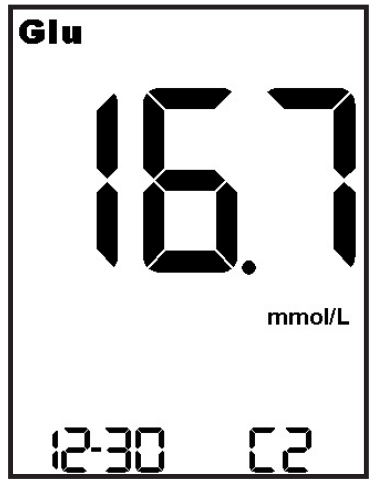
***NOTE:*** *A quick beep sounds when sufficient linearity/ proficiency solution has been added to the test strip.*

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

# Testing a Glucose Linearity/Proficiency Solution




Result in mg/dL




Result in mmol/L

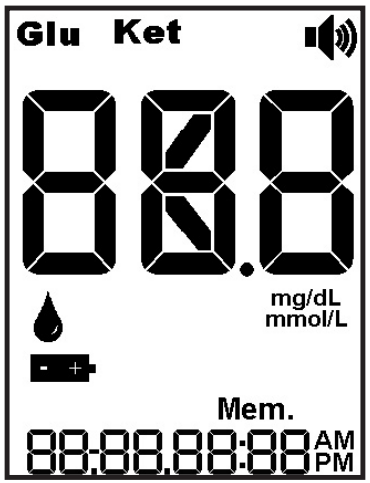
4. There is one long beep when the results are ready. There are 3 short beeps if test results are outside the measurement range of the test strip.

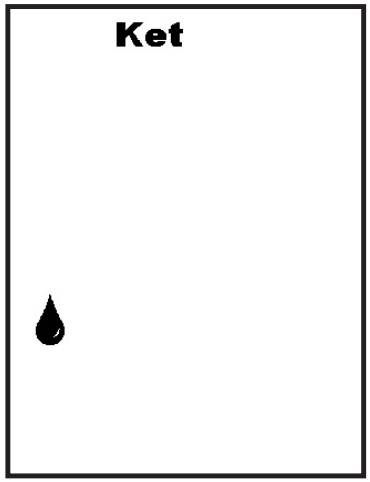
## Testing Ketone: QC/Linearity/Proficiency/Blood Samples

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

## Testing a Ketone Quality Control Solution

1. Insert a ketone test strip into the meter. All segments of the screen will display for 2 seconds. Then a flashing blood drop will display.

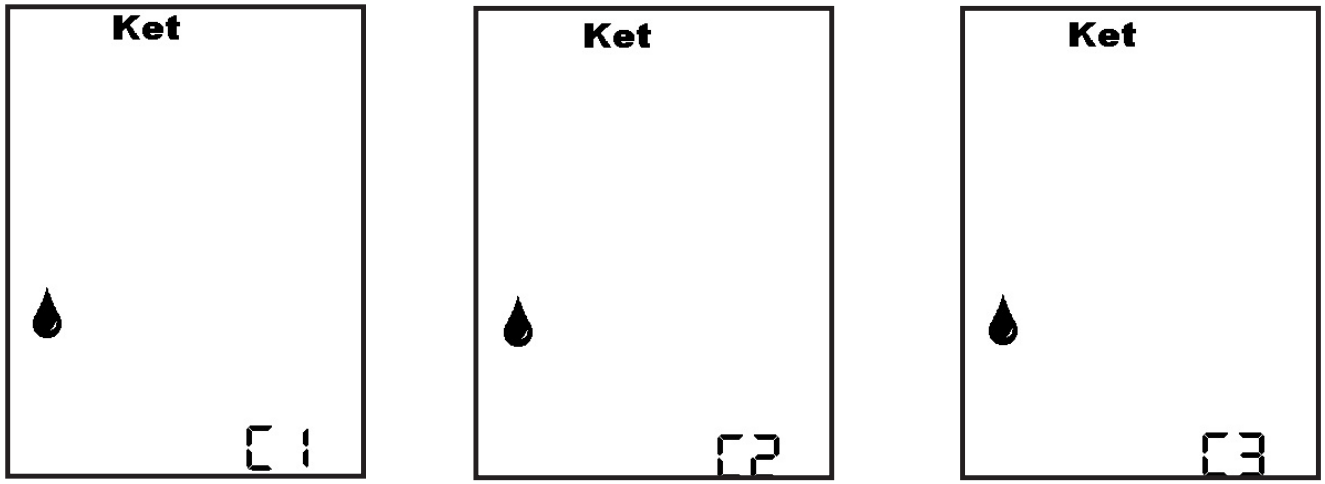



***NOTE:*** *If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.*

## Testing a Ketone 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 Ketone Quality Control Solution

4. Ketone quality control test results are available on-screen in 10 seconds.

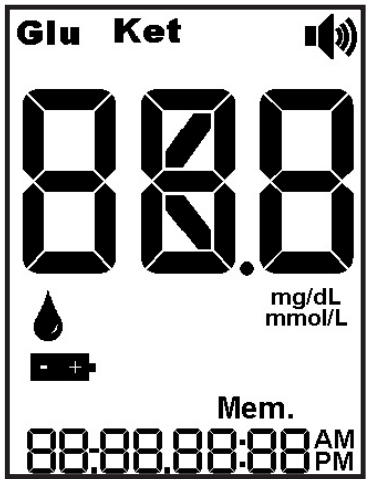

Result Displayed in **mmol/L**

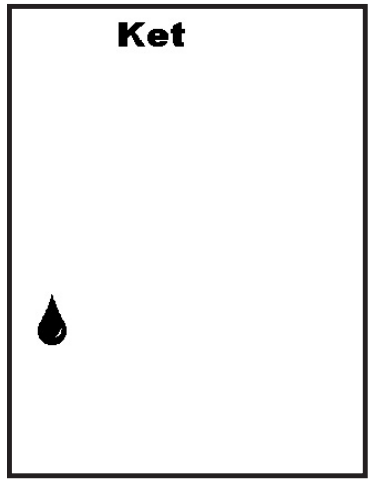
5. There is one long beep when the results are ready. There are 3 short beeps if test results are outside the measurement range of the test strip.

# Testing a Ketone Blood Sample

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

1. Insert a ketone test strip into the meter. All segments of screen will display for 2 seconds. Then a flashing blood drop will display.

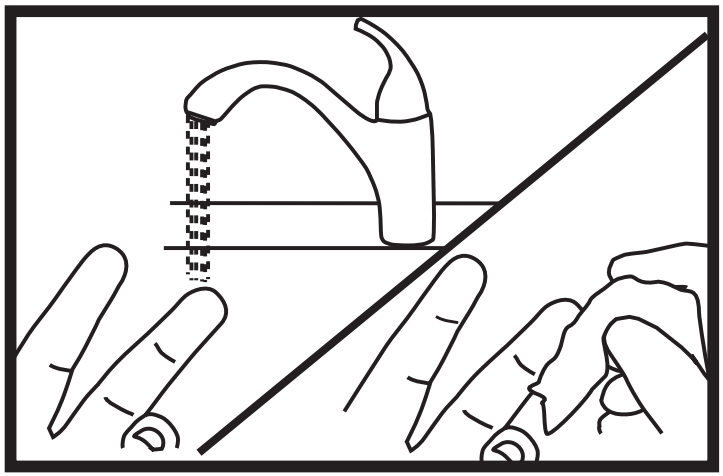



***NOTE:*** *If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.*

# Testing a Ketone Blood Sample

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



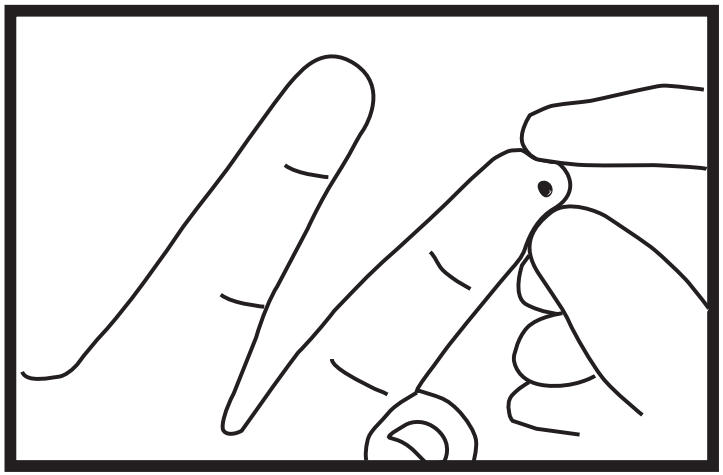
3. Holding hand downward, massage finger with thumb toward tip to stimulate blood flow.

4. Use a lancet to puncture the finger.

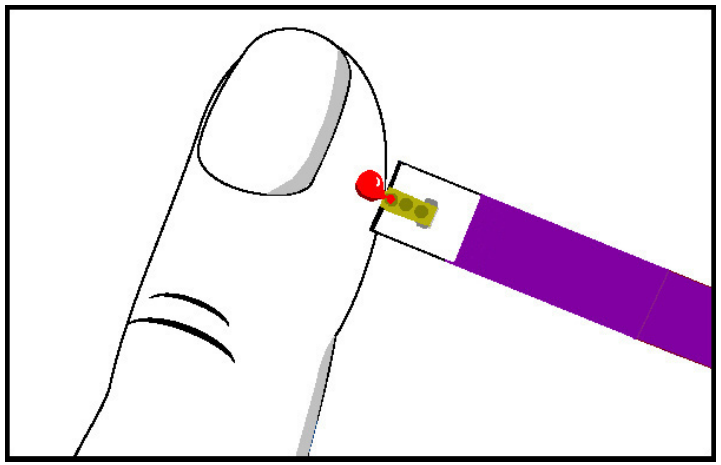
5. Squeeze the finger to form a drop of blood.

# Testing a Ketone Blood Sample

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. Ketone test results are available on-screen in 10 seconds.



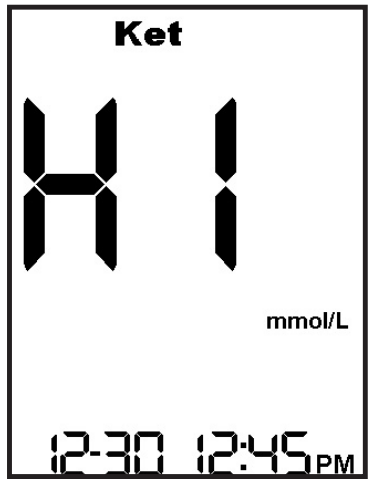
# Testing a Ketone Blood Sample


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 Ketone Blood Sample

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



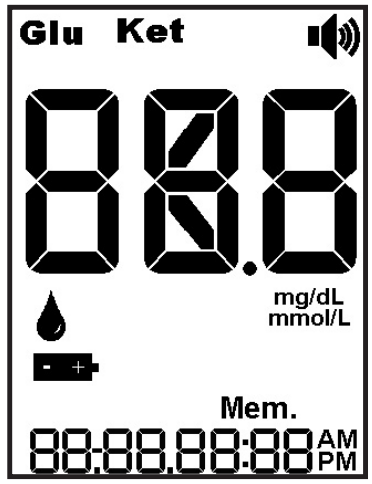

HI Result

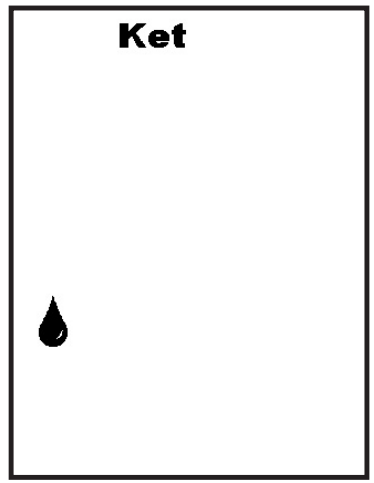
Ketone High
>8.0 mmol/L

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

## Testing a Ketone Linearity/Proficiency Solution

1. Insert a ketone test strip into the meter. All segments of screen will display for 2 seconds. Then a flashing blood drop will display.



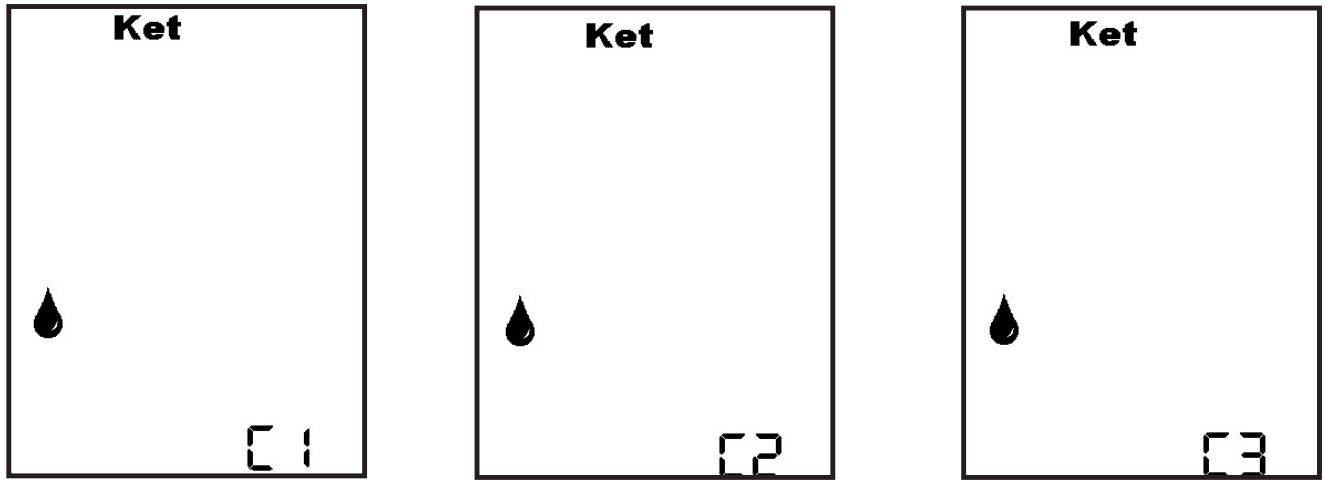




***NOTE:*** *If strip is removed before the test starts or is not used for over 2 minutes, the screen will go blank.*

2. Identify the sample as a Control; use the Left or Right button to find the desired control level:
C1 (for L1 or L2), C2 (for L3), or C3 (for L4 or L5).

## Testing a Ketone Linearity/Proficiency Solution

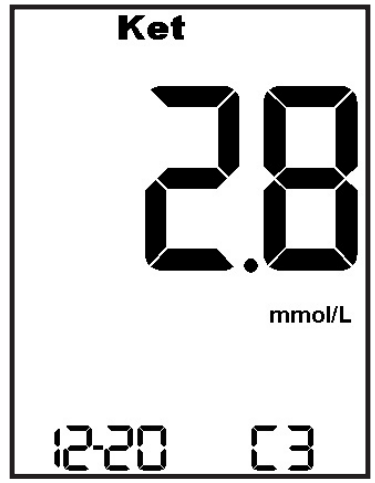
3. Touch the end of the test strip to a drop of linearity solution or proficiency solution until the test strip fills and the meter beeps.




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

4. Linearity or proficiency test results are available on-screen in 10 seconds.

# Testing a Ketone Linearity/Proficiency Solution




Result 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.

## Reviewing Test Results

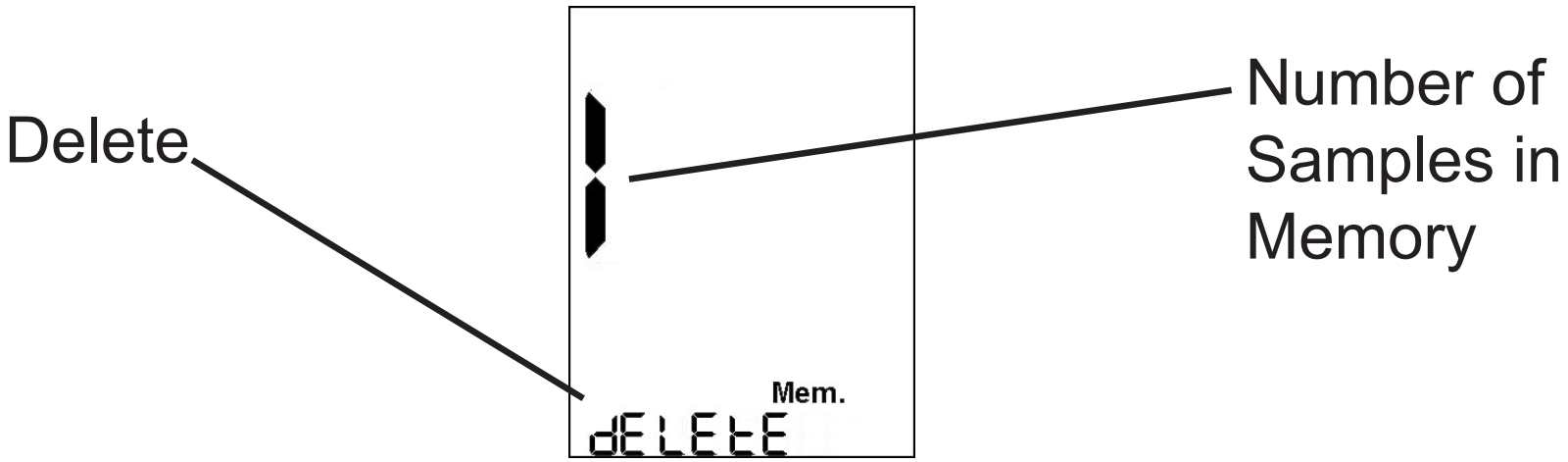
The meter is able to store up to 400 test results.

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

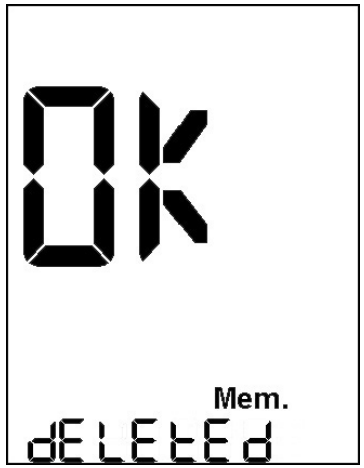
You can delete all stored test and QC results. Proceed as follows to delete all results:

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-i Glucose Ketone Hospital Meter.

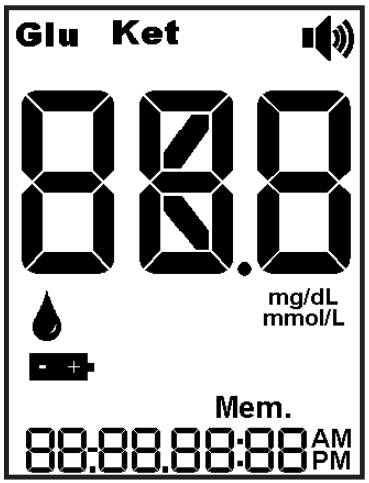
## Battery Check

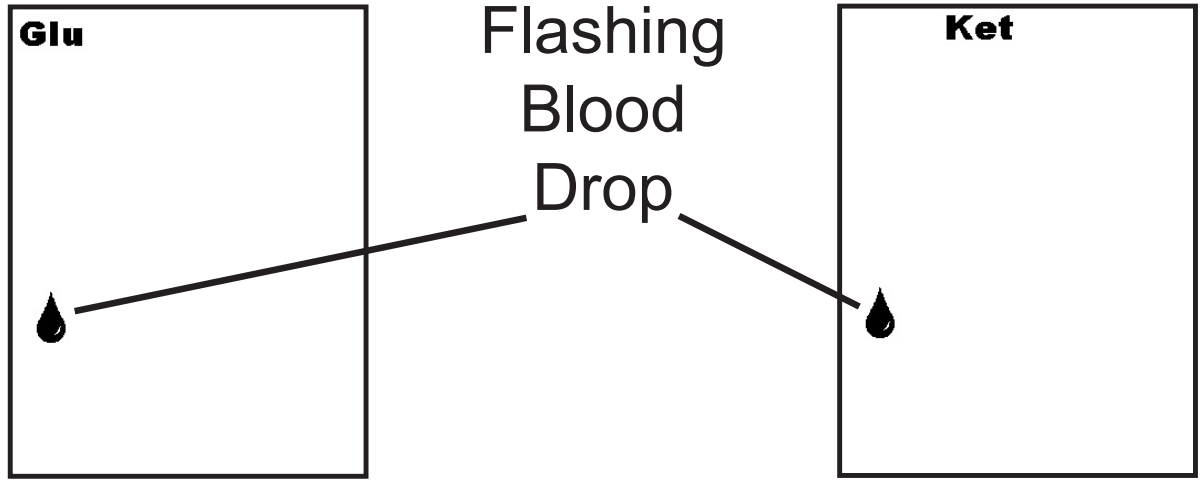
The battery provides sufficient power to operate for approximately 600 tests. A battery low warning will alert the user to replace the battery. Test results are stored in non-volatile memory to prevent test result loss.

# Troubleshooting

How to view the battery status of the meter:

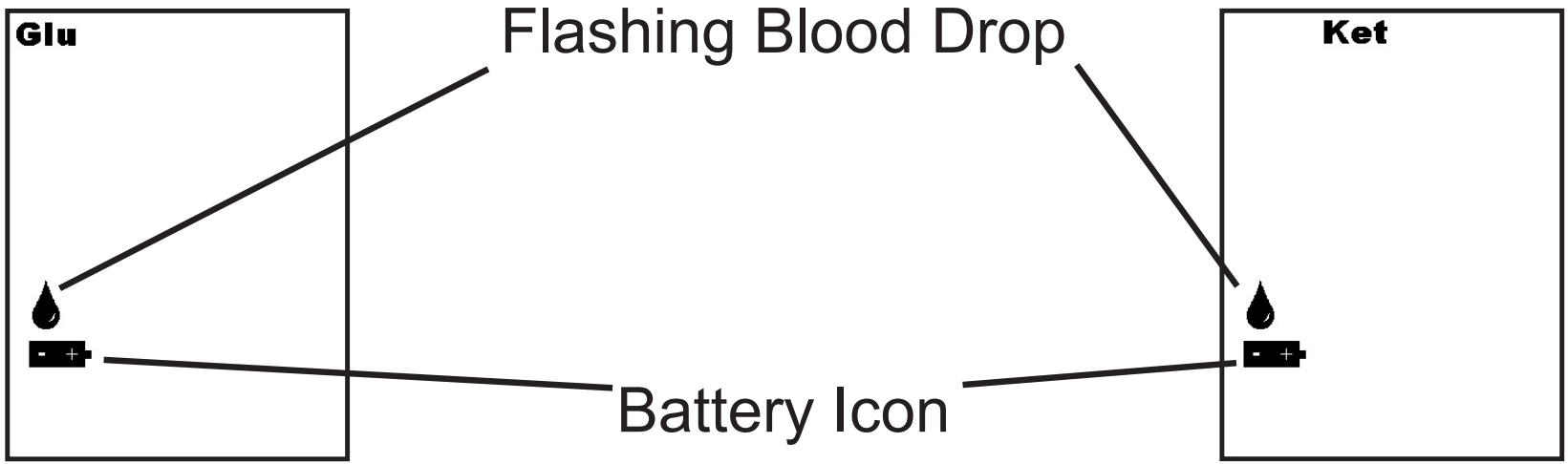
- Insert a test strip to the meter when it is turned off.
- All segments will display for 2 seconds.
- **Battery is OK:** a flashing blood drop appears at the lower left corner of the screen.
  Continue with testing as usual.



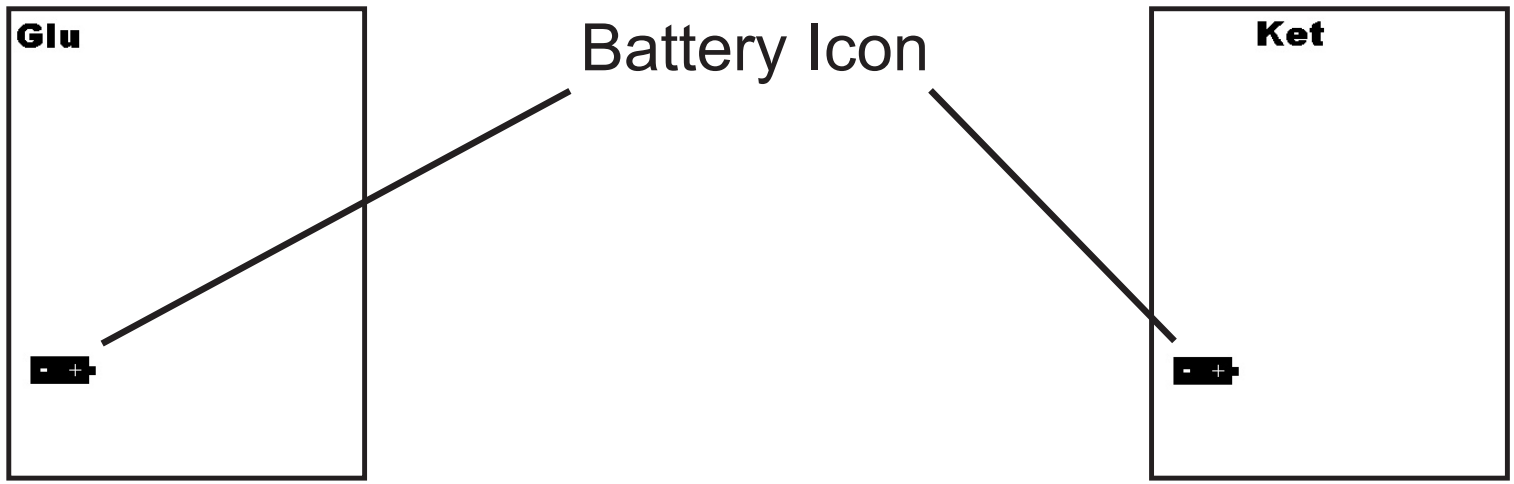
## Troubleshooting

- **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.



## Troubleshooting

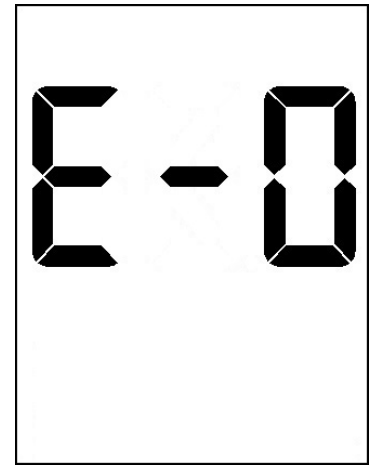
- **Battery is very Low:** battery icon at the lower left corner of the screen: battery charge insufficient for testing.
  Meter will not operate and battery icon disappears when the test strip is removed. Replace the battery.



## Error Codes

There are 7 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.

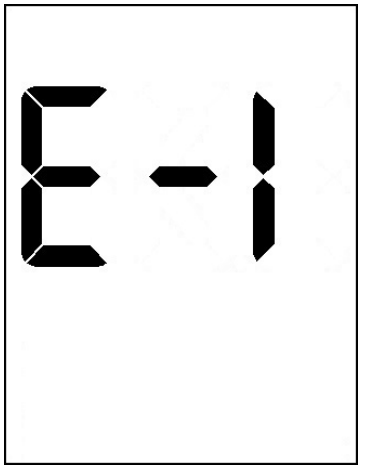
### E0 Software Error




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, contact your local Nova distribu

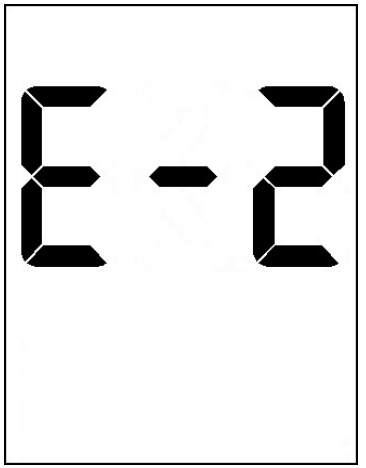
## E1 System Hardware Error




A system hardware error has been detected.

**Action:** Perform the test again. If you get the same error, contact your local Nova distributor.

## E2 Operating Temperature Error



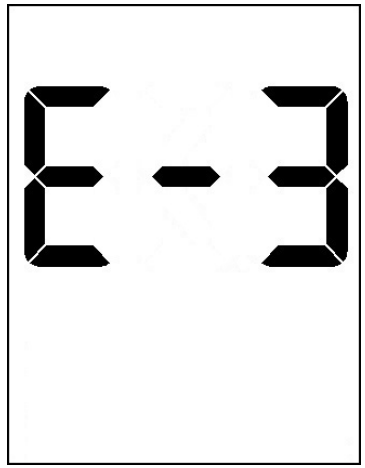

The Meter temperature is outside of the range for testing.

**Action:** Move the meter to an area where the temperature is acceptable (5°-40°C or 41°-104°F), allow meter to adjust to the temperature. Repeat the test.

## E3 Used Strip Error

The test strip was previously used.

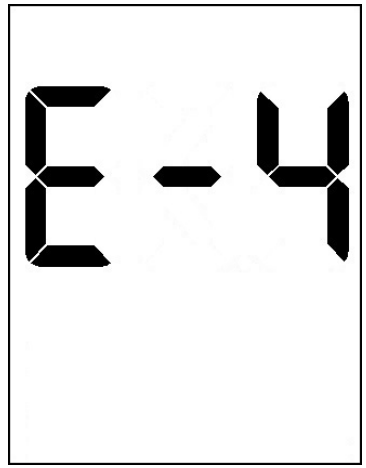
**Action:** Repeat the test with a new test strip.




## E4 Short Sample Error

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

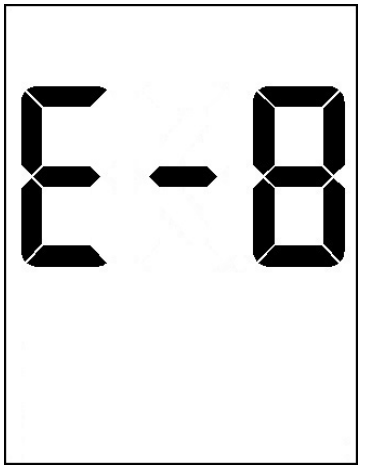
**Action:** Repeat the test with a new test strip.



## E8 Bad Strip Error

The test strip is defective or bad.

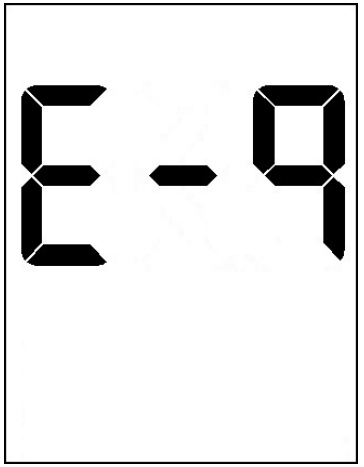
**Action:** Repeat the test with a new test strip.




## E9 Bad Sample Error

A problem was detected with the sample.

**Action:** Repeat the test with a new test strip.



# Appendix

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

# Appendix

## Specifications

| | |
|---|---|
| Tests Measured | Blood Glucose and Ketone (referred to Plasma Values) |
| Glucose Methodology | Enzyme, Amperometric |
| Ketone Methodology | Enzyme, Amperometric |
| Test Results | mmol/L |
| Sample Type | Whole blood |
| Glucose Test Range | 10 to 600 mg/dL or 0.6 to 33.3 mmol/L |
| Ketone Test Range | 0.0 to 8.0 mmol/L |
| Test Time | 6 seconds Glu/10 seconds Ket |
| Test Strip Volumes | 1.2 µL Glu/ 0.6µL Ket |
| Memory storage | 400 Tests |
| Battery Life (nominal) | 600 Tests |
| Battery Type | 2450 3V coin cell |

| | |
|---|---|
| Data Cable | Serial or USB |
| Operating Ranges: | |
| Temperature | 5° to 40°C (41° to 104°F) |
| 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) |

# Appendix

## 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] | 3.6 - 5.3 mmol/L |
| | 64.9 - 95.5 mg/dL |
| Fasting Ketone[2,3] | 0.02 - 0.27 mmol/L |


1. Burtis, Carl A. and Ashwood, Edward R., ed. 1994. *Tietz Textbook of Clinical Chemistry.* Philadelphia, PA: W. B. Saunders Co.
2. Koch, D.D. and Feldbruegge, D.H. 1987. Clin. Chem 33:1761.
3. Li. P.K, et.al. 1980. Clin. Chem. 26:1713.

# Appendix

## 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

## Ketone Methodology

The ketone measurement is based on the following methodology:

1. D-3-hydroxybutyrate + NAD $\xrightarrow{\text{Enzyme}}$ Acetoacetate + NADH + $H^+$

2. Mediator (ox) + NADH ——> Mediator (red) + NAD

3. Mediator (red) $\xrightarrow{-e^-}$ Mediator (ox)

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

# Appendix

## Quality Control Solution

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

## Chemistry Measurement

The typical imprecision for glucose and ketone both for within-run and day-to-day in mmol/L (mg/dL)

| 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

| Ketone Levels (mmol/L) | CV% or S.D. |
|---|---|
| 1 | 0.20 mmol/L (S.D) |
| 3 | 7% |
| 5 | 5% |
| 7 | 5% |

# Appendix

## Ordering Information

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

| DESCRIPTION | REF |
|---|---|
| Instructions for Use Manual | 46952 |
| Quick Reference Guide | 46963 |
| StatStrip Glucose Test Strips (1800), 72 vials, 25 per vial | 42214 |
| Nova StatStrip Glucose and ß-Ketone Control Solution, Level 1 | 46947 |
| Nova StatStrip Glucose and ß-Ketone Control Solution, Level 2 | 46948 |

# Appendix

Nova StatStrip Glucose and ß-Ketone
Control Solution, Level 3 ..... 46949
Nova StatStrip Glucose and ß-Ketone Linearity Kit . 46950
StatStrip ß-Ketone Test Strips .....46951
Battery (DL2450)..... 41221

# Appendix

## 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.*

# 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 within one (1) year from date of shipment 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 instru-

ment 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 the test strips and quality control solutions are warranted to be free of defects until the end of the expiration date or 90 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-i Glucose and ß-Ketone 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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For technical assistance outside the United States, call your local Nova subsidiary or authorized distributor.

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