Nova Max® Plus Glucose and ß-Ketone Monitoring System Owner's Guide

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Outside the USA, contact your Nova supplier.

Made in the USA by Nova Biomedical Corporation
U.S. Patent No. 6,258,229, 6,287,451, 6,837,976, 6,942,770, CA 2,375,089, CA 2,375,092, EP 1 212 609, EP 1 497 446, EP 1 497 449, JP 4050078, and other U.S. and foreign patents pending.

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nova biomedical

THANK YOU

Nova thanks you for choosing the Nova Max Plus Glucose and ß-Ketone Monitoring System. This Owner's Guide contains important information on the monitor and how it works. Please read it carefully before using your new monitor.
The Nova Max Plus Monitor is designed to be convenient and easy to use. It gives accurate results in just 5 seconds (for glucose) or 10 seconds (for ß-ketone) using a very small blood sample. This small sample allows you to use a thinner lancet because not as much blood is needed to do a Glucose or ß-Ketone test. The monitor also has memory that stores your Glucose or ß-Ketone test results to help you and your healthcare professional manage your diabetes, including diabetic ketoacidosis (DKA).
Before you get started, it is important to complete the Warranty Registration Card included in your kit and mail it back to Nova. Or complete the warranty card on www.novacares.com. Doing this will help us better serve your needs.

If you need to contact us, please call Customer Service 24 hours a day, 7 days a week, in the USA at 1-800-681-7390 or visit our website at www.novacares.com.
Outside the USA, contact your Nova supplier.

Privacy Policy: Nova Biomedical, as the manufacturer the Nova Max Plus Monitor, is committed to using your personal information responsibly and in compliance with the law. You have our pledge that we will not share or sell your personal information with marketers or third-parties. The information you voluntarily share with us will be used to help us serve you better in the future.

Important Safety Instructions!

- Before you begin using your new Nova Max Plus Monitor, please read all of the instructions provided in this Owner's Guide.
- Your monitor uses a CR2450 3-volt coin cell battery. To begin using your monitor, you need to install the enclosed battery. See Battery Replacement (page 38) to install a new battery.
- Perform all quality control checks recommended in your Owner's Guide.
- Consult with your diabetes healthcare professional and follow his/her guidance for your blood glucose or ß-ketone monitoring routine.
- The recommendations in this manual apply to all blood glucose and ß-ketone monitors and are supported by the *American Association of Diabetes Educators (AADE), the American Diabetes Association (ADA), the US Food and Drug Administration (FDA), and the Advanced Medical Technology Association (AdvaMed)*.

Notes, Cautions, and Warnings:

NOTES *provide 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.*

Table of Contents

Intended Use

The Nova Max Plus Glucose and ß-Ketone Monitoring System is intended to be used for the quantitative measurement of glucose or ß-hydroxybutyrate (ß-Ketone) in fresh capillary whole blood. It is intended for use by people with diabetes mellitus in the home and by healthcare professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Nova Max Plus Monitor is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood samples obtained from the fingertip, forearm, and palm or ß-ketone in fresh capillary whole blood samples obtained from the fingertip only.

- The Nova Max Plus Monitor is intended for use outside the body (*in vitro* diagnostic use).
- It should only be used with Nova Max Plus Glucose and ß-Ketone Test Strips and Nova Max Plus Control Solutions.
- It should be used for testing glucose (sugar) and ß-Ketone only with fresh capillary whole blood samples.
- It should **NOT** be used to diagnose DKA or to test newborns.
- It should **NOT** be stored in the refrigerator or in the car.

WARNING: *The Nova Max Plus Monitor contains small parts. Keep the monitor out of reach of small children and pets.*
If you have hypoglycemia unawareness, a blood glucose monitor is critical to your care. Since any monitor may fail, break, or be misplaced, you should always have a backup monitor.

Symbols

WARNING: *Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products with care. Wear gloves when performing measurements on another person. Items that are used to measure glucose or ß-ketone, i.e., test strips, lancets, and alcohol swabs, must be disposed of in accordance to local regulations to avoid risk to anyone.*

Symbols

The following are symbols that are used in this manual, on insert sheets, and on the Nova Max Plus Monitor.

IVD *In vitro* diagnostic medical device

Caution, consult accompanying documents

Consult instructions for use

Biological risk

REF Catalog number

Temperature limitation

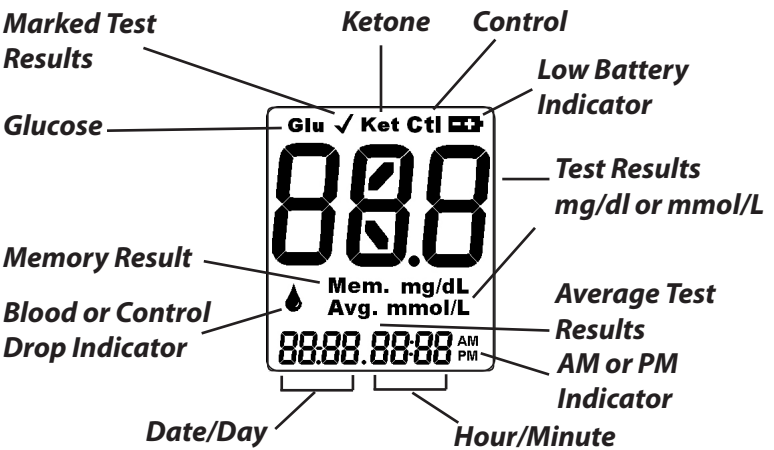
Monitor Components

Nova Max Plus Glucose and ß-Ketone Monitor

Monitor Display

When you turn the Nova Max Plus Monitor on, the all segments display appears briefly. This tells you that all the display segments are working properly.

Remove before use



Nova Max Plus Glucose and ß-Ketone Monitor Screen

Introduction

The Nova Max Plus Glucose and ß-Ketone Monitor

The monitor is a hand-held testing device that measures glucose (sugar) in capillary whole blood and ß-ketone in capillary whole blood. The test strip is touched to a drop of blood to initiate the test process. The monitor activates after a Nova Max Plus test strip is inserted. The screen displays "Glu" or "Ket," depending on which type of Nova Max Strip is inserted. The blue strip measures blood glucose levels, and the green strip measures ß-ketone levels.

- A simple one-step process provides a result.
- Test results are available in 5 (Glu) or 10 (Ket) seconds.
- There is memory for one common user's set of test results (400).
- The monitor is powered by a battery that can perform approximately 1000 tests.

CAUTION: *The monitor should be handled with care. Dropping, rough handling, etc. may damage the monitor. If the monitor is not to be used for an extended period of time, remove the battery to eliminate the risk of battery leakage. Also, protect the monitor from moisture, prolonged direct sunlight, and extreme temperatures.*

Overview

To perform a test, the operator simply inserts a test strip; waits for the blood drop symbol to appear on the screen ("Glu" or "Ket" also appears - the meter is ready); brings the test strip to the drop of blood; and obtains a test result in 5 (Glu) or 10 (Ket) seconds. The test result is automatically stored into the monitor's memory. The operator can recall and review test data stored in the monitor.

Introduction

Kit Contents*

1. Nova Max Plus Monitor
2. Vial of Nova Max Plus Glucose Test Strips (10)*
3. Lancing device*
4. Lancets*
5. Nova Max Glucose Control Solution, Normal (1 bottle)*
6. Battery (CR2450, 3V)
7. Quick Reference Guide
8. Owner's Guide
9. Log Book
10. Warranty Card
11. Two Ketone Test Strips*
12. Carry Case

* Contents are not the same for each kit. Your Nova Max Plus Kit may not have all the items listed above, Consult the Nova Max Plus monitor package for complete contents.

Environmental

- The storage temperature range for the monitor: -13°F to 115°F (-25°C to 46°C)
- The storage temperature range for the Test Strips: 59°F to 86°F (15°C to 30°C)
- The monitor operational temperature range: 57°F to 104°F (14°C to 40°C)
- The relative humidity range: 10% to 90% non-condensing

Introduction

Before Testing

Before testing and to ensure accurate results, wash your hands and the testing site then thoroughly dry these areas.
The Nova Max Plus Monitor can test your blood glucose on the fingers, forearm, or palm. The Nova Max Plus Monitor can test your blood ß-ketone on the **fingers only**.
The sample size is just 0.3 µL (Glu) or 0.8 µL (Ket) of blood.

Reasons to Check for Low Blood Glucose

- You have symptoms such as weakness, sweating, nervousness, headache, or confusion.
- You took insulin, but have delayed eating.
- Your doctor or healthcare professional advises you to do so.

Important Health Related Information

If you are experiencing symptoms that are not consistent with your blood Glucose or ß-ketone test results and you have followed all instructions described in the Owner's Guide, call your doctor or healthcare professional.

Introduction

Glucose Test Strips

The Nova Max Glucose Test Strips are designed for use with your Nova Max Plus Monitor only. Use each test strip only once, then discard. **DO NOT** reapply blood to the test strip.

- Requires a very small blood volume: 0.3 µL (glucose)
- Automatically draws blood into the test area of the strip
- Can be handled with clean, dry hands without affecting readings

Important Nova Max Glucose Test Strip Information

- Use only Nova Max Glucose Test Strips when testing for glucose.
- Remove the test strip from the vial only when ready to test.
- Store the test strip package in a cool, dry place below 86°F (30°C). Do not refrigerate or freeze.
- Do not store near heat or moisture.
- Store the test strips in their original vial only.
- After removing a test strip from the vial, immediately replace the vial cap and close tightly.
- Do not use test strips beyond the expiration date printed on the package as this may cause inaccurate results.

- Test strips should only be stored for 3 months after opening the vial. When first opening a new vial of test strips, count forward 3 months and write that date on the vial. Discard any remaining test strips after the date you have written on the vial.
- Do not tamper with the test strip.

WARNING: *The test strip vial contains small parts. Keep the test strips and vial away from children and pets.*

Ketone Test Strips

The Nova Max Ketone Strips are designed for use with your Nova Max Plus Monitor only. Use each test strip only once, then discard. **DO NOT** reapply blood to the test strip.

- Requires a very small blood volume: 0.8 µL (ketone)
- Automatically draws blood into the test area of the strip
- Can be handled with clean, dry hands without affecting readings

Important Nova Max Ketone Test Strip Information

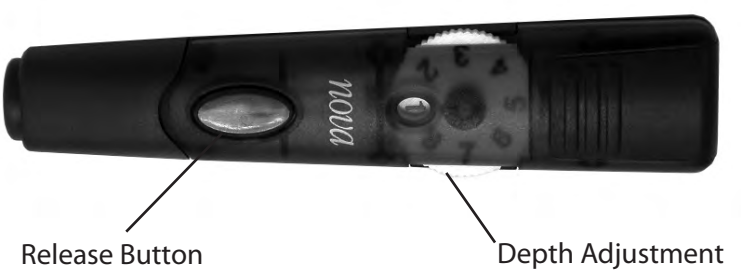
- Use only Nova Max ß-Ketone Test Strips when testing for ketone.
- Remove the test strip from the foil only when ready to test.

- Store the test strip package in a cool, dry place below 86°F (30°C). Do not refrigerate or freeze.
- Do not store near heat or moisture.
- Store the test strips in their original packaging only.
- Do not use test strips beyond the expiration date printed on the package as this may cause inaccurate results.
- Do not tamper with the test strip.

WARNING: *The test strip packaging contains small parts. Keep the test strips and packaging away from children and pets.*

Lancing Device

The diagram below shows the components of the Lancing Device. Refer to the Instructions for Use insert sheet for the Lancing Device for detailed instructions.



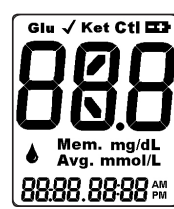
Setting the Time, Date, and Beeper

Having the correct time and date of each blood test result helps you and your healthcare professional track changes in your therapy. It is important to set the correct time and date so you have records of when you tested.

Your Nova Max Plus Monitor offers a beeper function that is pre-set "On." This tells you when enough blood is applied to the test strip, when test is completed, and prompts you through other steps in using your monitor.

NOTE: *Remember to adjust time and date settings as needed to match the local time or daylight savings time and after you replace the battery. Once you have completed a test, the last result will appear the next time your monitor is turned on. The date and time displayed is the date and time of your previous test result, not the current date and time.*

1. Press the MODE M button for longer than 3 seconds. The monitor, if in Sleep Mode, wakes up, displays all segments for 3 seconds, and enters the SETUP Mode.



Setting the Time, Date, and Beeper

This brings the monitor display to the first setup screen: Time.

MODES	SCREEN DISPLAY
Hour (Flashing)	"10":00"AM"
Minutes (Flashing)	10:"55"AM
Year (Flashing)	12-28 "2009"
Month (Flashing)	"12"-28 2009
Day (Flashing)	12-"28" 2009
Beep (ON or OFF)	"ON"
Sample Marking (ON or OFF)	"ON"
END (End of Setup Mode)	"END"

2. Repeatedly press the MODE  button to find the MODE you want to change.

3. Press the left/right arrow  buttons to choose a new setting for that MODE.

4. Press the MODE  button to select the new settings or to skip to the next MODE.

Running Control Solution

Control Solution

Control Solution is a liquid that contains a fixed amount of Glucose or ß-ketone.

- Use these solutions to verify that your monitor and test strips are working properly.
- Use this solution to practice or to check that you are following the correct testing procedure without using your own blood.

If the monitor reading is within the control solution's acceptable range, the meter is working properly.

Perform a Control Solution Test

The control solution test confirms that your monitor and test strips are working correctly. A control solution test is similar to a blood test, except you use Nova Max Control Solution and not a blood sample. You should run a control solution test:

- When you first get your monitor and at least once a week thereafter for glucose
- Each time you open and begin using a new vial of glucose test strips
- If you leave the glucose test strip vial cap open for any length of time
- If the monitor is dropped, damaged, or exposed to liquids
- If you think your test results are not accurate, or if your test results are not consistent with how you feel
- To check the performance of the monitor and test strips
- Nova Max High and Low Glucose Controls and Nova Max Plus ß-Ketone Low and High Controls are also recommended as an additional quality control check for your Nova Max Plus monitoring system.

Running Glucose Control Solution

Important Information for Glucose Control Solution

- Use only Nova Max Glucose Control Solutions for the test.
- Check the expiration date on the control solution vial. Do not use control solution past the expiration date or you may get inaccurate results.
- Store only for 3 months after first opening. When you open a new vial of control solution, count forward 3 months and write that date on the label of the control solution vial. Discard any remaining solution after the date you have written on the vial.
- Store the control solution tightly closed at room temperature below 86°F (30°C). Do not refrigerate or freeze.
- Shake the control solution well before using.

Caution: *The Nova Max Glucose Control Solution range printed on the glucose test strip vial is for control solution only. It is used to test the performance of the monitor and test strip. It is not a recommended range for your blood glucose level.*

If your control solution test results continue to fall outside the range printed on the test strip vial:

- The Nova Max Plus Monitor may not be working properly.
- Do not use the monitor to test your blood.
- Inside the USA, call Customer Service at 1-800-681-7390. Outside the USA, contact your Nova supplier.

Running Glucose Control Solution

Testing a Glucose Quality Control Solution

1. Insert a glucose test strip into the monitor. If monitor was off, the screen displays all segments for 2 seconds then the blinking blood drop symbol and "Glu" appear.

NOTE: *If the strip is removed before you start the test, the screen goes blank.*

2. Press the left/right  buttons to indicate this sample is a control. (CTL is shown on the display.)

NOTE: *It is important to select control solution test so the test result does not appear to be one of your blood test results.*

NOTE: *If a test is not performed within 2 minutes from the insertion of the test strip, the screen goes blank. To perform a test, take out then replace the test strip starting from Step 1.*

3. Shake the control solution vial. Discard a drop before use. Squeeze a drop of control solution onto a clean, hard, dry surface, i.e., control cap.

4. Pick up the monitor with test strip inserted and touch the test strip to the control solution drop.

Running Glucose Control Solution

NOTE: *The on-screen Control Symbol flashes on and off repeatedly until sufficient control solution has been added to the test strip. (Beeper sounds if enabled.)*

5. A glucose quality control test result is available on-screen in 5 seconds. The display does a countdown from 5 to 1.

6. Compare the result on the display with the range printed on the test strip vial. If the result falls within the range, your monitor and test strips are working correctly.

7. The result is automatically stored into memory.

8. If test result is above 600 mg/dL for glucose, the screen displays HI with Glu displayed.

   If test result is below 20 mg/dL for glucose, the screen displays LO.

Running Glucose Control Solution

Out-of-range results may be caused by the following:

- An error in performing the control test, retest and follow the instructions carefully.
- The control solution may have expired or have been contaminated. Check the expiration date on the control solution vial. Control solution is good for only 3 months after opening. Make sure the control solution vial is closed when not in use.
- Expired test strip - Check the expiration date on the test strip vial.
- The test strip may have been damaged. This can be caused by extreme temperature or by leaving the test strip vial cap open. Retest using a new test strip.
- Monitor malfunction - the monitor may not be working properly.

NOTE: *If the control solution test result is outside the range (is either higher or lower), your monitor and test strip may not be working as a system. Repeat the process using a new test strip.*

Do not use the monitor until test results fall within the appropriate range. If the problem continues, call toll-free, 24 hours a day, 7 days a week Customer Service at 1-800-681-7390 (inside the USA). Outside the USA, contact your Nova supplier.

Running Glucose a Test

1. Wash hands with soap and warm water then dry thoroughly. Or use alcohol pads to clean area; dry thoroughly after cleaning.

NOTE: *Cleaning of the puncture site is important.*

2. Insert a glucose test strip into the monitor. Glucose is a blue strip. If monitor was off, the screen displays all segments for 2 seconds.

NOTE: *If the strip is removed before you start the test, the screen goes blank.*

3. After 3 seconds, the blinking blood drop symbol appears with "Glu" displaying.

NOTE: *If a test is not performed within 2 minutes from the insertion of the test strip, the screen goes blank. To perform a test, take out then replace the test strip starting from Step 2.*

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

Running a Glucose Test

5. Use the lancing device, loaded with a new lancet, to puncture the finger. (See lancing device instructions for use.)

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

7. Touch the end of the test strip to the blood drop until the test strip is full and the on-screen countdown timer begins. (Beeper sounds if enabled.)

NOTE: *The Blood Drop symbol flashes on and off repeatedly until sufficient blood has been added to the test strip.*

8. A countdown on screen appears while test is in progress. A result is available on-screen in 5 seconds.

9. The result is automatically stored into memory.

10. Press the Left/Right buttons to move between marked (√) or unmarked results. Marked results and Control results are not included into the average.

11. Press the Mode M button to save the Marking Status: Marked (√) or Unmarked.

12. If test result is above 600 mg/dL for Glucose, the screen displays HI.
    If test result is below 20 mg/dL for Glucose, the screen displays LO.

NOTE: *The monitor will time out after 2 minutes of non-use or if the strip is removed. The keys are disabled until a strip is inserted. Results and marking status are saved if the monitor times out, the strip is removed, or the monitor is turned off.*

NOTE: *Lancets are for one-time use only. Use a new, sterile lancet each time you test. Test different areas on your fingertips to avoid developing calluses. Remove the used lancet from the lancing device. Follow your local disposal regulations where applicable.*

WARNING: *Your lancing device is for your personal use only. DO NOT share with others. Sharing the lancing device or lancets can transmit serious, even grave infections. To avoid accidental sticks, do not store used lancets in the device after testing or arm the lancing device with a new sterile lancet unless ready to use.*

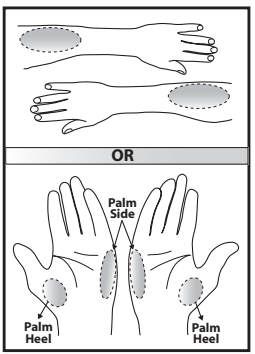
NOTE: *Do not press the test strip directly against the skin. Touch the test strip gently to the blood drop.*

Running a Glucose Test

Blood Sample (Glucose Only) from Forearm or Palm

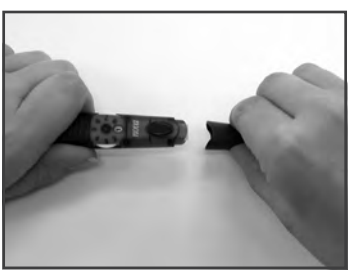
1a. Select the Forearm test site in the highlighted areas as shown.

NOTE: *Thick hair at the sample site may cause the blood drop to smear.*



1b. Select the Palm Heel or Palm Side test site in the highlighted areas as shown.

2. Attach the clear cap to the lancing device. Press and hold the lancing device **FIRMLY** against the Forearm (or Palm).



3. Continue to hold **FIRMLY** and press the release button to lance the area.

Running a Glucose Test

4. Continue to hold the device, pressing **FIRMLY** until a proper blood drop forms. The clear cap allows you to see the blood drop.

5. Apply blood drop to the edge of the test strip. The blood is drawn into the test strip. Hold the monitor to the blood drop until you hear a short beep or see the monitor begin to count down.

NOTE: *The blood in the strip should look similar to the red blood you are accustomed to seeing when you test your finger. If the sample looks clear, pink, or light in color, retest with a fingertip sample.*

6. The blood glucose test result is displayed and stored. The test is complete.

NOTE: *If you get an error message when testing on your forearm or palm or do not get a blood glucose reading after multiple attempts, test on your finger and call Customer Service toll-free, 24 hours a day, 7 days a week, in the US at 1-800-681-7390.* ***THIS NUMBER IS NOT FOR EMERGENCY OR MEDICAL INFORMATION.***
Outside the USA, contact your Nova supplier.

Limitations and Considerations: Forearm and Palm Testing

Some patients test their blood glucose at sites other than the finger because it is generally less painful.

NOTE: *Results from the forearm may be different from fingertip results when glucose levels are changing rapidly, e.g., after a meal, after taking insulin, or during or after exercise. Only use finger or palm testing during these times.*

The Nova Max Plus reduces the pain of blood glucose monitoring significantly by requiring only 0.3 µL of blood sample.

CAUTION: *Always seek the advice of your doctor or healthcare professional before choosing to use forearm and palm sites. Bruising may occur with forearm and palm testing.*

Limitations and Considerations: Forearm and Palm Testing (cont.)

Do not use forearm testing:

- **For a ß-ketone test**
- For at least 2 hours after you have eaten or injected insulin
- If you have recently exercised
- If you think that your blood glucose is low
- If you think that your blood glucose may be changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise)
- If you are not aware of symptoms when your blood glucose is low (hypoglycemic)
- If your forearm test results do not match the way you feel, retest using your finger or palm.

Consider **NOT** using forearm testing if you:

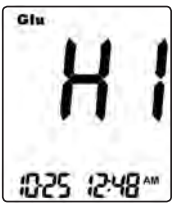
- Are ill
- Are under extra stress
- Routinely have widely fluctuating blood glucose values that are often low (hypoglycemic)

Values from the palm sample were shown to be equivalent to values from the finger samples.

Your Glucose Test Results

Your blood Glucose test result is displayed on the monitor.

If test result is higher than 600 mg/dL, the monitor displays "HI." You may have high blood sugar level. Retest your blood glucose immediately using a new test strip. If your reading is still high, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.



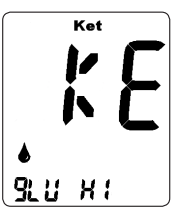
If test result is lower than 20 mg/dL, the monitor displays "LO." You may have low blood sugar. Retest your blood glucose immediately using a new test strip. If your reading is still low, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.
If you receive an Error Message, see page 40, Displays, Meanings, Actions of this Owner's Guide.

Your Glucose Test Results

NOTE: *Test results greater than 240 mg/dL may mean high blood sugar (hyperglycemia). Test results lower than 60 mg/dL may mean low blood sugar (hypoglycemia). If you get results in these ranges, retest your blood glucose. If your reading is still in these ranges, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.*

Ketone Test Alert: Glucose Value 250 mg/dL or Higher

If a blood glucose value is 250 mg/dL or higher for a blood test result only, not a control test, you will be alerted that a blood ß-ketone test should be performed. Screen prompts will display in 2 second increments: the Glucose result screen, CK screen, then KE screen. Every time the KE screen displays a 3-beep alert sounds. You are being alerted to check your ß-ketone. The alert will automatically stop after one minute or after the test strip is removed.



Running ß-ketone Control Solution

Important Information for ß-Ketone Control Solution

- Use only Nova Max ß-Ketone Control Solutions for the test.
- Check the expiration date on the control solution vial. Do not use control solution past the expiration date or you may get inaccurate results.
- Store only for 3 months after first opening. When you open a new vial of control solution, count forward 3 months and write that date on the label of the control solution vial. Discard any remaining solution after the date you have written on the vial.
- Store the control solution tightly closed at room temperature below 86°F (30°C). Do not refrigerate or freeze.
- Shake the control solution well before using.

Caution: *The Nova Max ß-Ketone Control Solution range printed on the test strip package insert is for control solution only. It is used to test the performance of the monitor and test strip. It is not a recommended range for your blood ß-ketone level.*

If your control solution test results continue to fall outside the range printed on the test strip package insert:

- The Nova Max Plus Monitor may not be working properly.
- Do not use the monitor to test your blood.
- Inside the USA, call Customer Service at 1-800-681-7390. Outside the USA, contact your Nova supplier.

Running ß-Ketone Control Solution

Testing a ß-Ketone Quality Control Solution

1. Insert a test strip into the monitor. If monitor was off, the screen displays all segments for 2 seconds then the blinking blood drop symbol and "Ket" appear.

NOTE: *If the strip is removed before you start the test, the screen goes blank.*

2. Press the left/right  buttons to indicate this sample is a control. (CTL is shown on the display.)

NOTE: *It is important to select control solution test so the test result does not appear to be one of your blood test results.*

NOTE: *If a test is not performed within 2 minutes from the insertion of the test strip, the screen goes blank. To perform a test, take out then replace the test strip starting from Step 1.*

3. Shake the control solution vial. Discard a drop before use. Squeeze a drop of control solution onto a clean, hard, dry surface, i.e., control cap.

4. Pick up the monitor with test strip inserted and touch the test strip to the control solution drop.

Running ß-Ketone Control Solution

NOTE: *The on-screen Control Symbol flashes on and off repeatedly until sufficient control solution has been added to the test strip. (Beeper sounds if enabled.)*

5. A ß-ketone quality control test result is available on-screen in 10 seconds. The display does a countdown from 10 to 1.

6. Compare the result on the display with the range printed on the test strip package insert. If the result falls within the range, your monitor and test strips are working correctly.

7. The result is automatically stored into memory.

8. If test result is above 8 mmol/L for ketone, the screen displays HI with Ket displayed.

Running ß-Ketone Control Solution

Out-of-range results may be caused by the following:

- An error in performing the control test, retest and follow the instructions carefully.
- The control solution may have expired or have been contaminated. Check the expiration date on the control solution vial. Control solution is good for only 3 months after opening. Make sure the control solution vial is closed when not in use.
- Expired test strip - Check the expiration date on the test strip pouch.
- The test strip may have been damaged. This can be caused by extreme temperature. Retest using a new test strip.
- Monitor malfunction - the monitor may not be working properly.

NOTE: *If the control solution test result is outside the range (is either higher or lower), your monitor and test strip may not be working as a system. Repeat the process using a new test strip.*

Do not use the monitor until test results fall within the appropriate range. If the problem continues, call toll-free, 24 hours a day, 7 days a week Customer Service at 1-800-681-7390 (inside the USA). Outside the USA, contact your Nova supplier.

Running a ß-Ketone Test

1. Insert a ß-ketone test strip into the monitor. Ketone is a green strip. If monitor was off, the screen displays all segments for 2 seconds.

NOTE: *If the strip is removed before you start the test, the screen goes blank.*

2. After 3 seconds, the blinking blood drop symbol appears with "Ket" displaying.

NOTE: *If a test is not performed within 2 minutes from the insertion of the test strip, the screen goes blank. To perform a test, take out then replace the test strip starting from Step 1.*

3. Wash hands with soap and warm water then dry thoroughly. Or use alcohol pads to clean area; dry thoroughly after cleaning.

NOTE: *Cleaning of the puncture site is important.*

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

Running a ß-Ketone Test

5. Use the lancing device, loaded with a new lancet, to puncture the finger. (See lancing device instructions for use.)

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

7. Touch the end of the test strip to the blood drop until the test strip is full and the on-screen countdown timer begins. (Beeper sounds if enabled.)

NOTE: *The Blood Drop symbol flashes on and off repeatedly until sufficient blood has been added to the test strip.*

8. A countdown on screen appears while test is in progress. A result is available on-screen in 10 seconds.

9. The result is automatically stored into memory.

10. Press the Left/Right buttons to move between marked (√) or unmarked results. Marked results and Control results are not included into the average.

11. Press the Mode M button to save the Marking Status: Marked (√) or Unmarked.

12. If test result is above 8.0 mmol/L for ß-Ketone, the screen displays HI with Ket displaying.
    If test result is below 0.1 mmol/L for ß-Ketone, the screen displays LO with Ket displaying.

CAUTION: ß-ketone testing must not use the forearm or palm site. Only use the fingertip for ß-ketone testing.

NOTE: *The monitor will time out after 2 minutes of non-use or if the strip is removed. The keys are disabled until a strip is inserted. Results and marking status are saved if the monitor times out, the strip is removed, or the monitor is turned off.*

NOTE: *Lancets are for one-time use only. Use a new, sterile lancet each time you test. Test different areas on your fingertips to avoid developing calluses. Remove the used lancet from the lancing device. Follow your local disposal regulations where applicable.*

WARNING: *Your lancing device is for your personal use only. DO NOT share with others. Sharing the lancing device or lancets can transmit serious, even grave infections. To avoid accidental sticks, do not store used lancets in the device after testing or arm the lancing device with a new sterile lancet unless ready to use.*

NOTE: *Do not press the test strip directly against the skin. Touch the test strip gently to the blood drop.*

Your ß-Ketone Test Results

Your blood ß-ketone test result is displayed on the monitor.

If test result is higher than 8.0 mmol/L (Ket), the monitor displays "HI." You may have high blood ß-ketone level. Retest your blood ß-ketone immediately using a new test strip. If your reading is still high, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.

If test result is lower than 0.1 mmol/L (Ket), the monitor displays "LO." No action is required.

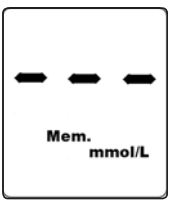
NOTE: *The normal adult blood ß-Ketone range for person without diabetes is less than 0.6 mmol/L. Consult with your heathcare professional for the blood ß-Ketone range that is appropriate for you. If the blood ß-Ketone result is between 0.6-1.5 mmol/L and glucose is more than 250 mg/dL, this may indicate development of a medical concern. You need to contact with your heathcare professional for assistance. If the blood ß-Ketone result is more than 1.5 mmol/L and glucose is more than 250 mg/dL, contact with your heathcare professional immediately. This indicates a risk of developing DKA.*

Review Test Results in Memory

NOTE: *If a test strip is inserted while in the Data Review mode, the monitor immediately switches to test mode.*

To review test results that are stored in memory, start with the monitor in the off position. The monitor is in the off position when the screen is completely blank. To turn off the monitor, hold the Mode button down until the screen goes blank then release the button.

1. With the monitor off, press the Mode button. The most recent test result should display. If there are NO results in memory, the screen displays 3 dashes.



2. Press the Left/Right button to view all the data in memory. The Left arrow goes back in time and the Right arrow goes forward in time. All results including control results, marked results, and unmarked results can be viewed.

3. At the end of reviewing individual test results, the screen displays "End Mem."

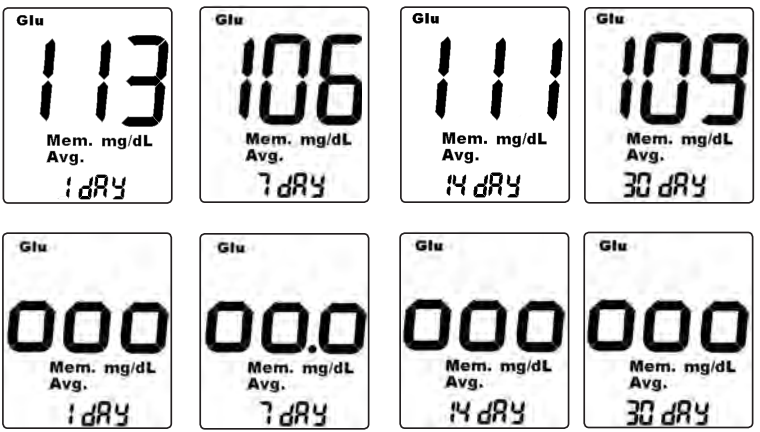
NOTE: *When the monitor memory is full (400 test results), each new test result stored in memory will remove the oldest test result stored in memory.*

Review Test Results in Memory

NOTE: *For data averaging,* ***only glucose results are averaged****. HI glucose results equal 600 mg/dL and LO results equal 20 mg/dL.*

4. To review 1 day, 7 day, 14 day, and 30 day average results, press the Mode M button.

5. If there are less than 2 test results in memory, the screen displays 000. If no results, the screen displays 3 dashes.

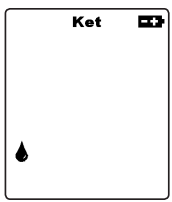


6. After reviewing the 30 day average, press the Mode M button to shut off the monitor, or press no buttons and the monitor will turn off automatically after 30 seconds.

Basic Upkeep

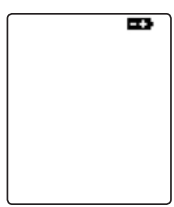
Battery Check

The monitor is powered by a single coin cell battery, CR2450 (3V). At the first displaying of the battery icon in the upper right corner of the screen and the blood drop at the lower left corner of the screen, the monitor has sufficient charge for 20 more tests. Continue with testing as usual; the battery indicator will remain on-screen.

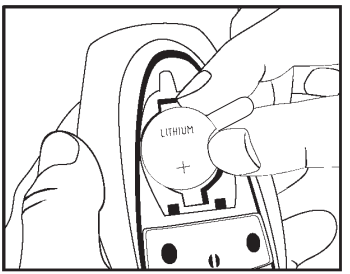


After 20 tests have been performed, there will be insufficient battery charge to continue testing, and the monitor will no longer operate until the battery is replaced. The battery icon will only appear when a strip is inserted and the icon will disappear when the strip is removed.

Battery low



Battery Replacement



Replace the battery as follows:

1. Remove the back battery cover on the monitor.

2. Remove the battery and replace with a new one with the + side facing up.

3. Replace the cover.

NOTE: *After the battery is replaced, the monitor displays the all segments screen. Then, the monitor displays the time set up. Reset to the current time and date. If needed, go to page 11 in this guide to review setting the time, date, and beeper. Discard batteries according to your local environmental regulations.*

Basic Upkeep

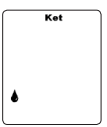
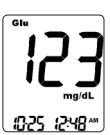
Cleaning and Care

The exterior of the Nova Max Plus Monitor should only be cleaned with alcohol wipes/swabs. Keep liquids from entering the test strip port or the Left, Right, and Mode buttons.

CAUTION: DO NOT *attempt to open the monitor to make any repairs. Your warranty and all claims will be void! Only an authorized service personnel can repair the monitor. Inside the USA, call Customer Service at 1-800-681-7390 if the monitor needs to be repaired or replaced. Outside the USA, contact your Nova supplier.*

Displays, Meanings, Actions

This section addresses the messages that appear on your displays, what they mean, and what action you need to take.

Display	What it Means	What to Do
	System Check. Verifies that all segments are working. Appears when: • Monitor is turned on for Setup and Memory Review. • Test strip is inserted into the monitor.	No action required. If all segments are not displayed on monitor, call Customer Service at 1-800-681-7390 (inside the USA). Outside the USA, contact your Nova supplier.
	Blood Drop Symbol: Monitor is ready to accept blood.	Apply a blood sample to the test strip. Refer to page 18 or page 31.
	Countdown screen: 5 seconds for glucose and10-second ß-ketone to calculate the test result.	No action required.
	A blood glucose test result is in mg/dL.	No action required. Result is automatically stored into memory.

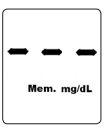
Displays, Meanings, Actions

Display	What it Means	What to Do
	A blood ß-ketone test result in mmol/L.	No action required. Result is automatically stored into memory.
 	Your blood glucose reading is higher than 600 mg/dL. You may have high blood sugar. Your blood ß-ketone reading is higher than 8 mmol/L. It indicates a risk of developing DKA.	Retest immediately. If your reading is still HI, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.
	Your blood glucose reading is lower than 20 mg/dL. You may have low blood sugar.	Retest your blood glucose immediately. If your reading is still LO, treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.
	Your blood ketone reading is lower than 0.1 mmol/L.	No action required.

Displays, Meanings, Actions

Display	What it Means	What to Do
	A blood glucose test result in mg/dL stored in the monitor's memory with date/time.	No action required.
	A blood ß-ketone test result in mmol/L stored in the monitor's memory with date/time.	No action required.
	End of Setup or Memory Review.	No action required.
	The average of all blood glucose test results taken in the last 24 hours.	No action required. **Glucose only**
	No test results in the last 24 hours.	No action required. **Glucose only**
	The average of all blood glucose test results taken in the last 7 days.	No action required. **Glucose only**

Displays, Meanings, Actions

Display	What it Means	What to Do
	No test results in the last 7 days.	No action required. **Glucose only**
	The average of all blood glucose test results taken in the last 14 days.	No action required. **Glucose only**
	No test results in the last 14 days.	No action required. **Glucose only**
	The average of all blood glucose test results taken in the last 30 days.	No action required. **Glucose only**
	No test results in the last 30 days.	No action required. **Glucose only**
	There are NO results in memory.	No action required.

Displays, Meanings, Actions

Display	What it Means	What to Do
	Battery is getting low, but you can still perform a test. Battery will appear on all screens.	We suggest that you replace the battery immediately. There is only enough power to perform 20 tests.
	A Glucose control solution test result.	No action required.
	A marked ß-Ketone sample test result.	No action required.
 	When a blood glucose value is 250 mg/dL or higher, these 2 screens cycle with the glucose result.	Perform a blood ß-ketone test.

Displays, Meanings, Actions

Display	What it Means	What to Do
	Software Error	Inside the USA, call 1-800-681-7390. Outside the USA, contact your Nova supplier.
	System Hardware Error	Inside the USA, call 1-800-681-7390. Outside the USA, contact your Nova supplier.
	Operating Temperature Error	Monitor is outside the required testing temperature range of 57° to 104°F (14° to 40°C). Move the monitor to a warmer or cooler area and wait a few minutes.
	Used Strip Error: Used or damaged strip.	Retest with a new strip.
	Blood Sample Error	Incorrect application of blood sample or control solution onto the test strip, or the test strip may be damaged. Review your sampling technique.

Displays, Meanings, Actions

Display	What it Means	What to Do
Monitor does not turn on after inserting a test strip.	• Test strip is inserted upside down or not completely in.	Insert the test strip correctly with the Nova name and white tip facing up and out.
	• Battery is dead.	Replace the battery.
	• Battery is installed incorrectly or there is no battery in the monitor.	Check that the battery is correctly installed with the "+" sign facing you. Inside the USA, call 1-800-681-7390. Outside the USA, contact your Nova supplier.
Monitor does not begin test countdown after applying a blood sample.	• Not enough blood sample.	Repeat the test with a new test strip.
	• Sample applied after monitor automatically turned off.	Repeat the test with a new test strip.
	• Test strip may be damaged.	Repeat the test with a new test strip.
	• Monitor may not be working properly.	After 3 attempts, call 1-800-681-7390 (inside the USA). Outside the USA, contact your Nova supplier.

Appendix

Specifications

Test Measured	Blood Glucose & ß-Ketone
Glucose Methodology	Glucose oxidase biosensor
ß-Ketone Methodology	ß-hydroxybutyrate dehydrogenase biosensor
Glucose Test Results	mg/dL (Plasma values)
ß-Ketone Test Results	mmol/L (Plasma values)
Sample type	Capillary whole blood
Glucose Test range	20 to 600 mg/dL
ß-Ketone Test range	0.1 to 8.0 mmol/L
Acceptable Hematocrit range	25% to 60%
Length of Test	5 seconds (Glu), 10 seconds (Ket)
Test Strip Volumes	0.3 µL (Glu), 0.8 µL (Ket)
Battery Life (nominal)	1000 Tests
Low Battery Life	About 20 Tests
Data Output Port	Serial, USB
Operating Ranges	
Temperature	57° to 104°F (14° to 40°C)
Humidity	10% to 90% relative humidity
Altitude	Up to 10,000 ft (3000 m)
Weight	2.65 oz (75 g)
Size	3.6x2.3x0.9 in (91.4x58.4x22.9 mm)
Monitor data storage	400 Results

Appendix

Chemistry Measurement

Glucose test imprecision
6% or 5.4 mg/dL (whichever is greater)
ß-Ketone test imprecision
6% or 0.15 mmol/L (whichever is greater)

Limitations

The Nova Max Test Strips give accurate results when the following limitations are observed:

- The test strips should not be used to diagnose diabetes, DKA, or to test newborns.
- Each test strip is for single use only. Do not reuse. Use a new sterile Nova Max Plus Test Strip each time you test.
- Your test strips are for personal use only. DO NOT share with others.
- Use only fresh capillary whole blood. **Do not use serum or plasma.**
- There is no effect on blood glucose or ß-ketone values for altitudes up to 10,000 feet (3000 meters) above sea level.
- Refer to the Owner's Guide for operating temperature range for the monitor.
- Extremes in humidity (higher than 90% and lower than 10%) may affect results.

Appendix

- The Nova Max Test Strips are calibrated against plasma.
- The anticoagulant sodium and lithium heparin may be used. EDTA is not recommended for use with Nova Max Test Strips.
- Interferences for elevated levels of acetaminophen, tolazamide, uric acid, bilirubin, ephedrine, and methyldopa may affect results.
- Glucose test results may be falsely low if the patient is severely dehydrated.
- Critically ill patients should not be tested with the Nova Max Plus Monitor.

Instructional Notes

1. If in setup mode when the test strip is inserted, the monitor saves all values entered up to that point and immediately switches to test mode. Upon exiting test mode the monitor screen goes blank and does not return to setup mode.
2. If in Data Review mode when the test strip is inserted, the monitor immediately switches to test mode. Upon exiting test mode the monitor screen goes blank and does not return to Data review mode.
3. Battery low icon is displayed in every mode except setup.
4. Once battery level goes below the threshold that triggers the "low battery" warning, it continues to give the warning until the monitor becomes unusable due to low battery.

5. The Monitor responds to the pressing and the holding of keys:

Left/Right  **buttons**

- The Left/Right button moves forward/backward through a series of stored test result screens or increments of value.
- Hold down the Left/Right button to speed up screen change process.

MODE  **button**

- When the MODE button is pressed less than 1.5 seconds to advance to the next function, the monitor advances to next screen immediately when button is pressed.
- While monitor is in sleep mode (OFF), pressing the MODE button less than 1.5 seconds wakes up the monitor and enters data review mode.
- While monitor is in sleep mode (OFF), pressing the MODE button greater than 3.0 seconds wakes up the monitor and enters setup mode.
- While monitor is awake (ON), pressing the MODE button greater than 1.5 seconds manually turns off the monitor (sleep mode).

6. With no activity, time-out occurs after the following times:
   - 1 minute for all screens
   - 2 minutes during test mode
   - 3 minutes when download connector inserted

Appendix

Warranty

Your Nova Max Plus Monitor is warranted to be free of material and workmanship defects for 3 years from the date of purchase (except as noted below). If at any time during the first 3 years after purchase, your Nova Max Plus Monitor does not work for any reason (other than as described below), it will be replaced with a new monitor, or a substantial equivalent, free of charge.

Limitations on Warranty: This warranty is subject to the following exceptions and limitations:

1. This warranty is applicable only to the original purchaser.
2. This warranty does not apply to units which malfunction or are damaged due to obvious abuse, misuse, alteration, neglect, unauthorized maintenance or failure to operate meter in accordance with instructions.
3. We have no knowledge of the performance of the Nova Max Monitor when used with test strips other than Nova Max Test Strips. Therefore, we make no warranty as to the performance of the Nova Max Plus Monitor when used with any test strips other than Nova Max Test Strips.
4. There is no other express warranty for this product. The option of replacement, described above, is the warrantor's only obligation under this warranty.

For warranty service: The original purchaser must contact in the USA Nova Customer Service at 1-800-681-7390. Outside the USA, contact your Nova supplier.