Nova Max Link™ Blood Glucose Monitor Owner's Guide

REF 44619 Rev A   12/2007

nova

THANK YOU

Nova thanks you for choosing the Nova Max Link™ Blood Glucose Monitor. 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 Link Blood Glucose Monitor is designed to be convenient and easy to use. The Nova Max Link is designed for wireless communication with Paradigm® Model 512, 712, or higher insulin infusion pumps. It gives accurate results in just 5 seconds 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 blood sugar test. The monitor also has memory that stores your blood sugar test results to help you and your healthcare professional manage your diabetes care.

Before you get started, it is important to complete the Warranty Registration Card included in your kit and mail it back to Nova. 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 US at 1-800-681-7390 or visit our website at www.novacares.com.

Important Information!

- Before you begin using your new Blood Glucose 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 34) to install a new battery.

nova

Important Information!

- 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 monitoring routine.
- These recommendations apply to all blood glucose 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 (AdvMed)*.

For the Blood Glucose Monitor with radio frequency (RF) turned on: This device complies with the United States Federal Communications Commission and international standards for Electromagnetic Compatibility regarding its use.

This device complies with Part 15 of the FCC rules. Operation is subject to the following 2 conditions:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesirable operation.

These standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference. Operation is subject to the following 2 conditions:

1. This device has been tested and found to comply with the regulations governing such devices in your area. Please contact Nova at 1-800-681-7390.

nova

Important Information!

2. This device generates, uses, and can radiate radio frequency energy and, if installed and used in accordance with the instruction, may cause harmful interference to radio communications. If the device does cause interference to radio or television communications. If the device does cause interference to radio or television communications, the user is encouraged to try to correct the interference by one or more of the following measures:
   - Reorient or relocate the blood glucose monitor.
   - Increase the separation between the blood glucose monitor and the device that is receiving/emitting interference.
   - If you have questions, please contact Nova at 1-800-681-7390.

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.*

nova

Table of Contents

nova

nova

Intended Use

The Nova Max Link Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in capillary whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. The Nova Max Link Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood capillary samples obtained from the fingertip, palm and forearm.

- The Nova Max Link Blood Glucose Monitor is intended for use outside the body (*in vitro* diagnostic use).
- It should only be used with Nova Max Test Strips and Nova Max Control Solution.
- It should be used for testing glucose (sugar) and only with fresh capillary whole blood samples.
- It should **NOT** be used to diagnose diabetes or to test new-borns.
- It should **NOT** be stored in the refrigerator or in the car.

WARNING: *The Nova Max Link Blood Glucose 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.

nova

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, 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 Link Blood Glucose Monitor.

| IVD | *In vitro* diagnostic medical device |

Caution, consult accompanying documents

Consult instructions for use

Biological risk

REF   Catalog number

Temperature limitation

Rf emitter

nova

Monitor Components

Test Strip Goes Here

LCD Display

Ctl

Mem.   mg/dL
Avg.   mmol/L

88:88. 88:88 AM PM

Right Arrow Button

Left Arrow Button

Mode Button
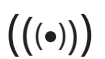
Nova Max Link Blood Glucose Monitor

Introduction

Monitor Display

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

Nova Max Link Monitor Screen

nova

Introduction

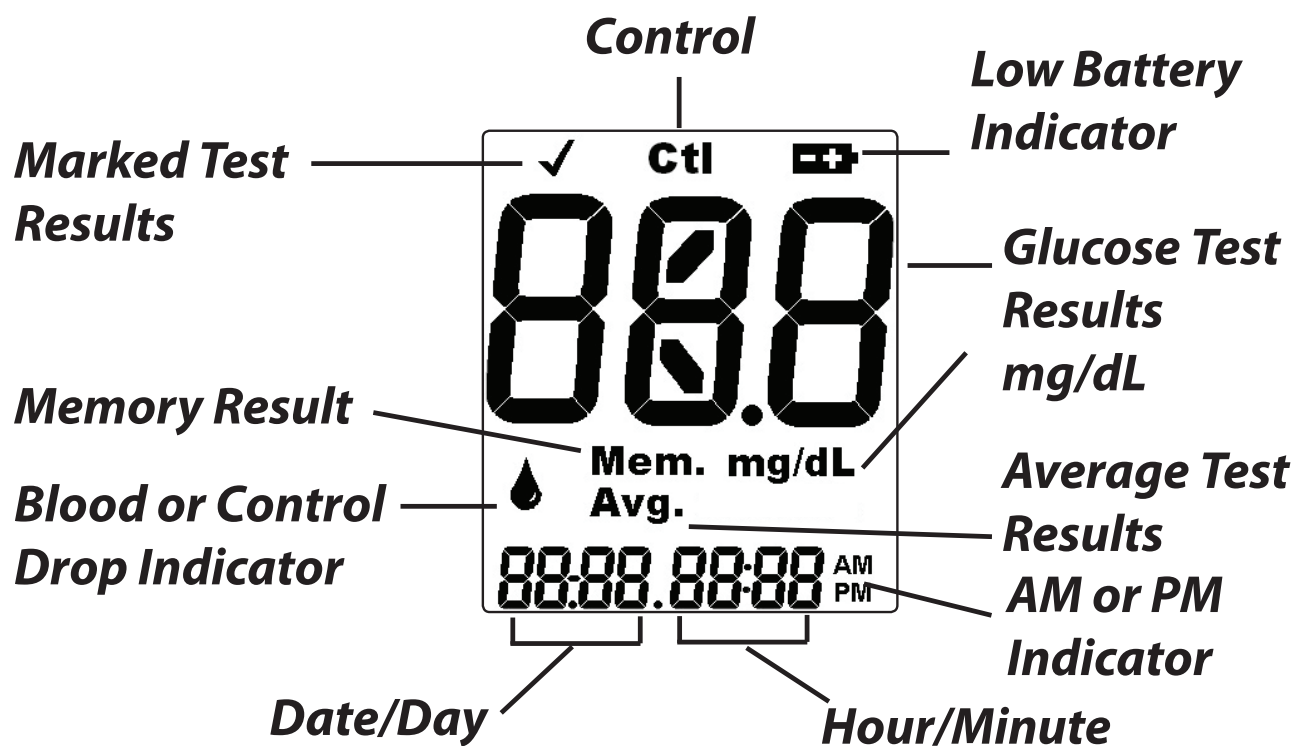## The Nova Max Link Blood Glucose Monitor

The monitor is a hand-held testing device that measures glucose (sugar) in capillary blood. The test strip is touched to a drop of blood to initiate the test process.

- A simple one-step process provides a blood glucose result.
- Test results are available in 5 seconds.
- There is memory for one common user's set of test results (400).
- The monitor is powered by a battery that can perform for approximately 500 tests when the "Snd" function is on.

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; brings the test strip to the drop of blood; and obtains a glucose test result in 5 seconds. The test result is automatically stored into the monitor's memory. The operator can recall, delete, and review test data stored in the monitor, including the average for user results.

Introduction

Kit Contents

1. Nova Max Link™ Blood Glucose Monitor
2. Lancing device*
3. Nova Max™ Blood Glucose Control Solution, Normal (1 bottle)*
4. Lancets (10)*
5. Day Case
6. Battery (CR2450, 3V)
7. Owner's Guide
8. Quick Reference Guide
9. Getting Started Poster
10. Warranty Card
11. Clear Cap and Instructions for Forearm and Palm Testing

*   These items are not included in the mail order version of the monitor.

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

nova

Before Testing

Before testing and to ensure accurate glucose results, wash your hands and the testing site then thoroughly dry these areas.
The Nova Max Link Blood Glucose Monitor can test your blood glucose on the fingers, forearm, or palm.
The sample size is just 0.3 µL 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 test results and you have followed all instructions described in the Owner's Guide, call your doctor or healthcare professional.

Introduction

Test Strips

The Nova Max Test Strips are designed for use with your Nova Max Link Blood Glucose Monitor. 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
- Automatically draws blood into the test area of the strip
- Can be handled with clean, dry hands without affecting glucose readings

Insert This End Into Monitor

nova

Apply Blood Drop to Front Edge

Important Nova Max Test Strip Information

- Use only Nova Max Test Strips when testing.
- 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 strip vial away from children and pets.*

Lancing Device

The diagram below shows the components of the Lancing Device.

Depth Adjustment

nova

Release Button

Force Adjustment
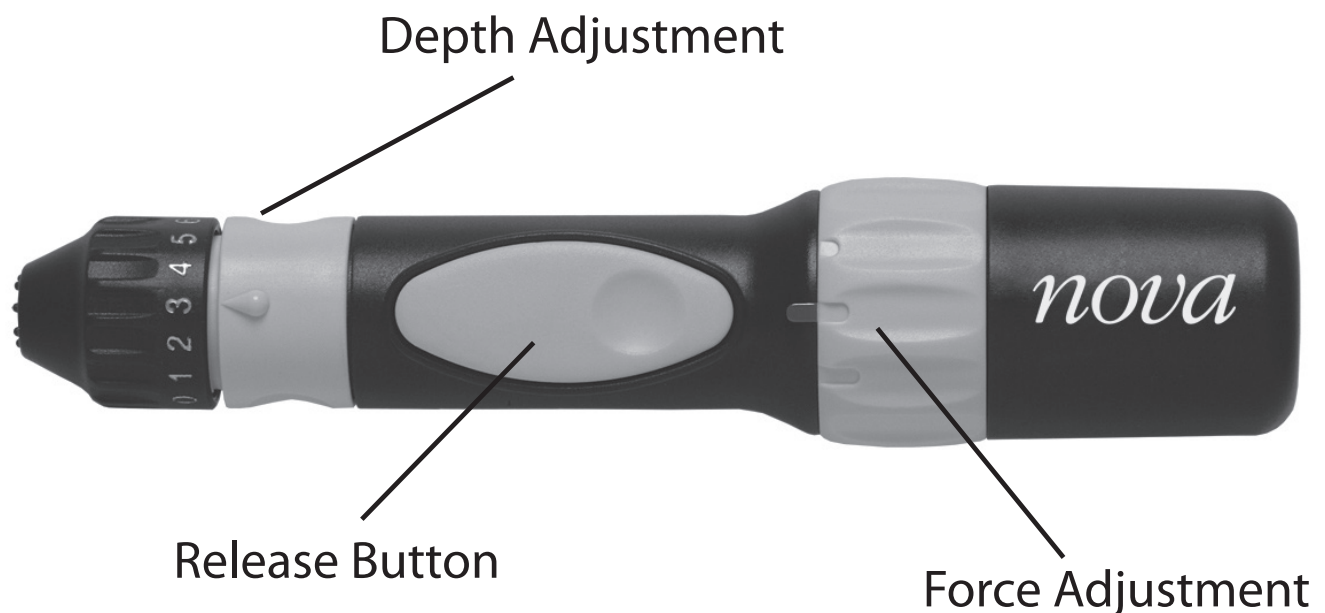
Introduction

Talking to Your Pump

Your Nova Max Link Blood Glucose Monitor arrives with its "Snd" function already turned on. Every time the meter displays a new blood glucose test result, the meter automatically sends the result to the your Paradigm® Model 512, 712, or higher insulin pump. However, your pump will only listen for a blood glucose test result if you have programmed the pump with the meter's ID number. The pump will accept up to 3 different meter ID numbers. The Nova Max Link is designed to communicate with the Paradigm Model 512, 712, or higher insulin pump. Please refer to your Paradigm Model 512, 712, or higher insulin pump User Guide or the Getting Started poster to see how to program your meter's ID number into the pump.
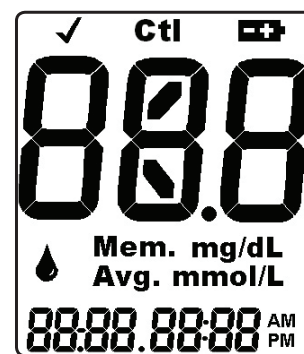
Setting the Time, Date, and Beeper

Having the correct time and date of each blood glucose 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. If you do not set the time and date, all blood glucose monitoring results will be marked and will not be included in averages.

Your Nova Max Link Blood Glucose Monitor offers a beeper function that is preset "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 blood glucose or control solution 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 blood sugar or control solution 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.

```
12:00 AM
```
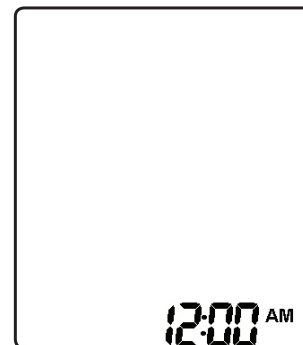
MODES	SCREEN DISPLAY
Hour (Flashing)	"10":00"AM"
Minutes (Flashing)	10:"55"AM
Year (Flashing)	1-28 "2008"
Month (Flashing)	"1"-28 2008
Day (Flashing)	1-"28" 2008
Sample Marking (ON or OFF)	"ON"
Beep (ON or OFF)	"ON"
END (End of Setup Mode)	"END"

2. Repeatedly press the MODE ⬇M 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 ⬇M button to select the new settings or to skip to the next MODE.

nova

Using the Send (Snd) Function

Your Nova Max Link Blood Glucose Monitor has a send function. The Send Function allows you to turn on or off sending blood glucose results to your Paradigm Model 512, 712, or higher insulin pump.

NOTE: *The "Snd" function is turned on when you receive your monitor.*

Setting the Send Function

The monitor is off, with no test strip inserted in the test strip slot.

1. Begin Setup: Press and continue to hold the Mode button. You will hear 2 short beeps and see "Snd" and the word "On." Release the Mode button.

    NOTE: *If you release the Mode button too soon, turn off your monitor by pressing and holding the Mode button. Repeat Step 1.*

2. Set glucose test result transfer to insulin pump. The glucose test result transfer to insulin pump is preset to "On." Press the left/right arrow buttons to select the setting "On" or Off."

3. Press the Mode button briefly to confirm your choice and to advance to set insulin recording function.

Running Control Solution

Control Solution

Control Solution is a liquid that contains a fixed amount of glucose.
- Use this solution to test that your monitor with test strip is 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 glucose 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
- Each time you open and begin using a new vial of test strips
- If you leave the 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 are also recommended as an additional quality control check for your blood glucose monitoring system.

nova

Running Control Solution

Important Information for Control Solution

- Use only the Nova Max Control Solution 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 Control Solution range printed on the 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 Link Blood Glucose Monitor may not be working properly.
- Do not use the monitor to test your blood.
- Call Customer Service at 1-800-681-7390.

Running Control Solution

Testing a 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 appears.

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

2. Press the left/right ◀ ▶ buttons to move between unmarked sample or marked control sample (CTL); select control.

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

    ***CAUTION:** It is important to mark a control solution test prior to applying blood to the test strip, so the test result does not appear to be one of your blood glucose test results, and also to prevent it from being included in your blood glucose average. Also, this will prevent the meter from sending a control solution test result to your Paradigm Model 512, 712, or higher insulin pump.*

    ***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.

nova

Running Control Solution

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

    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, the screen displays HI; test result cannot be stored.
    If test result is below 20 mg/dL, the screen displays LO; test result cannot be stored.

    NOTE: *Results that are marked as control solution will not flash because they are not sent to your pump.*

Running 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.

nova

Running a Test

1. Insert a test strip into the monitor. 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.*

Insert this End Into Monitor

nova

Apply Blood Drop Here

2. After 3 seconds, the blinking blood drop symbol appears.

   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.

Testing a Blood Sample

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. Glucose result is available on-screen in 5 seconds.

9. The result is automatically stored into memory.

NOTE: *The glucose result will flash while the monitor is transmitting the glucose result to the insulin pump. Removing the strip will not automatically turn off the monitor while Rf transmission is in progress (flashing). You can stop the transmission by manually turning off the monitor or inserting a new test strip. The glucose result will stop flashing (transmitting) when the pump receives the glucose result or after 60 seconds.*

Testing a Blood Sample

NOTE: *Your monitor arrives from the factory with "Snd" set to "On." If the glucose result does not flash and the insulin pump does not receive the glucose result, then set "Snd" to "On."*

10. Press the Left/Right ◀ ▶ buttons to move between marked (√) or unmarked results. Marked results are not included into the average test results. Hi, Lo, 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, the screen displays HI; test result cannot be stored.
    If test result is below 20 mg/dL, the screen displays LO; test result cannot be stored.

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.*

Testing a Blood Sample

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.*

NOTE: *If you are not using a pump, then you may choose to set "Snd" to Off" to save battery power.*
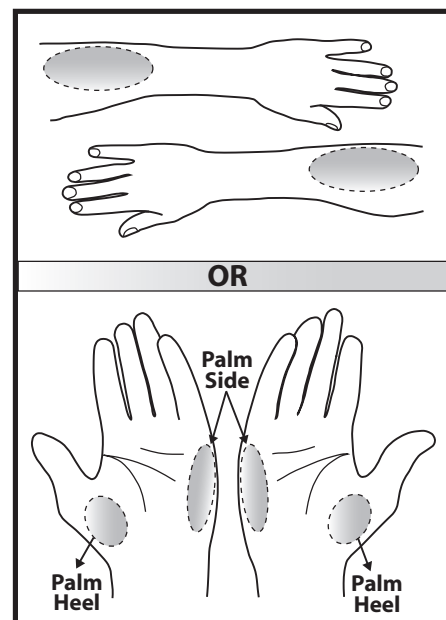
nova

Testing a Blood Sample

## Getting and Applying a Blood Sample from Forearm or Palm

1a. Select the Forearm test site in the high-lighted 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).
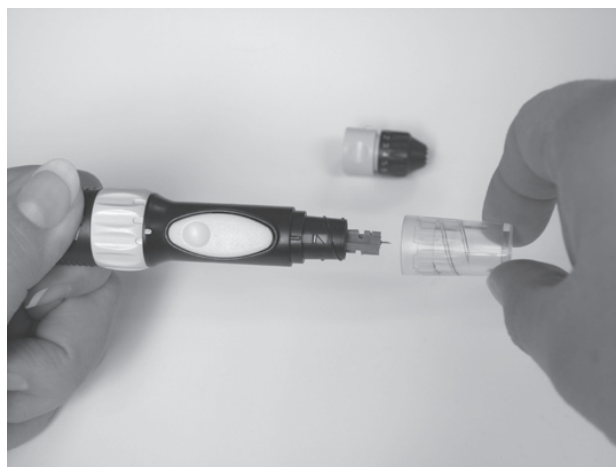
3. Continue to hold **FIRMLY** and press the release button to lance the area.

Testing a Blood Sample

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.**

nova

Testing a Blood Sample

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 Link 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.*

Testing a Blood Sample

Do not use forearm testing:
- 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.
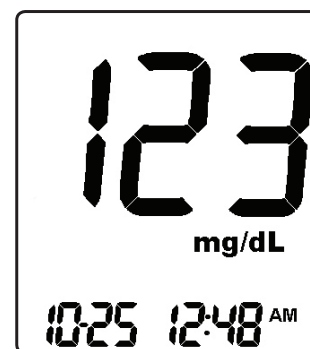
Consider **NOT** using forearm testing if you:
- Are ill
- Are under extra stress
- Routinely have widely fluctuating blood glucose values that are often low (hypoglycemic)

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

Your Test Result

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. 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.
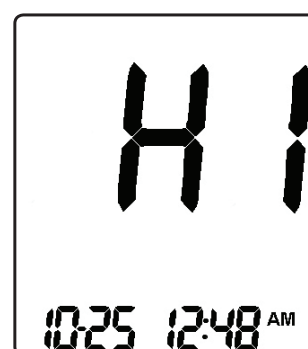
If test result is lower than 20 mg/dL, the monitor displays "LO." You may have low blood sugar. Retest your blood glucose immediately using a new test strip. If your reading is still low, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.
If you receive an Error Message, see page 31, Displays, Meanings, Actions of this Owner's Guide.

Your Test Result

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.*

NOTE: *Hi and Lo values will not transmit to the insulin pump even if "Snd" is "On" in setup.*

Sending a Blood Glucose Result to Your Paradigm Model 512, 712, or Higher Insulin Pump

Your Nova Max Link Blood Glucose Monitor arrives with "Snd" turned "On." Thus, when a new blood glucose result is displayed, the monitor will send the result to your pump. The new result will flash on the monitor display while the monitor is sending the result to your Paradigm Model 512, 712, or higher insulin pump. The monitor will stop flashing when the pump receives the result, or after 60 seconds.

A pump is only capable of receiving a blood glucose result if you have entered the monitor's ID number into the pump. No one else's pump can receive your blood glucose result, unless they enter your monitor's ID number into their pump. Please refer to your Insulin Pump User Guide or the Getting Started Poster to learn how to enter the monitor's ID number into your pump.

nova

Sending a Blood Glucose Result

NOTE: *If the monitor displays "HI" or "LO," no blood glucose result is sent to the pump.*

The monitor uses radio frequency (RF) signals to send the blood glucose result to the pump. If you set "Snd" to "OFF," your monitor will not send a RF signal to your pump. You may want to turn off the "Snd" feature to save battery power, if you do not have a pump.

NOTE: *To set up the "Snd" function, refer to Page 13.*

Marking a Single Blood Glucose Test So It Is Not Sent to Your Paradigm Model 512, 712, or Higher Insulin Pump

If you want to take a single blood glucose measurement and not have that result sent to your Paradigm Model 512, 712, or higher insulin pump, you can mark it as a control solution test.

1. Insert a Test Strip into the monitor.
2. A blinking blood drop tells you the monitor is ready for the next step.
3. Press one of the arrow buttons before applying blood to the test strip.
4. "Ctl" will appear on the display indicating that the result is a control solution test. After you apply blood or control solution to the test strip, the result will not be sent to your pump. You may want to mark a result as a control test if:
   - You are using control solution on a test strip to test your monitor.
   - You lend your monitor to someone else and you do not want their result to appear on your pump.
   - You do not want to generate an RF signal, such as if you have been asked to turn off electronic devices on an aircraft.

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 re-sults, the screen displays "End Mem."
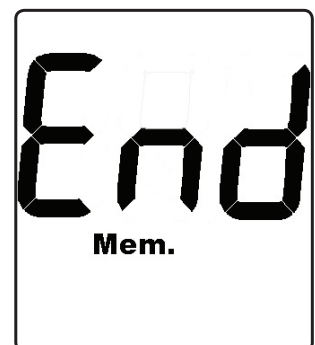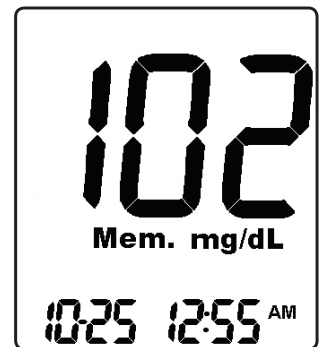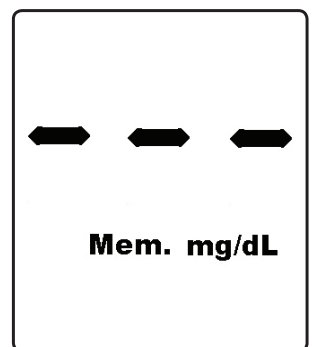
    NOTE: *For data averaging, HI results equal 600 mg/dL and LO results equal 20 mg/dL.*

Review Test Results in Memory

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.

113
Mem. mg/dL
Avg.
1 dRY

106
Mem. mg/dL
Avg.
7 dRY

111
Mem. mg/dL
Avg.
14 dRY

109
Mem. mg/dL
Avg.
30 dRY

000
Mem. mg/dL
Avg.
1 dRY

000
Mem. mg/dL
Avg.
7 dRY

000
Mem. mg/dL
Avg.
14 dRY

000
Mem. mg/dL
Avg.
30 dRY
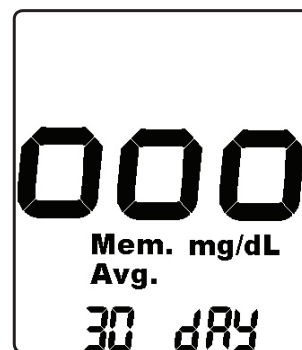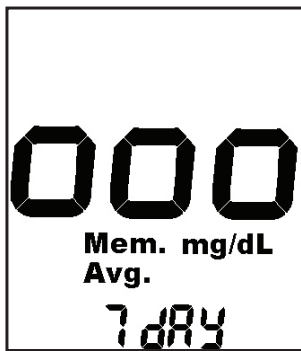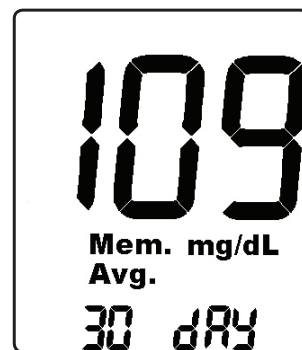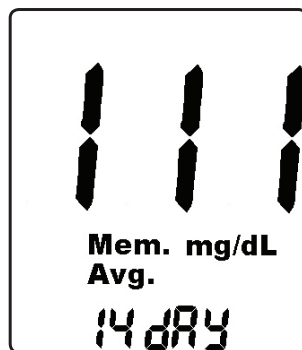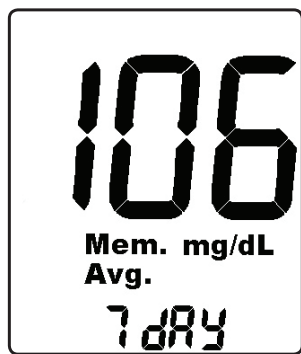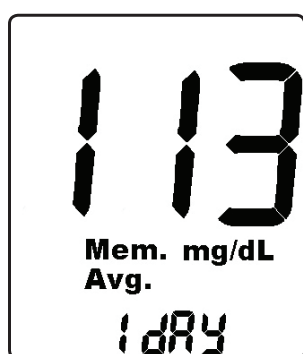
6. After reviewing the 30 day average, press the Mode ⌄M⌄ button to shut off the monitor, or press no buttons and the monitor will turn off automatically after 30 seconds.

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.*

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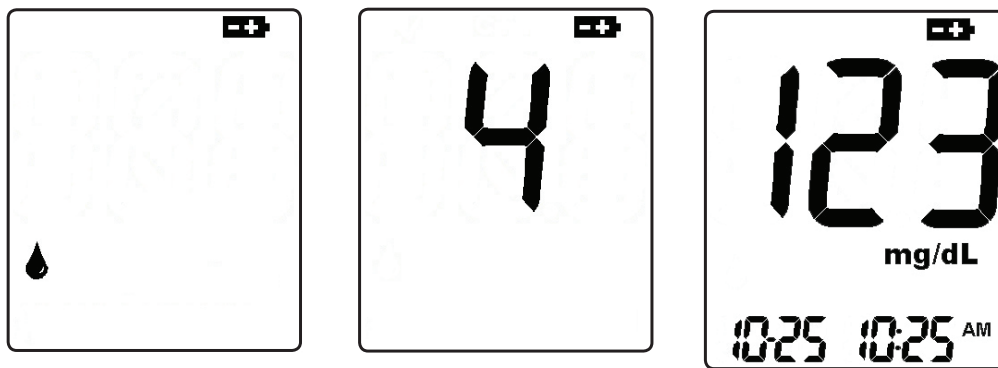
After 20 tests have been performed, there will be insufficient battery charge to continue testing, and the monitor will no longer operate until the battery is replaced. The battery icon will only appear when a strip is inserted and the icon will disappear when the strip is removed.

Battery low
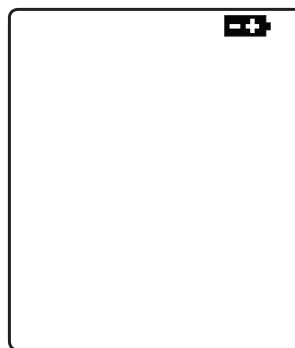
Battery Replacement

Replace the battery as follows:

1. Remove the back battery cover on the monitor.

2. Remove the battery and re-place with a new one with the **+** side facing up.

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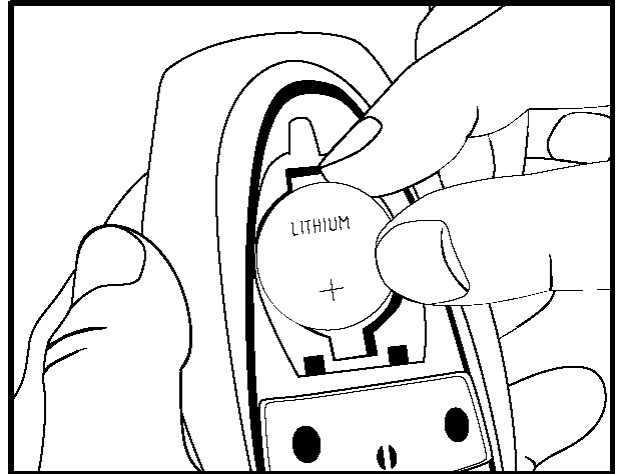
NOTE: *After the battery is replaced, the monitor displays the all segments screen. Then, the monitor displays the time set up. Reset to the current time and date. If needed, go to page 11 in this guide to review setting the time, date, and beeper. Discard batteries according to your local environmental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

Basic Upkeep

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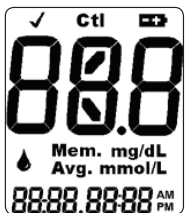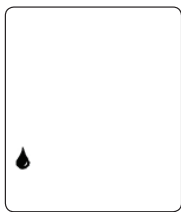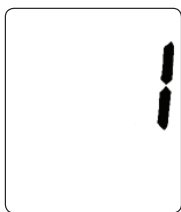
The exterior of the Nova Max Link Blood Glucose Monitor should only be cleaned with alcohol wipes/swabs. Keep liquids from entering the test strip port or the Left, Right, and Mode buttons.

__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. Call Customer Service at 1-800-681-7390 if the monitor needs to be repaired or replaced.

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
✓ Ctl ▭▸ **88.8** Mem. mg/dL Avg. mmol/L 88:88 88:88 AM/PM	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.
◆	Blood Drop Symbol: Monitor is ready to accept blood.	Apply a blood sample to the test strip. Refer to page 19, Running a Test.
I	Countdown screen: 5-second countdown as monitor calculates the blood glucose test result.	No action required.

Displays, Meanings, Actions

Display	What it Means	What to Do
123 mg/dL 1025 12:48 AM	A blood glucose test result in mg/dL.	No action required. Result is automatically stored into memory.
123 mg/dL 1025 12:48 AM	If "Snd" is "On," the result 123 will be flashing during RF transmission to the Paradigm Model 512, 712, or higher insulin pump. It will stop flashing once the monitor receives an acknowledgement from the insulin pump or after 1 minute.	Record the result in your logbook.
102 Mem. mg/dL 1025 12:55 AM	A blood glucose test result in mg/dL stored in the monitor's memory with date/time.	No action required.

nova ⬤37

Displays, Meanings, Actions

Display	What it Means	What to Do
HI 10:25 12:48 AM	Your blood glucose reading is higher than 600 mg/dL. You may have high blood sugar.	Retest your blood glucose immediately. If your reading is still HI, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.
LO 10:25 12:48 AM	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.
End	End of Setup or Memory Review.	No action required.

nova

Displays, Meanings, Actions

Display	What it Means	What to Do
113 Mem. mg/dL Avg. 1dAY	The average of all blood glucose test results taken in the last 24 hours.	No action required.
000 Mem. mg/dL Avg. 1dAY	No test results in the last 24 hours.	No action required.
106 Mem. mg/dL Avg. 7dAY	The average of all blood glucose test results taken in the last 7 days.	No action required.
000 Mem. mg/dL Avg. 7dAY	No test results in the last 7 days.	No action required.
111 Mem. mg/dL Avg. 14dAY	The average of all blood glucose test results taken in the last 14 days.	No action required.
000 Mem. mg/dL Avg. 14dAY	No test results in the last 14 days.	No action required.
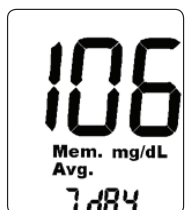
nova

Displays, Meanings, Actions

Display	What it Means	What to Do
109 Mem. mg/dL Avg. 30 dAY	The average of all blood glucose test results taken in the last 30 days.	No action required.
000 Mem. mg/dL Avg. 30 dAY	No test results in the last 30 days.	No action required.
- - - Mem. mg/dL	There are NO results in memory.	No action required.
123 mg/dL 10:25 12:48 AM	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.
ctl **123** mg/dL 10:25 12:48 AM	A control solution test result.	No action required.
✓ **123** mg/dL 10:25 12:48 AM	A marked sample test result.	No action required.
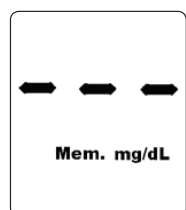
40

nova

Displays, Meanings, Actions
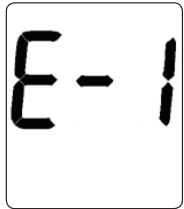
Display	What it Means	What to Do
E-0	Software Error	Call Customer Service at 1-800-681-7390, 24 hours a day, 7 days a week.
E-1	System Hardware Error	Call Customer Service at 1-800-681-7390, 24 hours a day, 7 days a week.
E-2	Operating Temperature Error	Monitor is outside the required testing temperature range of 57° to 104°F (14° to 40°C). Move the monitor to a warmer or cooler area and wait a few minutes.
E-3	Used Strip Error: Used or damaged strip.	Retest with a new strip.
E-4	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.
		Call Customer Service 1-800-681-7390, 24 hours a day, 7 days a week.
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 Customer Service at 1-800-681-7390, 24 hours a day, 7 days a week.

nova

Appendix

Specifications

Test Measured	Blood Glucose
Glucose Methodology	Glucose oxidase biosensor
Glucose Test Results	mg/dL (Plasma values)
Sample type	Capillary whole blood
Glucose Test range	20 to 600 mg/dL
Acceptable Hematocrit range	25% to 60%
Length of Test	5 seconds
Test Strip Volumes	0.3 µL
Battery Life (nominal)	500 Tests (Send on)
Low Battery Life	About 10 Tests
Radio Frequency (RF)	916.5 MHz
Data Output Port	Serial, USB
Operating Ranges	
Temperature	57° to 104°F (14° to 40°C)
Humidity	10% to 90% relative humidity
Weight	2.65 oz (75 g)
Size	3.6x2.3x0.9 in (91.4x58.4x22.9 mm)
Monitor data storage	400 Results

Chemistry Measurement

Glucose test imprecision
6% or 5.4 mg/dL (whichever is greater)

nova

43

Appendix

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 or to test newborns.

- Each test strip is for single use only. Do not reuse. Use a new sterile Nova Max 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 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.

- The Nova Max Test Strips are calibrated against plasma.

- The anticoagulant sodium 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.

nova

Appendix

- Test results may be falsely low if the patient is severely dehydrated.

- Critically ill patients should not be tested with home blood glucose monitors.

Appendix

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.

nova

Appendix

- 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

Warranty

Your Nova Max Link Blood Glucose 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 Link 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 Link 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 Link 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 Nova Customer Service by calling toll-free at 1-800-681-7390.

Privacy Policy: Both Nova, as manufacturer, and Sanvita, as the Nova Max Link exclusive distributor, are 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.

nova