Contour®NEXT LINK

WIRELESS BLOOD GLUCOSE
MONITORING SYSTEM

USER GUIDE

USES BAYER'S CONTOUR® OR CONTOUR®NEXT
BLOOD GLUCOSE TEST STRIPS

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INTENDED USE: The CONTOUR®NEXT LINK wireless blood glucose monitoring system is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only. The CONTOUR NEXT LINK blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only.

The CONTOUR NEXT LINK wireless blood glucose monitoring system may be used to transmit glucose values to compatible Medtronic Minimed devices and facilitate transfer of information to Medtronic's CareLink® Therapy Management software through use of radio frequency communication.

The CONTOUR NEXT LINK wireless blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Information for Safety

Read your CONTOUR NEXT LINK user guide, the MICROLET®2 lancing device insert and all instructional materials provided in your meter kit before testing. Please follow all instructions for use and care exactly as described to help avoid inaccurate results.

Wash and dry your hands well before testing.

Used test strips and lancets are possible biohazards and must be disposed of as medical waste.

WARNING:

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients![1,2]
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For complete instructions on cleaning and disinfecting your meter and lancing device, please see page 29.

Important: Examine product for missing, damaged, or broken parts. Contact Bayer Diabetes Care Customer Service at 1-800-348-8100 for replacement parts.

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Thank you for choosing the CONTOUR®NEXT LINK blood glucose monitoring system! We are proud to be your partner in helping you manage your diabetes.

Bayer's CONTOUR NEXT LINK meter automatically transmits blood glucose results using a wireless, radio frequency transmission to your compatible Medtronic MiniMed Paradigm® Insulin Pump (512/712, 515/715), Paradigm® REAL-Time System (522/722, 522K,722K), Paradigm® REAL-Time Revel™ System (523/723, 523K/723K) or Guardian® REAL-Time Continuous Glucose Monitoring System (CS7002/CS7002K). (Hereafter, the compatibility with these model numbers will be referred to as Medtronic MiniMed device.)

Bayer's CONTOUR NEXT LINK meter will work with Medtronic's CareLink® Personal Therapy Management Software and Bayer's GLUCOFACTS® DELUXE diabetes management software.

Your Meter Features

Easy: *The CONTOUR NEXT LINK blood glucose monitoring system is about simplicity. You will notice its simple approach the first time you see it.*

Automatic: *You no longer have to worry about coding your meter or marking a control test result. Bayer's CONTOUR NEXT LINK meter is designed with No Coding™ technology, to automatically code itself every time you insert a test strip. It will even tell you when a test strip is underfilled.*

NO CODING®

Programmed: *Bayer's CONTOUR NEXT LINK meter has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter). In some countries, the meters are preset to display units in mmol/L (millimoles of glucose per liter);*

- *Results in mg/dL will **never** have a decimal point;*
- *Results in mmol/L will **always** have a decimal point.*

Example: $93\ ^{mg}/_{dL}$ ***or*** $5.2\ ^{mmol}/_{L}$

Check your display to ensure that results are displayed in mg/dL. If they are not, contact Bayer Diabetes Care Customer Service, 1-800-348-8100.

Customizable: *Bayer's CONTOUR NEXT LINK meter allows you to set personal choices for some features. For more information, please see the Set Up and Testing sections in this user guide.*

"Talks" to Your Compatible Medtronic MiniMed Device

Bayer's CONTOUR NEXT LINK meter can automatically send your blood glucose result directly to your compatible Medtronic MiniMed device. This eliminates the need to manually enter your blood glucose result into the insulin pump's Bolus Wizard® calculator, that calculates and suggests a bolus or correction dose if needed. Bayer's CONTOUR NEXT LINK meter can also transmit your fingertip blood glucose result directly to your compatible Guardian REAL-Time CGM System, eliminating the need to manually enter the result when calibrating the system.

See page 8 for initial setup options. Your compatible Medtronic MiniMed device will only accept the glucose result if the Meter Option in your device's Utility Menu is set to on and you have programmed the device with the meter's ID (serial) number. Up to three different meter ID numbers can be accepted. See page 8 in "Initial Setup". If you have entered your meter's ID number into your compatible Medtronic MiniMed device, it can receive your blood glucose result. No one else's insulin pump or continuous glucose monitoring system can receive your glucose result, unless your meter ID number has been entered into that device. The meter uses a wireless signal to send the blood glucose result to the compatible Medtronic MiniMed device when the *Send* option is set to **Always** or **Ask**. See page 9 of this user guide. Your CONTOUR NEXT LINK meter and compatible Medtronic MiniMed device must be within 4 feet of each other. If you are not using the meter link feature on your compatible Medtronic MiniMed device, you may want to turn the *Send* option off on your CONTOUR NEXT LINK meter and Medtronic MiniMed device to save battery power.

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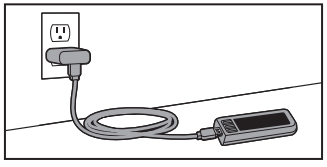
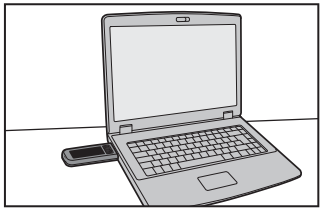
Bayer's CONTOUR®NEXT LINK Blood Glucose Monitoring System

Bayer's CONTOUR NEXT LINK blood glucose monitoring system works with Bayer's CONTOUR or CONTOUR NEXT test strips.

Rechargeable Battery

Your Bayer's CONTOUR NEXT LINK meter has a permanent rechargeable battery. **Before you do anything else,** charge your meter with the wall charger included with your kit. You may also charge your meter by plugging the USB connector into a computer. Be sure the computer is turned on and not in sleep, hibernate or power saving mode. Your meter will briefly display "Do Not Test-Charging" and the test strip port light will flash. For more details see page 65.





CONTOUR® or CONTOUR®NEXT Test Strip

Gray Electrode End: Insert this end into test strip port with gray end face up.

Sample Tip: Blood is drawn in here.

***CAUTION:** Bayer's CONTOUR NEXT LINK meter only works with CONTOUR or CONTOUR NEXT test strips!*

Meter Front

Display Screen

Menu Button: Provides access to features. See page 8.

Selection/Scrolling Buttons: See page 6.

USB Connector

Test Strip Port: Insert the test strip here. To turn on the port light, see pages 7 and 24.

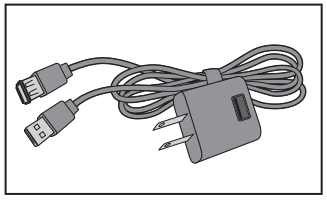
Protective USB Cap

***CAUTION:** Keep out of reach of children. Accidental swallowing could cause suffocation.*

You cannot do a blood glucose test while the battery is charging. When charging is finished, the test strip port light will turn off. Unplug your CONTOUR NEXT LINK meter to test.

A USB extension cable and a wall charger are included for your convenience.

For more information on Battery Status Displays and Charging see pages 63-65.



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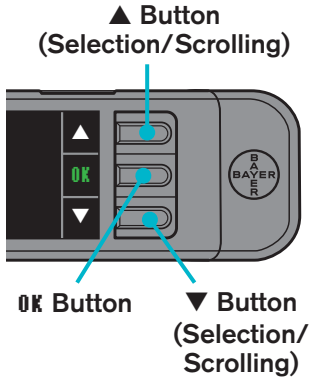
Meter Overview

Using the Buttons

Bayer's CONTOUR®NEXT LINK meter is **simple** to use. Every screen gives you choices. The three buttons next to the screen allow you to make your selection by pressing the button next to your choice.



Using the Selection/Scrolling Buttons –

When the ▲ or ▼ arrows appear on the screen, the buttons are used for scrolling. When your choice is highlighted, make a selection by pressing the **OK** button.

NOTE: *Pressing and holding the ▲ or ▼ buttons will scroll through the list faster.*

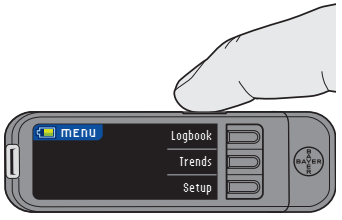
Using the Menu Button

- **To turn on the meter, press and hold the Menu button until the meter turns on.**

The Main Menu has 3 choices: **Logbook**, **Trends** and **Setup**.

- Select one by pressing the button next to your choice. See the following pages for more details on "Setup".

- To **go back** to the previous screen, **press the Menu button once.**
- To turn the meter off, press and hold the Menu button for 2 seconds.



- To turn the test strip port light on with the meter off, give the Menu button two quick presses. Two quick presses of the Menu button will also turn off the light.

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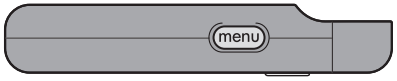
Initial Setup

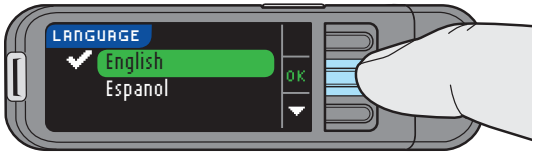
First charge your meter. You can use your computer or the included wall charger to charge your meter. When you first turn on your CONTOUR®NEXT LINK meter, a setup sequence begins. The Setup process walks you through the steps for meter setup and allows your meter to connect to your compatible Medtronic MiniMed device. Your compatible Medtronic MiniMed device must be nearby.

1. **Press and hold the Menu button until the meter turns on.** After a welcome screen, you will see the **Select Language** screen.

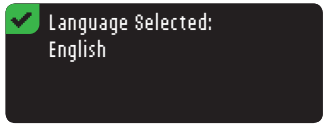
TOP VIEW



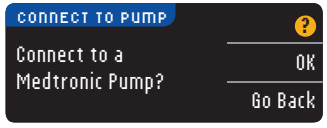
2. Press the ▲ or ▼ button to select your desired language. When highlighted, press the **OK** button.



A screen confirms your language.

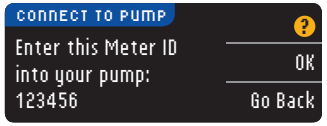


3. Press **OK** on the next screen to start the connection process. Follow the steps on your Medtronic MiniMed Paradigm Insulin Pump or Guardian REAL-Time CGM System.



NOTE: Pump on meter screen refers to your compatible Medtronic MiniMed device.

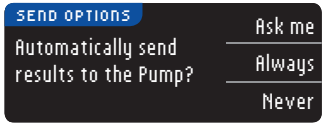
4. The next screen on your blood glucose meter displays the meter ID needed to complete the connection steps. Do not press **OK** on this screen until connection process is complete.



IMPORTANT: Refer to the separate Medtronic User Guide for instructions on connecting Bayer's CONTOUR NEXT LINK meter to your compatible Medtronic MiniMed device.

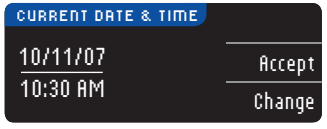
Meter Send Options

5. After the meter and compatible Medtronic MiniMed device are connected, you will set your SEND options. This controls how your meter will send blood glucose readings to your compatible Medtronic MiniMed device. Choose the SEND option that is best for you. A screen message will confirm the choice made (**Ask Me** = "Meter will ask you before sending results," **Always** = "Meter will always send results," **Never** = "Meter will never send results.") If you select **Never**, you can set up your choice later for sending results to your pump.



Date and Time Should Match

6. The date and time on the meter should match your pump. If they match, press **Accept**. If they do not match, press **Change**. Follow the meter instructions to change the date and time.



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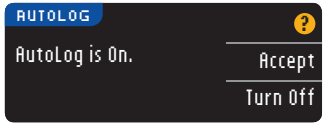
Additional Meter Settings

AutoLog Feature

Your meter comes with a simple AutoLog feature that lets you mark your test result as **Before Meal** or **After Meal** during the 5 second test countdown. You can select **No Mark** if you are testing at times other than before or after a meal.

Your meter comes with AutoLog turned on. We recommend that you keep this feature turned on to get the most benefit from your meter features. AutoLog can be turned off in Setup if you choose to do so at a later time (see page 55).



7. Accept or turn off the AutoLog feature. See pages 24–26 for details about testing with AutoLog on or off.

Targets

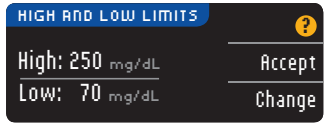
8. The next screen displays the default blood sugar **target range** for (Before Meal) and (After Meal) blood sugar.

Before you change or accept the target ranges, discuss with your healthcare professional what target ranges are best for you.

High and Low Limits

The high and low limits feature alerts you when you go above or below the settings you choose. Alerts appear as large orange numbers (see page 34).

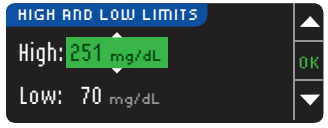
Before you change or accept the high and low limits, discuss with your healthcare professional what high and low limits are best for you.



9. Choose **Accept** to use the default settings for high and low limits. The default high limit is 250 mg/dL and the default low limit is 70 mg/dL.

10. Choose **Change** if you wish to use different limits.

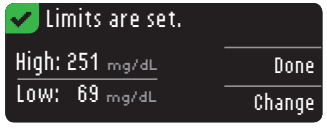
11. Press the ▲ or ▼ button to select your high limit. Press **OK**.



12. Press the ▲ or ▼ button to select your low limit. Press **OK**.

NOTE: *Pressing and holding the ▲ or ▼ buttons will scroll through the list faster.*

13. The next screen confirms your choices. Press **Done**.



Initial Setup is complete. You may now check your blood glucose.

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Information for Safety

- ***Always keep the test strips in the original bottle. Tightly close the bottle immediately after removing a test strip.*** The bottle is designed to keep the test strips dry. Exposure to room humidity from leaving the bottle open or not storing them in the original bottle can damage your test strips. This could lead to inaccurate results.
- ***Wash and dry your hands well before testing.***
- ***Test strips are for single use only. Do not use a test strip that appears damaged or has been used.***
- ***Your test strip is designed to easily "sip" the blood into the sample tip.*** Do not drop blood directly on the flat surface of the test strip.
- ***Do not press the test strip against your finger when testing.*** This may block the sample tip.
- ***Let the meter and test strips adjust to the temperature where you are testing.*** Whenever the meter is moved from one location to another, allow approximately 20 minutes for the meter to adjust to the temperature of a new location before performing a blood glucose test. The meter has been designed to give accurate results at temperatures between 41°F and 113°F. Please be aware that USB ports in some computers and self-powered USB hubs can become much warmer than the room. A USB cable has been provided for your convenience. If you wish to test immediately after disconnecting from your computer, please use the USB cable.
- ***Check the expiration dates on your test strips and control solution.*** It is important to not use the test strips or control solution if the expiration date printed on the bottle label and carton has passed. For the control solution, do not use if it has been six months since you first opened the bottle. It will help to write the six month discard date on the control solution label.

- ***Have all the materials you will need ready before you begin testing.*** This includes your CONTOUR®NEXT LINK meter, CONTOUR® or CONTOUR®NEXT test strips, and the MICROLET®2 lancing device and MICROLET® lancets. You will also need control solution made for your test strips to perform a quality control check.
- ***The MICROLET 2 lancing device is intended for self testing by a single patient. It must not be used on more than one person due to the risk of infection.***
- ***Use a new MICROLET lancet each time you test because it is no longer sterile after use.***
- See pages 29 – 32 for instructions on cleaning and disinfecting your meter and lancing device.
- Do not perform a blood glucose test when the CONTOUR NEXT LINK meter is connected to an external device, e.g., computer.
- Use only approved equipment from the manufacturer or certified body such as UL or TUV.

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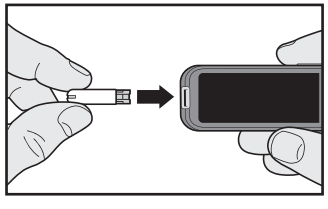
The following steps are shown in the proper order for performing a blood glucose test (pages 14-28).

Preparing Your Test Strip

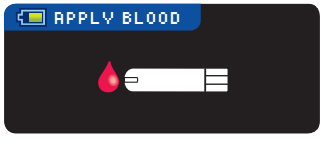
1. Wash and dry your hands well before testing.
2. Remove a test strip from CONTOUR®NEXT or CONTOUR® bottle. **Tightly close the bottle lid immediately after you have removed the test strip.**

3. Hold the test strip with the gray end facing up.
4. Insert the gray end into the test strip port on the meter.



After the meter turns on, a solid **gray screen with a white border** will appear for one second to show that the screen is working properly.

The logo screen will briefly appear before the **Apply Blood** screen. The meter is now ready to test a blood drop.



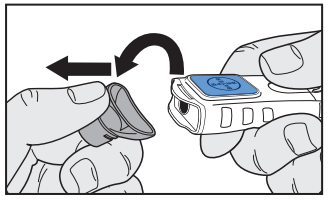
Preparing Your Lancing Device

Read the MICROLET®2 lancing device insert for complete instructions. For Alternative Site Testing instructions, see page 21.

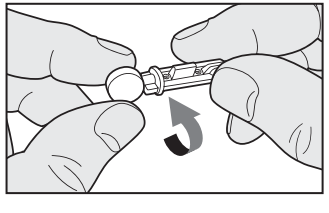
Warning: Potential Biohazard

The MICROLET 2 lancing device is intended for single patient use only. The MICROLET 2 device should not be used for assisted blood draws by healthcare providers or at healthcare provision sites, and should never be shared with anyone else, even a family member due to risk of infection. Use a new MICROLET® lancet each time you test because it is no longer sterile after use.

1. To remove the endcap, hold the device with your thumb on the grip indent and hold the endcap dial in the other hand. Snap the endcap off from top to bottom.



2. Loosen the round protective cap on a lancet by rotating it ¼ turn, but do not remove it.



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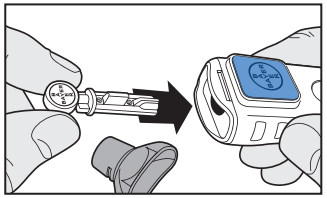
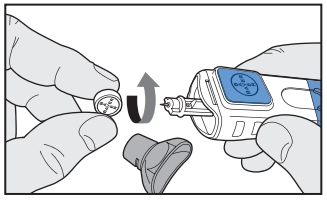
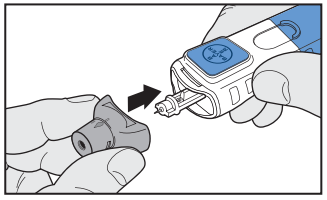
3. Insert the lancet firmly into the lancing device until it comes to a full stop.



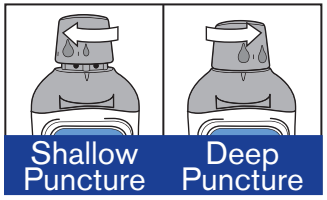
4. Twist off the round protective lancet cap. Save it for disposing of the used lancet.



5. Replace the gray endcap.



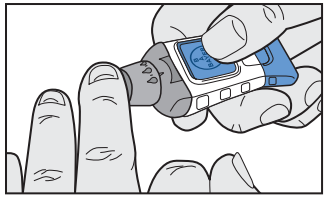
6. Rotate the endcap dial to adjust the puncture depth. The amount of pressure applied to the puncture site also affects puncture depth.



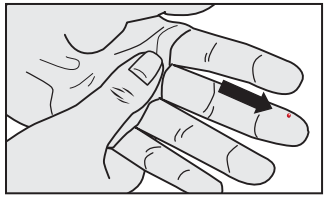
Getting the Blood Drop

For fingertip testing

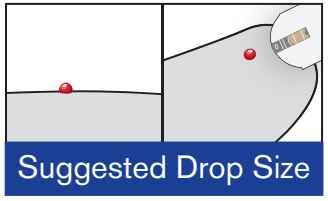
1. Press the endcap firmly against the puncture site and press the blue release button with your thumb.



2. Stroke your hand and finger towards the puncture site to form a drop of blood. Do not squeeze around the puncture site.



3. Test immediately after you have formed a small, round blood drop (0.6 µl).



If the first blood drop is not enough, the meter may beep twice and display "**STRIP UNDERFILLED**." You have 20 seconds to apply more blood onto the same strip.

If you selected fingertip testing, turn to page 18 to continue reading testing instructions.

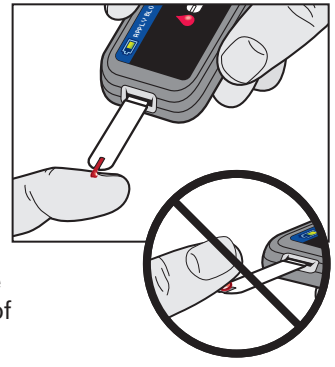
MST_CntrNextLINK_UG_EN_FpBp_v6.indd 16-17
5/18/11 3:01 PM

Warning:

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients![1,2]
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

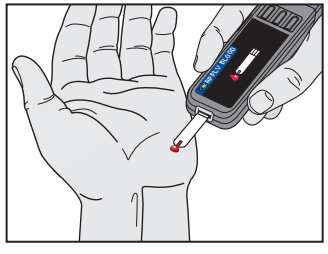
For complete instructions on cleaning and disinfecting your meter and lancing device, please see page 29.

4. Immediately touch the **tip** of the test strip to the drop of blood.* The blood is pulled into the test strip through the tip.

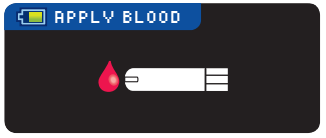


Hold the tip of the test strip in the blood drop until the meter beeps.

Do not press the tip against the skin or place the blood on top of the test strip or you could get inaccurate results or errors.



***NOTE: If you do not apply blood to the test strip within 1 minute**, the meter screen will dim and the meter beeps. Press any button and the **Apply Blood** screen will become active again. After a total of 3 minutes of inactivity the meter turns off.



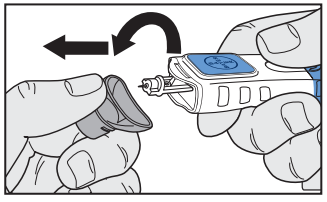
If you are using a CONTOUR® test strip, and your blood drop is not enough, you will need to remove the test strip and apply more blood to a new test strip. You will see the **Too Little Blood** screen.

If you are using a CONTOUR®NEXT test strip, you have 20 seconds to apply more blood onto the same strip. If you are not able to provide more blood within that time, discard that strip and start over with a new strip. Follow the instructions on the meter screen.

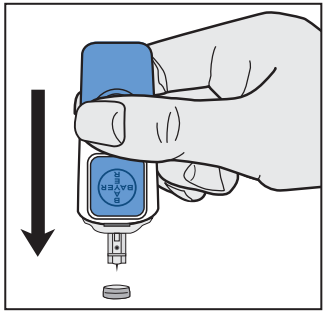
MST_CntrNextLINK_UG_EN_FpBp_v6.indd 18-19
5/18/11 3:01 PM

Removing the Used Lancet

1. In one hand, hold the lancing device with your thumb on the grip indent, with your other hand, hold the gray endcap dial as shown, and gently snap off the endcap.

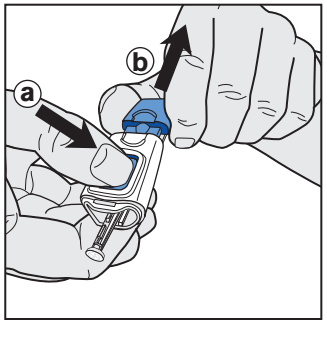


2. Place the round protective lancet cap on a flat surface with the Bayer logo facing down.



3. With the used lancet still in the lancing device, push the lancet needle completely into the middle of the exposed side of the cap.

4. While pressing the release button (**a**), pull the re-setting handle (**b**), and the lancet will drop into the container you have selected.



5. Dispose of the used lancet as medical waste.

   Do not reuse lancets. Use a new MICROLET® lancet each time you test.

Need Help? Call toll free: 1-800-348-8100

CAUTION: CONTOUR® test strips should not be used for Alternative Site Testing (AST) with the CONTOUR®NEXT LINK meter.

For Alternative Site Testing (palm only) with CONTOUR®NEXT test strips

IMPORTANT: Do not use Alternative Site Testing under the following conditions. Use fingertip testing in any of these cases:

- If you think your blood glucose is low (hypoglycemia).
- When blood glucose is changing rapidly (after a meal, insulin dose or exercise).
- If you have hypoglycemic unawareness (lack of symptoms).
- If you get alternative site blood glucose results that do not agree with how you feel.
- During illness or times of stress.
- If you will be driving a car or operating machinery.
- For calibration of CGM System.

AST testing should not be used for Bolus Wizard, to calibrate a device or verify a low blood glucose level.

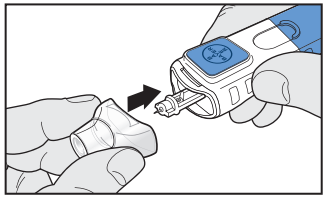
Consult your healthcare professional to determine if alternative site testing is right for you.

MST_CntrNextLINK_UG_EN_FpBp_v6.indd 20-21
5/18/11 3:01 PM

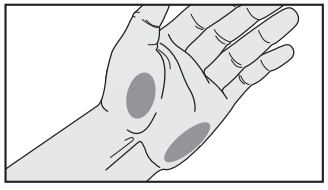
For Alternative Site Testing (cont'd)

Alternative Site Testing on the palm can only be performed using the CONTOUR®NEXT test strip. Alternative Site Testing is recommended only when it is more than two hours after a meal, diabetes medication, or exercise.

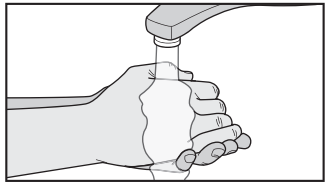
1. Attach the **clear** AST endcap to the MICROLET®2 lancing device.



2. Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones, and tendons.



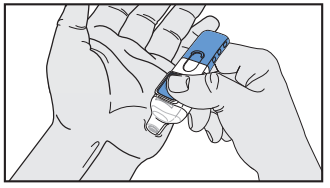
3. Wash your hands and the puncture site with soap and warm water. Rinse and dry well.



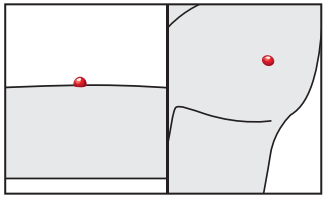
For Palm Testing

NOTE: AST testing (palm only) can only be done using a CONTOUR NEXT test strip.

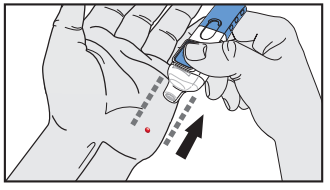
4. Press the **clear** endcap firmly against the puncture site and then press the blue release button.



5. Maintain steady pressure until a small, round blood drop forms.



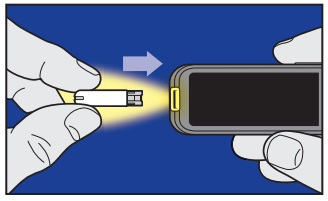
6. Lift the device straight up and away from the skin without smearing the blood.



Do not test the blood sample from palm if you get:
Smeared blood ▪ Clotted blood ▪ Runny blood ▪ Clear fluid mixed with the blood.

MST_CntrNextLINK_UG_EN_FpBp_v6.indd 22-23
5/18/11 3:01 PM

Testing in the Dark



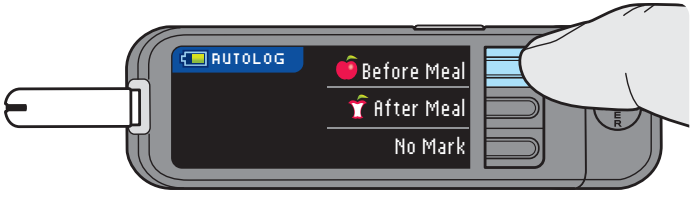
Your meter has a lighted test strip port to help you test in the dark.

With the meter off, give the Menu button two quick presses to turn on the test strip port light. Insert a test strip and the display screen will appear. Once blood is applied to the test strip the light will go off. Continue with your test.

Two quick presses of the Menu button will turn the light off.

Testing with AutoLog On

Before your test result is displayed, the AutoLog screen appears. **Select Before Meal, After Meal or No Mark by pressing the button next to it. Your test result will not display until you make a selection.**



However, if your result is below 70 mg/dL or above 250 mg/dL, you will always see your result without pushing a button. For a high or low blood glucose result, you will always see your result after a 5-second countdown.

NOTE: If you changed the default settings, your alerts will be based on those settings.

Your meter features a count-down timer. If you make your selection very quickly, you may see the remainder of the testing countdown.

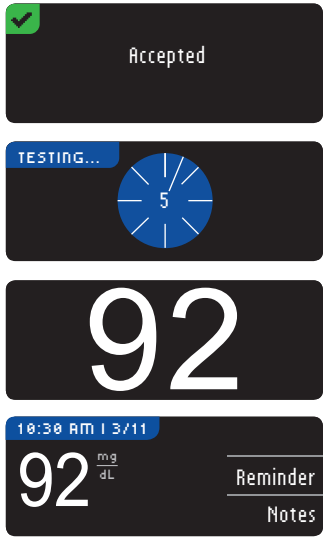
Your test result shows as large numbers and then changes to the normal test result screen.

MST_CntrNextLINK_UG_EN_FpBp_v6.indd 24-25
5/18/11 3:01 PM

Testing with AutoLog Off

After applying blood to the test strip when AutoLog is turned off, your result will appear after the 5 second countdown (see page 55).

NOTE: You will see the Accepted screen only when testing with a CONTOUR®NEXT test strip.



You may add a Note or Reminder.

Depending on what you have chosen in setup, you will have the option to send your test result to your pump or it will be sent automatically. For results under 20 mg/dL or over 600 mg/dL, see page 33.

You can now set an optional **Reminder** (see page 38) or add a **Note** (see page 45).

Remove the test strip from the meter. Hold the menu button to turn off the meter, or press the menu button to go to the main menu.

Always dispose of test strip and lancet as medical waste. All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.

Please refer to your MICROLET®2 package insert for instructions on how to properly remove and dispose of the lancet.

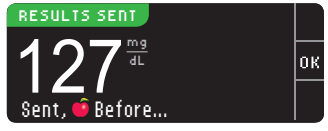
Stopping a Result While it is Being Sent

If you want to stop the transmission of a result, press **Cancel** immediately and the transmission will be cancelled. (The transmission typically occurs in 5 seconds.) Be aware that the result **cannot** be resent later.

Sending Test Results

Depending on how you have set up your options, you can send your test results or not. If you have selected **Ask Me**, you can always send or not send.

If you have selected **Always**, your test result will be sent automatically to your compatible Medtronic MiniMed device.



MST_CntrNextLINK_UG_EN_FpBp_v6.indd 26-27
5/18/11 3:01 PM

IMPORTANT:

- You may want to test with **Send Options** set to off if you do not want to create a wireless signal (for example, if you have been asked to turn off all electronic devices on an aircraft).
- Always check the display on your compatible Medtronic MiniMed device to ensure that the glucose result shown agrees with the meter display.

Test Results

Expected Values: Blood sugar values will vary depending on food intake, medication dosages, health, stress, or activity. Non diabetic plasma glucose concentrations are normally maintained within a relatively narrow range, roughly 70 – 110 mg/dL in the fasting state.[3] ***You should consult with your healthcare provider for expected values specific to your needs.***

Cleaning and Disinfecting

Your CONTOUR®NEXT LINK system should be cleaned and disinfected as recommended.

Cleaning is the removal of visible dirt and debris, but does not reduce the risk for transmission of infectious diseases. Your CONTOUR NEXT LINK system should be cleaned of dirt and debris as needed.

Disinfecting (if performed properly) reduces the risk of transmitting infectious diseases. It should be disinfected at least once a month or when contamination with blood is suspected or is visible and before anyone assists you with the testing of your blood glucose.

For more assistance call: 1-800-348-8100

www.bayerdiabetes.com/us

More information can be found at:

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Cleaning your Meter

Supplies Necessary for Cleaning:

- Mild detergent
- Paper towels

1. If the meter is soiled, clean with a drop of mild detergent on a moist (not wet) paper towel. *Do not allow cleaning solution to run into the meter through areas such as the data or strip ports or around the buttons*. Wipe away any detergent residue and dry as necessary with a clean paper towel.

MST_CntrNextLINK_UG_EN_FpBp_v6.indd 28-29 5/18/11 3:01 PM

Disinfecting your Meter

Supplies Necessary for Disinfecting:

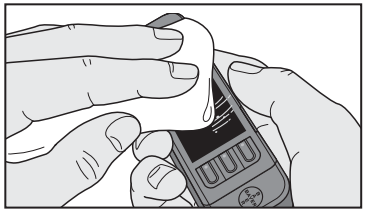
- Household bleach spray with 1.84% sodium hypochlorite
- Paper towels • Cotton swabs • Timing device

1. Before disinfecting, if the meter is soiled it must be cleaned as described in CLEANING YOUR METER (see page 29).

DO NOT SPRAY BLEACH DIRECTLY ON YOUR METER

2. To disinfect, spray a clean and dry paper towel with bleach spray until wet but not dripping.
3. Wipe all exposed surfaces of the meter until wet. *Do not allow disinfecting solution to run into the meter through areas such as the data or strip ports or around the buttons.*

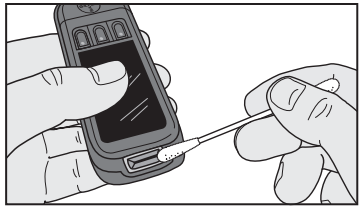
WIPING CONTINUOUSLY, KEEP ALL METER SURFACES WET FOR 60 SECONDS.



Disinfecting your Meter (cont'd)

4. To disinfect the test strip port, moisten a cotton swab with bleach spray and wipe all strip port surfaces until wet. *Again, do not allow disinfecting solution to run into the meter.*

KEEP ALL STRIP PORT SURFACES WET FOR 60 SECONDS, WIPING CONTINUOUSLY.



5. Dry all meter surfaces and test strip port using a clean paper towel if needed.

Cleaning your Lancing Device

Supplies Necessary for Cleaning:

- Mild detergent • Paper towels

1. If the MICROLET®2 is soiled, clean with a drop of mild detergent on a moist (not wet) paper towel. Wipe away any detergent residue and dry as necessary with a clean paper towel.

Disinfecting your Lancing Device

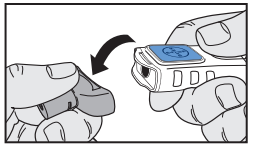
Supplies Necessary for Disinfecting:

- Household bleach spray with 1.84% sodium hypochlorite
- Paper towels • Cotton swabs • Timing device

MST_CntrNextLINK_UG_EN_FpBp_v6.indd 30-31
5/18/11 3:01 PM

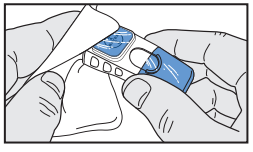
Disinfecting your Lancing Device (cont'd)

1. Before disinfecting, if the lancing device is soiled it must be cleaned as described in CLEANING YOUR LANCING DEVICE (see page 31).
2. To disinfect, spray a clean and dry paper towel with bleach spray until wet but not dripping.
3. Remove the end cap and lancet if present.



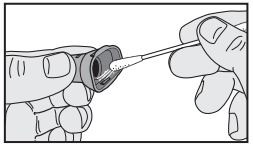
4. Wipe all exposed surfaces of the lancing device until wet.

WIPING CONTINUOUSLY, KEEP ALL LANCING DEVICE SURFACES WET FOR 60 SECONDS.



5. Moisten a cotton swab with bleach solution and wipe all internal and external surfaces of the end cap until wet.

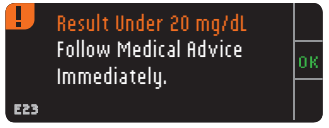
WIPING CONTINUOUSLY, KEEP ALL END CAP SURFACES WET FOR 60 SECONDS.



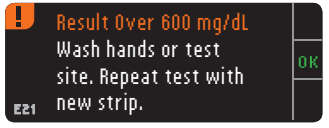
6. Dry all lancing device surfaces and end cap with a clean paper towel if needed.

High and Low Blood Sugar Alert Screens

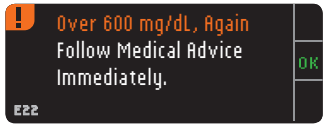
- If your blood sugar reading is under 20 mg/dL, the "Follow Medical Advice Immediately" screen will display and the meter will beep twice. Contact your healthcare professional.



- If your blood sugar reading is over 600 mg/dL the next screen will tell you to retest. The meter will beep twice.



- If results are still over 600 mg/dL, "Follow Medical Advice Immediately" is displayed. Contact your healthcare professional for advice.



CAUTION:

- ***If your blood sugar reading is under 50 mg/dL, follow medical advice immediately.***
- ***If your blood sugar reading is over 250 mg/dL, wash and dry your hands well and repeat the test with a new strip. If you get a similar result, call your healthcare professional as soon as possible.***
- ***Always consult your healthcare professional before changing your medication based on CONTOUR®NEXT LINK test results.***

MST_CntrNextLINK_UG_EN_FpBp_v6.indd 32-33
5/18/11 3:01 PM

High and Low Blood Sugar Readings

Your meter has been preset with a hypoglycemic (low blood sugar) value of 70 mg/dL and a hyperglycemic (high blood sugar) value of 250 mg/dL. These are the default values, but can be customized by you and/or your healthcare professional.

Low Blood Sugar

If your blood sugar reading is under 70 mg/dL:

- A screen with large orange numbers will alert you that your blood sugar is low.

High Blood Sugar

If your blood sugar reading is over 250 mg/dL:

- A screen with large orange numbers will alert you that your blood sugar is high.

- If AutoLog is on and you were not able to mark it before the high or low alert appeared, press the **Notes** button. You may now select **Before Meal**, **After Meal** or **No Mark** by pressing the button next to it.

Control Solution Testing

Use only Bayer's control solutions (Normal, Low and High) with Bayer's CONTOUR®NEXT LINK blood glucose monitoring system. CONTOUR® control solution should only be used with CONTOUR test strips. CONTOUR®NEXT control solution should only be used with CONTOUR NEXT test strips. Using any other control solution or any other combination of control solution and strips could present incorrect results.

Perform a control test:

- When using your meter for the first time
- When you open a new bottle or package of test strips
- If you think your meter may not be working properly
- If you have repeated, unexpected blood sugar results.

Normal, Low or High control solutions are available. **Always use** Bayer's control solutions specific to your test strips. Other brands could present incorrect results. If you need help locating Bayer's CONTOUR or CONTOUR NEXT control solutions, call Bayer Diabetes Customer Service at 1-800-348-8100.

1. Wash and dry your hands well before testing.
2. Remove a test strip from the bottle and **firmly snap the lid closed**.

NOTE: *Check the expiration date on the test strip bottle and the expiration and discard dates on the control solution. Do not use expired materials. Make sure the test strip does not appear torn or damaged.*

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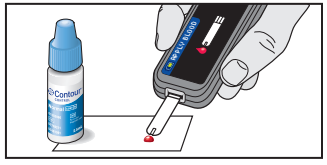
3. Prepare to run a control test by inserting a test strip into the meter.
4. Gently rock the control bottle before opening to ensure it is mixed well.
5. Squeeze a small drop of control solution onto a clean non-absorbent surface, such as a piece of wax paper. **Do not apply control solution to the test strip directly from the bottle**.
6. Replace the cap on the control solution bottle.
7. Immediately touch the **tip** of the test strip to the drop of control solution.
8. Hold it in the drop until the meter beeps.



NOTE: The **Accepted** screen displays only when using CONTOUR®NEXT test strips.

9. Compare your control test result with the Normal Control range printed on the test strip bottle label or on the bottom of the test strip box.

The result will automatically be marked as a control test and stored in the meter memory. Control results will not be included in your blood sugar average or sent to your pump. To turn your meter off, hold down the menu button for 2 seconds.

The Low and High control range values can be found on the bottom of the test strip box.

If your control test result falls out of the specified range, call Customer Service, 1-800-348-8100. Do not use the meter for blood glucose testing until you resolve this issue.

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Setting a Reminder

A Reminder for your next test can be set after testing or from the Setup menu.

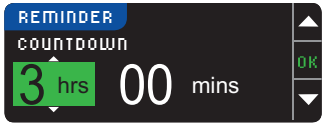
After Testing

1. Press the **Reminder** button.

2. Press the **Start** button to begin the countdown. The default time is 2 hours or the last reminder time that was set.

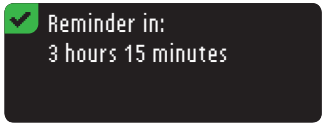
You can change the Reminder countdown time to the time you wish by pressing the **Change** button.

1. Press the ▲ or ▼ button to select the correct hours. Press the **OK** button.

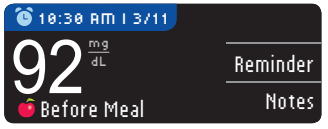


2. Press the ▲ or ▼ button to select the minutes (in 15 minute increments). Press the **OK** button.

A screen confirms the Reminder countdown time. The meter will return to the test result screen.



When the Reminder feature is on, the clock symbol is in the blue header.



3. Remove the test strip from the meter.

The meter retains the Reminder time that you set as the default.

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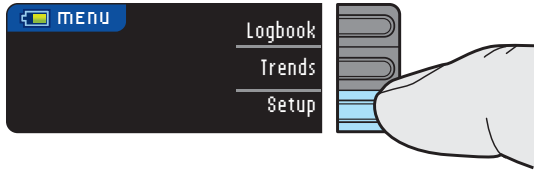
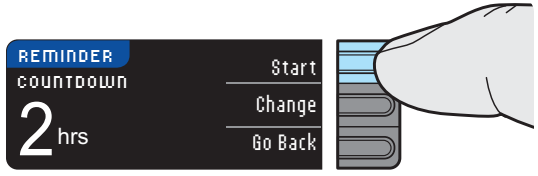
From the Setup Menu

1. Go to the Main Menu. Press the **Setup** button.

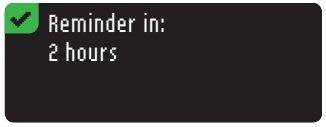


2. If Reminder is set to off, press the **OK** button to change the Reminder settings.

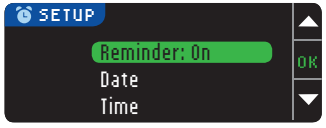
3. To start the countdown press the **Start** button or press the **Change** button to scroll to a different countdown time. Follow the instructions on the previous page.



A screen confirms the Reminder time set.



When the Reminder feature is on, the clock symbol is in the blue header.



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Turning Off a Reminder

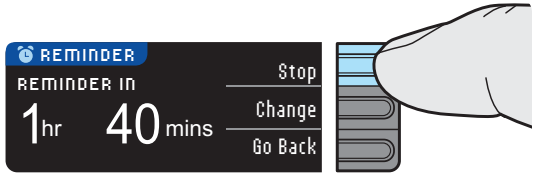
A Reminder can be turned off or changed after testing or from the Setup menu.

After Testing

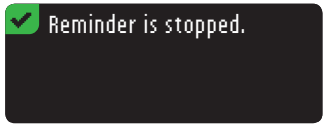
1. Press the **Reminder** button.

If the countdown is currently on, the screen will read "Reminder In:" with the remaining amount of time displayed.

2. To stop the Countdown press the **Stop** button.



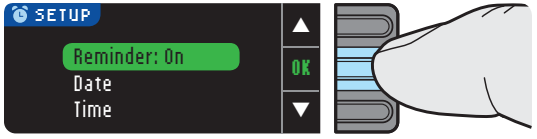
A screen confirms your choice.



The Countdown is now stopped and the clock symbol will no longer appear on the screen.

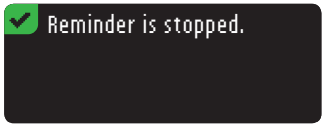
From the Setup Menu

1. Press the **OK** button.



2. Press the **Stop** button. The countdown is now stopped. The Reminder screen displays the remaining time.

A screen confirms your choice.



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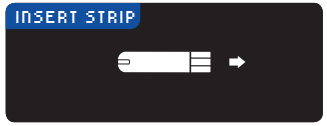
Getting a Reminder

When the Reminder time is reached, 20 beeps will sound. The meter will turn on and a Reminder screen will appear. You can stop the beeps by pressing the **OK** button or inserting a test strip.

1. Press the **OK** button.

2. Proceed with testing (see page 14).



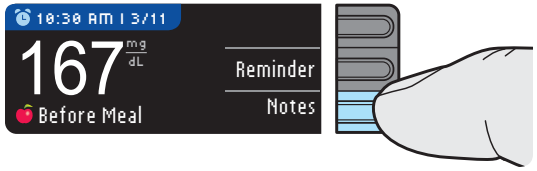
If you are testing within 15 minutes of the reminder, neither screen will appear and the countdown will be stopped.

Need Help? Call toll free: 1-800-348-8100

Adding Notes

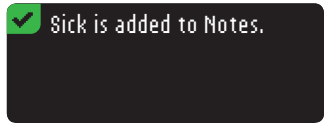
You may add **Notes** to your test result that may help explain results. Your notes will be saved in the Logbook.

1. From the test result screen, press the **Notes** button.

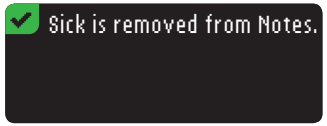


2. Press the ▲ or ▼ button to scroll through the choices. Some may not be visible until you scroll up or down. Press the **OK** button when your choice is highlighted.

A screen confirms your choice.



After the confirmation screen disappears, you may remove the note or add additional **Notes** by repeating the steps above. The notes will scroll across the bottom so that you can read them all.



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Menu Button

- **To turn on the meter, press and hold the Menu button until the meter turns on.**

The Main Menu has 3 choices: **Logbook**, **Trends** and **Setup**.

- Select one by pressing the button next to your choice.
- To go back a screen, press the Menu button once.

- To turn the meter off, press and hold the Menu button for 2 seconds.
- To turn the test strip port light on with the meter off, give the Menu button two quick presses. Two quick presses of the Menu button will also turn off the light.

Logbook

To access the Logbook, press the Logbook button from the Main Menu.

In Logbook you can scroll through all the stored test results in memory by pressing the ▲ or ▼ button.

Need Help? Call toll free: 1-800-348-8100

The most recent result is shown first and the oldest result last. When you reach the oldest entry you will see the **End of Logbook** screen. Your meter will store 1000 test results.

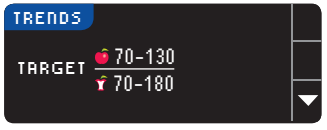
Trends

Trends displays your averages and your results as they compare to your targets, over a period of time that you select.

1. Press the **Trends** button to view averages.

14 days is the default. You can change the **Trends** time range to 7 or 30 days in **Setup** (see page 57).

If AutoLog is on, the (Before Meal) and (After Meal) target ranges will appear. To set personalized target ranges, see page 56.



If AutoLog is off, you will only see one target range (no Before Meal/ After Meal).

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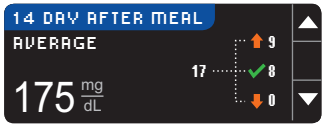
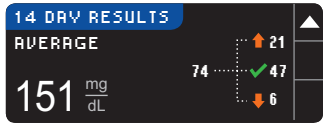
The next three screens will show 14 day Before Meal, 14 day After Meal and 14 day total average. Also shown are the total number of test results included in the average, the number of tests ↑ (above), ✓ (within) and ↓ (below) target.

2. Press the ▼ button to display the 14 Day Before Meal Average. This example shows that your Before Meal average is 128 mg/dL and 38 test results are included in the Before Meal average with 26 in the ✓ target range, 8 ↑ over your target range and 4 ↓ under the target range.

3. Press the ▼ button to go to the 14 Day After Meal Average.



4. Press the ▼ button to go to the 14 Day Results screen.



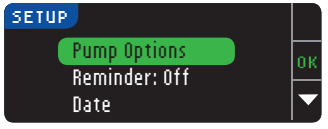
NOTE: *If you turn off AutoLog, only the 14 Day Results total will display. You will not see before and after meal averages.*

Setup

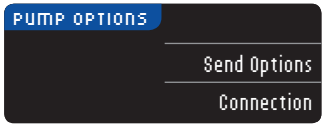
Pump Options

Go to the pump options in the setup menu if you want to change your original choices.

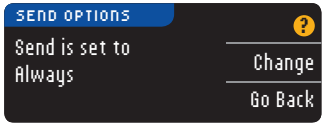
1. Make your selection: **Send Options** or **Connection**. Send options controls when your blood glucose readings are sent to your compatible Medtronic MiniMed device. Choosing Connection will display steps to connect your CONTOUR®NEXT LINK meter to your compatible Medtronic MiniMed device. (Go to Step 6)



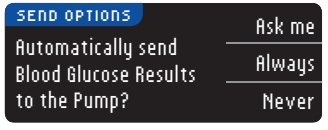
2. Press **Send Options** to change your current setting.



3. Then press **Change**. Or press **Go Back** if you do not wish to change **Send Options**.



4. Choose the setting that is best for you. The choices are: **Ask Me**, **Always**, or **Never**.



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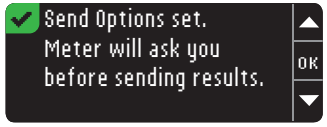
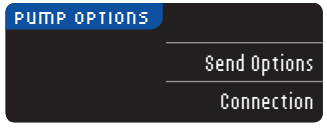
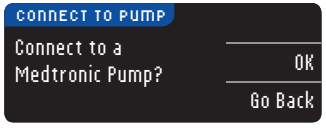
5. The next screen confirms your choice. Press **OK**.



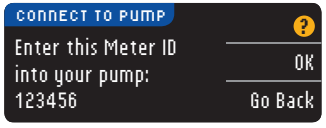
6. Choose **Connection** from the Pump Options menu to connect your CONTOUR®NEXT LINK meter to your compatible Medtronic MiniMed device.



7. Press **OK** to continue the connection process. Press **Go Back** if you do not wish to continue the connection.



8. Follow the instructions on your compatible Medtronic MiniMed device to connect with your meter (refer to the separate Medtronic User Guide.) Do not press **OK** on your meter screen until connection process is complete.



NOTE: Pump on meter screen refers to your compatible Medtronic MiniMed device.

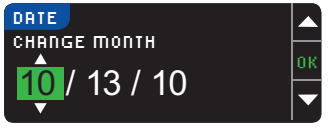
Setting the Date

1. Press the Menu button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the ▲ or ▼ button to select Date. Press the **OK** button.

4. To change the date, press the **Change** button.
5. Select either the **Month/Day/Year** or **Day.Month.Year** button.

6. Press the ▲ or ▼ button to select the correct year. Press the **OK** button.

7. Press the ▲ or ▼ button to select the correct month. Press the **OK** button.



8. Press the ▲ or ▼ button to select the correct day. Press the **OK** button.

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A screen confirms the date you entered. If correct, press the **Done** button and the Setup menu will appear.

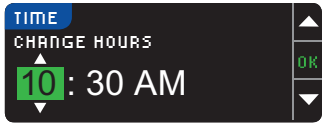
If you need to make changes, press the **Change** button and repeat the process.

Setting the Time

1. Press the Menu button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the ▲ or ▼ button to select Time. Press the **OK** button.

4. To change the time, press the **Change** button.
5. Select either the **12 hour clock** or **24 hour clock** button.

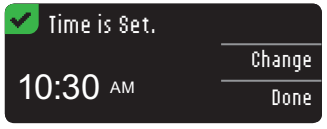
6. Press the ▲ or ▼ button to select the correct hour. Press the **OK** button.



7. Press the ▲ or ▼ button to select the correct minute. Press the **OK** button.

8. Press the ▲ or ▼ button to select the correct AM/PM. Press the **OK** button.

A screen confirms the time you entered. If correct, press the **Done** button and the Setup menu will appear.



If you need to make changes, press the **Change** button and repeat the process.

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Turning the Sound On/Off

Sound is turned ON when you receive your meter. It can be turned off using the Setup menu. Some error messages and the Reminder bell will override the Sound off setting. One long beep indicates a confirmation. Two beeps indicate an error or situation that requires your attention.

1. Press the Menu button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the ▲ or ▼ button to select Sound. Press the **OK** button.

4. To turn the sound off, press the **Turn Off** button.

   To keep the sound on, press **Accept.**

A screen confirms your choice. The Setup menu will appear.

Turning AutoLog On/Off

The AutoLog feature lets you mark your test result as Before Meal or After Meal during the test countdown. You can select No Mark if you are testing at times other than before or after a meal. Your meter comes with AutoLog turned on. We recommend that you keep this feature turned on.

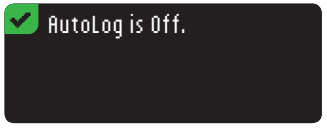
NOTE: When AutoLog is ON, a result will not appear unless marked as Before Meal, After Meal, or No Mark; or if the result is outside the High/Low limits.

1. Press the ▲ or ▼ button to select AutoLog. Press the **OK** button.

2. To turn the AutoLog off, press the **Turn Off** button.

   To keep the AutoLog on, press the **Accept** button.

A screen confirms your choice. The Setup menu will appear.



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Changing the Blood Glucose Target Range

Your CONTOUR®NEXT LINK meter comes preset with 70–130 mg/dL for Before Meal testing and 70–180 mg/dL for After Meal testing. Ranges can be changed to personal targets decided by you and/or your healthcare professional.

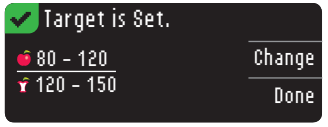
1. Press the Menu button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the ▲ or ▼ button to select **Target**. Press the **OK** button.

4. To make changes to your target range, press the **Change** button, otherwise **Go Back**. Press ? for **Help**.

5. Press the ▲ or ▼ button to select your desired **(Before Meal)** low target. Press the **OK** button.

Repeat this process to set your personal **(Before Meal)** high target and **(After Meal)** low and high targets. Press the **OK** button after each selection.

A screen confirms that all target ranges are set. If correct, press the **Done** button. You will be returned to the Setup menu.

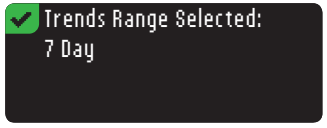


To make changes, press the **Change** button and repeat the process.

Setting Trends Range

1. The default setting for the Trends Range is 14 days. To choose another Trends Range, press **Change**. The other Trends Range options are 7 or 30 days.

2. The next screen will confirm your selection.



MST_CntrNextLINK_UG_EN_FpBp_v6.indd 56-57
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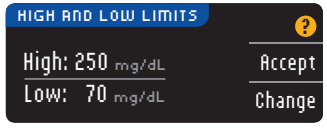
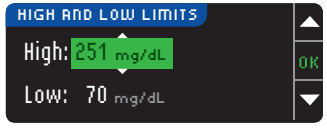
High and Low Limits

1. Choose **Accept** to use the default settings. The default high limit is 250 mg/dL and the default low limit is 70 mg/dL.

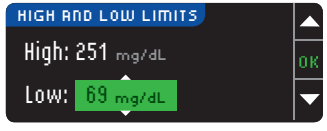


Choose **Change** if you wish to use different limits.

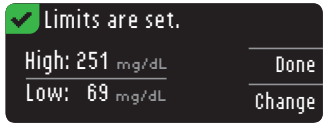
2. Press the ▲ or ▼ button to select your high limit. Press **OK**.



3. Press the ▲ or ▼ button to select your low limit. Press **OK**.



4. The next screen confirms your choices. Press **Done**.



Setting the Language

1. Press the Menu button to go to the Main Menu.
2. Press the **Setup** button.
3. Press the ▲ or ▼ button to select **Language**. Press the **OK** button.

4. Press the ▲ or ▼ button to select the language you prefer. Press the **OK** button.

A screen confirms your choice. The Setup menu will appear in the language you selected.

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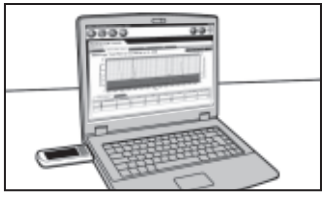
Transferring Data to Medtronic's CareLink® Personal Therapy Management Software



You can easily transfer blood glucose results from the CONTOUR®NEXT LINK meter to CareLink Personal Therapy Management software. You can also wirelessly transfer data from your compatible Medtronic MiniMed device to CareLink Personal Therapy Management software using your CONTOUR NEXT LINK meter.

1. Refer to the CareLink Personal Therapy Management software user guide for instructions on how to set up CareLink and load the required drivers onto your computer.
2. If you are running Bayer's GLUCOFACTS® DELUXE diabetes management software on your computer, you must close it.
3. Start up CareLink Personal. Follow the instructions on each window, then, when instructed, plug your CONTOUR NEXT LINK meter into a USB port on your computer. CareLink Personal will automatically find the CONTOUR NEXT LINK meter and your compatible Medtronic MiniMed device.

Your CONTOUR NEXT LINK meter is also compatible with Bayer's GLUCOFACTS DELUXE diabetes management software.

IMPORTANT:

Bayer's CONTOUR NEXT LINK meter has only been tested for use with Medtronic's CareLink Personal Therapy Management Software and Bayer's GLUCOFACTS DELUXE diabetes management software. Bayer is not responsible for any erroneous results from the use of other software.

For more information, call our Customer Service Department (1-800-348-8100), or visit our website at www.bayerdiabetes.com/us.

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Error Detection Displays

An error screen will always have an "E" with a number in the lower left hand corner of the display.

If there is an error (hardware, software, testing errors) detected by your meter, your meter will beep twice. You will see specific instructions to guide you. The first line of the error screen will tell you what the error is. The next lines describe what you should do. When an error screen has an **OK** shown, press the button next to it to continue.

NOTE: If your screen displays a "connection error", your test result was not sent to your compatible Medtronic MiniMed device. Make sure your CONTOUR®NEXT LINK meter is within 4 feet of your compatible Medtronic MiniMed device and the device is set to accept meter results. Your meter ID must be programmed into the device. Refer to the separate Medtronic User Guide.

Check the device display to see if your meter's glucose result has been received. If it has not, you can enter the test result manually. If you continue to have problems, contact Bayer Customer Service at 1-800-348-8100.

Battery Status Displays

The battery status will be displayed with a battery symbol on the Apply Blood screen and the Main Menu screen. It shows how much battery life is left. This screen displays full battery.

As the battery is used, the battery symbol on the screen gradually shows less fill color. The color of the battery fill turns yellow when the battery is low and then red when your battery is almost out of charge.

A series of low battery alerts will tell you that the battery is low and to charge soon.

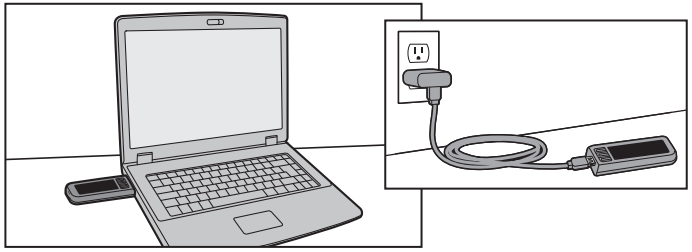
Error Detection and Battery Status/Charging/Removal

Technical, Service & Care

MST_CntrNextLINK_UG_EN_FpBp_v6.indd 62-63 5/18/11 3:01 PM

If you do not charge the battery, a display will alert you: “Shutting down, Battery is dead.” Charge immediately.

Plug the meter into your wall charger or computer. Be sure your computer is turned on and not in sleep, hibernate or power save mode. Please be aware that USB ports in some



computers and self-powered USB hubs can become much warmer than the room. A USB cable has been provided for your convenience. If you wish to test immediately after disconnecting from your computer, please use the USB cable.

The test strip port light will flash during charging and stop flashing when charging is complete. Please remove the meter and store in the wallet until you are ready to test.

Battery Charging

When you plug your meter into your wall charger or computer, it will start to charge immediately. While the battery charges, the strip port light flashes slowly.

Press the Menu button at any time to display the charging status.

Rapid Charge

If the battery is low when you plug in your meter, it will Rapid Charge for about 1 minute. You can run a blood glucose test as soon as Rapid Charge is complete.

Normal Charging

When Rapid Charge ends, normal charging is expected to last up to 2 hours. When the battery is full, the strip port light turns off.

NOTES: *CONTOUR®NEXT LINK requires a high-power USB port. If the charging status displays “Low Power Charging,” your CONTOUR NEXT LINK meter may be plugged into a low-power USB port. Please try a different USB port on your computer. If you are unsure whether your computer has a high-power USB port, please check your computer user manual or with the computer manufacturer.*

You should only connect your meter to a computer with current anti-virus software installed and running.

Wall Charger

For information about your wall charger please refer to the insert contained in your meter kit.

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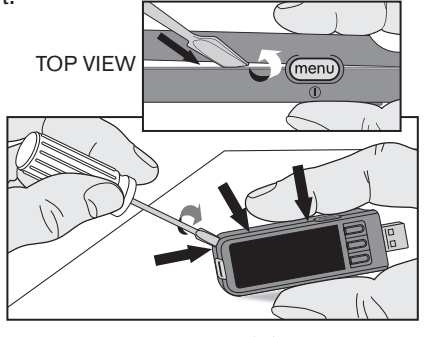
End of Meter Life/Battery Removal

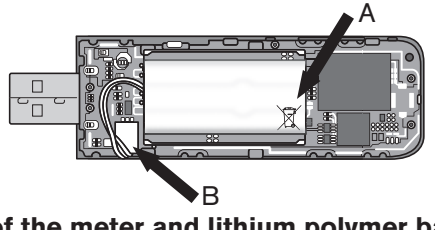
***NOTE:* Carry out this process only when you no longer intend to use the meter. Meter will not be functional once opened to remove the battery.**

To remove the battery for proper disposal, you will need to pry the upper and lower cases apart.

With a screwdriver, beginning near the strip port, insert the tip of the screwdriver and twist to pry the case loose. Continue to do this down the side until the upper case comes apart.



Pry up rechargeable battery here (A).
Disconnect battery by pulling battery connector (B).



Dispose of the meter and lithium polymer battery in accordance with your local/country laws and regulations.

Symptoms of High and Low Blood Sugar

You can better understand your test results by being aware of the symptoms of high or low blood sugar.

According to the American Diabetes Association, some of the most common symptoms are:

Low blood sugar (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- irritability
- seizure
- extreme hunger
- dizziness

High blood sugar (Hyperglycemia):

- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

Ketones (Ketoacidosis) (often accompanied by very high blood sugar):

- shortness of breath
- nausea and vomiting
- very dry mouth

Information for Safety

If you are experiencing any of these symptoms, test your blood sugar. If your test result is under 50 mg/dL or above 250 mg/dL, contact your healthcare professional immediately.

For additional information and a complete list of symptoms, contact your healthcare professional or refer to the website of the American Diabetes Association: www.diabetes.org.

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System Performance Information

Capillary samples may be drawn from fingertip (CONTOUR® strip) and fingertip and palm (CONTOUR®NEXT strip). The test provides a quantitative measurement of glucose in whole blood from 20 to 600 mg/dL.

CAUTION:

- ***For in vitro diagnostic use only.***
- ***Potential Biohazard:***
  The CONTOUR®NEXT LINK meter is intended for use with only one person. All products or objects that come in contact with human blood, even after cleaning, should be handled as if capable of transmitting infectious diseases.

System Requirements

Computer with High-Power USB port

For latest compatibility: www.bayerdiabetes.com/us

Principles of the Procedure: The CONTOUR NEXT LINK blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required.
Comparison Options: The CONTOUR NEXT LINK system is designed for use with capillary whole blood. Comparison to a laboratory method must be done simultaneously with aliquots of the same sample. **NOTE:** Glucose concentrations drop rapidly due to glycolysis (approximately 5–7% per hour).

Limitations

Unless specified below, these limitations apply to the CONTOUR NEXT LINK meter using CONTOUR NEXT test strips, as well as the CONTOUR NEXT LINK meter using CONTOUR test strips.
Preservatives: Blood may be collected by healthcare professionals into test tubes containing heparin. Do not use other anticoagulants or preservatives.
Altitude:

CONTOUR NEXT test strips: Up to 20,673 feet (6301 meters) does not significantly affect results.

CONTOUR test strips: Up to 10,000 feet (3048 meters) does not significantly affect results.

Lipemic Specimen:

CONTOUR NEXT: Cholesterol concentrations >1168 mg/dL or triglyceride concentrations >4709 mg/dL may produce inaccurate results.

CONTOUR: Cholesterol concentrations >500 mg/dL or triglyceride concentrations >3000 mg/dL may produce inaccurate results.

Peritoneal dialysis solutions: Icodextrin does not interfere with CONTOUR or CONTOUR NEXT test strips.
Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
Contraindications: Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension, hyperosmolar hyperglycemia and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.[4]
Interference: Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect results. The limiting concentrations of these compounds are listed on your test strip insert.

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Federal Communications Commission (FCC) Certified Device

This equipment has been tested and found to meet the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.

This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population / uncontrolled exposure.

If you have questions, please contact Bayer Customer Service at 1-800-348-8100.

Warning (Part 15.21)
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Precision and Accuracy Summary

Technical Information

The CONTOUR®NEXT LINK blood glucose monitoring system was tested on 100 capillary blood samples using CONTOUR®NEXT test strips. Results were compared to the YSI® glucose analyzer, which is traceable to the CDC hexokinase method. The tables below compare the performance of the two methods.

Table 1 — System accuracy results for CONTOUR NEXT LINK meter using CONTOUR NEXT test strips at glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
84/90 (93.3%)	90/90 (100.0%)	90/90 (100%)

Table 2 — System accuracy results for CONTOUR NEXT LINK meter using CONTOUR NEXT test strips at glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ±20%
401/510 (78.6%)	504/510 (98.8%)	510/510 (100.0%)	510/510 (100.0%)

The CONTOUR NEXT LINK blood glucose monitoring system also was tested on 100 capillary blood samples using CONTOUR® test strips. Results were compared to the YSI® glucose analyzer, which is traceable to the CDC hexokinase method. The tables on the next page compare the performance of the two methods.

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Technical Information (cont'd)

Table 3 — System accuracy results for CONTOUR®NEXT LINK meter using CONTOUR® test strips at glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
47/90 (52.2%)	85/90 (94.4%)	89/90 (98.9%)

Table 4 — System accuracy results for CONTOUR NEXT LINK meter using CONTOUR test strips at glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ±20%
248/510 (48.6%)	419/510 (82.2%)	492/510 (96.5%)	507/510 (99.4%)

Acceptance criteria in ISO 15197 are that 95% of all differences in glucose values (i.e., between reference method and meter) should be within 15 mg/dL for glucose values less than 75 mg/dL, and within 20% for glucose values greater than or equal to 75 mg/dL.

Service Information

If you have a problem and none of the problem solving messages on the meter help, call Bayer Diabetes Care Customer Service. In the USA, call toll free: 1-800-348-8100 (7 days a week/24 hours a day). We have trained specialists to help you.

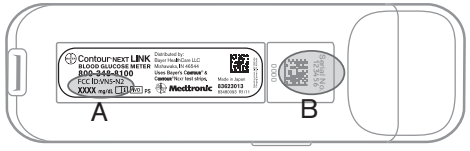
Important:
Speak to a Bayer Diabetes Care Customer Service Representative before returning your meter for any reason. He/she will give you the information needed to handle your problem correctly and efficiently.

Have your CONTOUR NEXT LINK blood glucose meter and CONTOUR or CONTOUR®NEXT test strips available when you phone. It would also be helpful to have a bottle of control solution suitable for your test strips nearby.

Check List:
This check list may be helpful when speaking with Bayer Diabetes Care Customer Service:

1. Locate the model number (A) and serial number (B) on the back of the meter. _____
2. Locate the test strips' expiration date on the bottle. _____
3. Check the battery symbol on the screen. (See page 63, Battery Status Displays and Charging.)

METER BACK VIEW



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Symbols Used

The following symbols are used throughout the product labeling for the CONTOUR®NEXT LINK blood glucose monitoring system (meter packaging and labeling, and reagent and control solution packaging and labeling).

LOT Batch code

Consult instructions for use

IVD *In Vitro* Diagnostic Medical Device

System Specifications

Test Sample: Capillary whole blood
Test Result: Referenced to plasma/serum glucose
Sample Volume: 0.6 µL
Measuring Range: 20–600 mg/dL
Countdown Time: 5 seconds
Memory: Stores most recent 1000 test results
Battery Type: Non-serviceable, 310mAh rechargeable lithium polymer battery, 3.4v – 4.2v (5V input voltage)
Meter/Battery Life: 5 years
Charging Current: 500mA
Strip Storage Temperature Range: 48° – 86°F
Normal Control Storage Temperature Range: 59° – 86°F
Meter Operating Temperature Range: 41° – 113°F
Humidity: 10–93% RH
Dimensions: 3.8 in (H) x 1.2 in (W) x 0.8 in (T)
Weight: 48 grams

Sound: A beep sounds when the meter is turned on or off, a test strip is inserted, when a test strip is filled with blood, or when a test result appears on the screen. Two beeps sound when a strip is removed and the meter is turned off, or to alert the user. Twenty beeps will sound when a programmed Reminder sounds.

Electromagnetic Compatibility (EMC):
The CONTOUR NEXT LINK meter complies with the electromagnetic requirements specified in ISO 15197. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the CONTOUR NEXT LINK. Immunity to electrostatic discharge meets the requirements of IEC 61000-4-2. It is advisable to avoid use of electronic devices in very dry environments especially if synthetic materials are present.

The CONTOUR NEXT LINK meter has been tested for radio frequency interference at the frequency range and test levels specified by ISO 15197. To avoid radio frequency interference do not use the CONTOUR NEXT LINK meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

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Caring for Your Meter

- *CAUTION: Only connect to a computer or charger that is certified to UL 60950-1, 5V maximum. A charging current of 500 mAh minimum is required.*
- If you use a cable, use the one provided in your meter kit.
- Store your meter in the carrying case provided whenever possible.
- Wash hands and dry them well before handling to keep the meter and test strips free of oils and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.
- See page 29–32 for instructions on cleaning and disinfecting your meter.
- The USB cap of your CONTOUR®NEXT LINK meter is designed to protect the USB port. Should you lose the cap, call 1-800-348-8100 for a replacement.

Supplies

When calling or writing for supplies be sure to include the number with the name of the replacement part or accessory item.

REPLACEMENT PARTS

Part Number* Item

XXXXXXXX CONTOUR NEXT LINK user guide
83480158 CONTOUR NEXT LINK quick reference guide
81363014 Bayer's USB extension cable
81675369 USB cap
81675377 wall charger
06707261 CONTOUR® test strips
06707431 CONTOUR control solution
83624796 CONTOUR®NEXT test strips
83624818 CONTOUR NEXT control solution

*Part numbers are subject to change without notice.

These parts are available in the United States from:

Bayer HealthCare LLC
Customer Service Department
Order Entry P.O. Box 2004
Mishawaka, Indiana 46546
or call 1-800-348-8100 to order

References

1 FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens; Initial Communication (2010). http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

2 CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens (2010). http://www.cdc.gov.injectionsafety/Fingerstick-DevicesBGM.html

3 Fauci, A. *et al.*: *Harrison's Principles of Internal Medicine-17th Edition*, 2008.

4 Atkin, S. *et al.*: Fingerstick Glucose Determination in Shock. *Ann. Int. Med. 114*:1020-24; 1991.

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Warranty

Manufacturer's Warranty: Bayer Diabetes Care warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5-year period, Bayer Diabetes Care shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

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

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Bayer Diabetes Care shall not be required to replace any units which malfunction or are damaged due to abuse, accidents, alteration, modification, misuse, neglect, maintenance by someone other than Bayer Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Bayer Diabetes Care assumes no liability for malfunction or damage to Bayer Diabetes Care instruments caused by the use of reagents other than the appropriate reagents (e.g., CONTOUR® or CONTOUR®NEXT test strips) manufactured or recommended by Bayer Diabetes Care.
3. Bayer Diabetes Care reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.
4. Bayer Diabetes Care has no knowledge of the performance of the CONTOUR®NEXT LINK blood glucose meter when used with any test strips other than CONTOUR or CONTOUR NEXT test strips, and therefore makes no warranty of the performance of the CONTOUR NEXT LINK meter when used with any test strips other than CONTOUR or CONTOUR NEXT test strips or when the CONTOUR or CONTOUR NEXT test strip is altered or modified in any manner.
5. Bayer Diabetes Care makes no warranty of the performance of the CONTOUR NEXT LINK meter or test results when used with any control solution other than CONTOUR or CONTOUR NEXT control solution.

BAYER DIABETES CARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS BAYER DIABETES CARE'S ONLY OBLIGATION UNDER THIS WARRANTY.

IN NO EVENT SHALL BAYER DIABETES CARE BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you. This warranty gives you specific legal rights and you may also have other rights which vary from state to state.

For warranty service: Purchaser must contact the Customer Service Department of Bayer Diabetes Care, by calling toll free 1-800-348-8100, for assistance and/or instructions for the use of this instrument.

Warranty
Technical, Service & Care

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Bayer HealthCare

Bayer HealthCare LLC
Mishawaka, IN 46544 USA
Call Toll Free: 1-800-348-8100
www.bayerdiabetes.com/us

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Medtronic

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