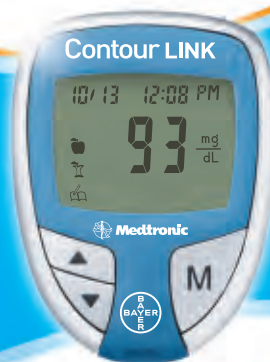




Contour LINK

WIRELESS BLOOD GLUCOSE
MONITORING SYSTEM



USER GUIDE



Medtronic

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Thank you for choosing Bayer's **CONTOUR® LINK** blood glucose monitoring system! We are proud to be your partner in helping you manage your diabetes. The **CONTOUR® LINK** meter does much more than test your blood glucose — it automatically sends your blood glucose result to compatible* designated Medtronic partner devices using a wireless, radio frequency transmission.

The **CONTOUR LINK** blood glucose monitoring system is intended for use by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only. The **CONTOUR LINK** blood glucose monitoring system is indicated for use with capillary whole blood samples drawn from the fingertip.

Critically ill patients (e.g. those with severe hypotension or shock, hyperglycemic-hyposmolar state, hypoxia, severe dehydration, diabetic ketoacidosis) should not be tested with blood glucose meters because inaccurate results may occur.

Additional Materials

- **CONTOUR® Test Strips**—Use for blood glucose or control solution testing. Supplied in a handy bottle with an easy-to-open flip-top lid.
- **MICROLET®2 Lancing Device**—Use for fingertip puncture with Bayer's **MICROLET** lancet.
- **BATTERIES**—Use two 3-volt (DL2032 or CR2032) lithium batteries. Replace when necessary.

For short simple instructions, a quick reference guide is also provided. It can be more convenient when traveling.

* For information on compatible Medtronic devices, contact Medtronic Customer Service at 1-800-646-4633.

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Important

Testing

Options

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Important Information

When the **Send** option on the **CONTOUR LINK** meter is set to **ON**:

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

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

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

FCC Statement

This equipment has been tested and found to comply with 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 of the following measures:

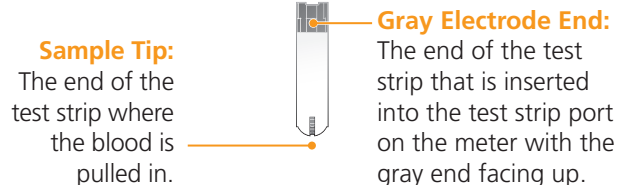
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- If you need help, please contact the Bayer Diabetes Care Customer Service at 1-800-348-8100

Need Help? Bayer Diabetes Care: 1-800-348-8100

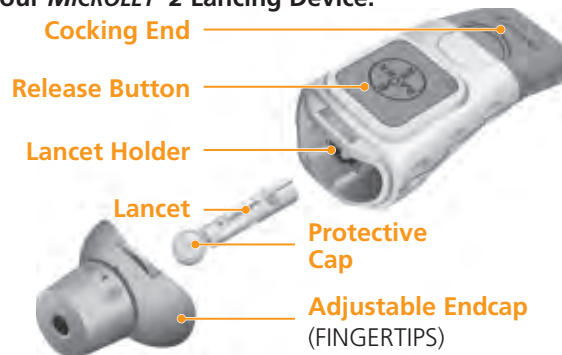
Your **CONTOUR® LINK** Meter:



Your **CONTOUR®** Test Strip:



Your **MICROLET®2** Lancing Device:





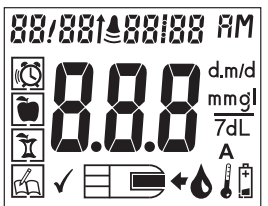









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Your Meter Display

The picture below shows all the symbols that will appear on your meter display. When the meter is off, press and continue holding the ▲ or ▼ button. All segments will be displayed and remain on while holding the button down for 10 seconds. Repeat as needed to compare your meter to the display shown below.

While all characters are displayed, it is most important to verify that 8.8.8 is fully displayed. If it is not, see Error Codes and Symbols (page 40). This may affect the way you see your results.

 Top area on the display presenting date and time.	 Indicates <i>Send</i> option is turned on.  Indicates beeper is turned on.	AM or PM will appear if the meter is in 12 hour setup.
 Indicates an alarm has been set.		d.m/d Displays the date format. mmgl 7dL Results are displayed along with the preset units of measure. The 7 appears when viewing the number of results over the past 7 days.
 Pre-meal result marker.	8.8.8 Center area on the display that shows either your test result or any error codes.	A Average.
 Post-meal result marker.	 Control result marker.  Indicates the meter is ready to test.	 Indicates the batteries are low and need to be changed.
 Identifies a test result as unique or different.	 Indicates it is too cold or too hot for your meter to test accurately.	

Important Safety Instructions

The *CONTOUR® LINK* meter and *MICROLET®2* lancing device are intended for self-testing of blood glucose by people with diabetes to monitor their blood sugar in whole blood.

The *MICROLET®2* lancing device included in this kit is not intended for use on multiple patients by healthcare professionals.

Neither the *CONTOUR® LINK* meter nor the *MICROLET®2* lancing device or lancets should be used with more than one person due to the risk of infection. 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.

After first use, all parts of the *CONTOUR® LINK* kit are considered contaminated with body fluids (blood) and could potentially transmit infectious diseases, even after you have performed the recommended cleaning and disinfection process.

Used test strips and lancets are possible biohazards and must be disposed of properly.

Always wash your hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

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 18.

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Your Meter Features

Programmed: Your *CONTOUR LINK* meter has been preset at the factory with the standard date and time. To change these settings or to use advanced meter features, such as meal markers, read through the Options section of your User Guide.

Easy: The *CONTOUR LINK* blood glucose monitoring system is all about simplicity. You will notice its uncomplicated approach the first time you see it. Simple things like the use of three large buttons and a clear display are sure to make this your favorite meter right from the start.

Automatic: You no longer have to worry about **coding** your meter or marking a control test result. The *CONTOUR LINK* meter does it automatically. It will even tell you when a test strip is under-filled.

Makes Sense: You will find features asked for by customers *just like you*. Practical features like a **fast** test time, a very **small** blood sample size, and a simple testing procedure (No Coding™ technology!) make the *CONTOUR LINK* meter *your* meter.

Convenient: Your *CONTOUR LINK* meter takes up about as much room in your pocket or bag as your key ring. The meter's small size, sleek design, and ease of use allow you to take it everywhere. You will be likely to test more often, which can mean better control of your diabetes.

"Talks" to Your Compatible Medtronic Device: Your *CONTOUR LINK* meter has the ability to automatically send your glucose result directly to your compatible Medtronic MiniMed Paradigm Insulin Pump. This eliminates the need to manually enter your blood glucose result into the insulin pump's Bolus Wizard® Calculator, which calculates an estimated bolus to support your food intake or to correct a high blood glucose. Your *CONTOUR LINK* meter can also send your fingertip blood glucose result directly to your compatible MiniMed Paradigm or Guardian REAL-Time CGM System, eliminating the need to manually enter the result when calibrating the system.



Important Things to Know

Your *CONTOUR LINK* blood glucose meter is specific for glucose and has been referenced to plasma/serum values. Methods calibrated to plasma/serum can be 9% to 15% higher than the results of whole blood glucose assay methods.

▶ **Always keep the test strips in the original bottle. Tightly close the bottle immediately after removing a test strip. The bottle is specially designed to provide a dry environment for the test strips. Extended exposure to room humidity from leaving the bottle open or not storing the test strips in the original bottle will damage your test strips.**

- ▶ Avoid excessive "milking" of your finger when forming a drop of blood and test immediately after forming the blood drop.
- ▶ **DO NOT use a test strip that appears damaged or has been used.** Test strips are for single use only.

IMPORTANT NOTE: Your meter has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter). Test results in mg/dL will **never** have a decimal point. In some countries, the meters are preset to display units in mmol/L (millimoles of glucose per liter). Results in mmol/L will **always** have a decimal point. Check your display to ensure that results are being displayed in the expected units; if they are not, contact Bayer Diabetes Care Customer Service at 800-348-8100.

Example: $96 \frac{\text{mg}}{\text{dL}}$ or $5.3 \frac{\text{mmol}}{\text{L}}$

IMPORTANT: When a low battery warning displays on the meter, replace the battery as soon as possible to avoid a test result not being stored in the meter memory.

First Things First: Talking to Your Compatible Medtronic Device

Your *CONTOUR LINK* meter is already set with the *Send* option turned on. (To turn the option off, see page 26.) Every time the meter displays a new blood glucose test result, the result is automatically sent to your compatible Medtronic device. However, your Medtronic device will only accept the glucose result if the Meter Option in your device's Utilities 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 your Medtronic device addendum that is included in your device box.

1. Program your meter ID number into your compatible Medtronic device. The ID number is the serial number found on the left side of the back label of your meter. It is a 6-digit numeric or alphanumeric number (0–9, A–F); for example, 1204620 or B12B3C. *See the User Guide for your Medtronic device for complete information on this step.*
2. Set your meter to the same time and date as your Medtronic device (see page 27 in this User Guide).

The Medtronic device can receive a glucose result only if you have entered your meter's ID number into the device. Conversely, 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 Medtronic device. However, the *Send* option must be set to ON (see page 26) and the meter and Medtronic device must be within 4 feet of each other. If you are not using the link functionality on your Medtronic device, you may want to turn the *Send* option off to save battery power.

Need Help? Bayer Diabetes Care: 1-800-348-8100

Before You Begin

1. Have all the materials you will need ready before you begin testing. This includes your *CONTOUR LINK* meter, the *CONTOUR* test strips, and the *MICROLET2* lancing device with *MICROLET* lancets. You may also need *CONTOUR* control solution to run a quality control check.
2. Read your User Guide and all instructional materials provided in your meter kit before testing.
3. Let the meter and test strips adjust to the temperature of the location where you are testing. Whenever the meter is moved from one location to another, allow 20 minutes for the meter to adjust to the temperature of that new location before performing a blood glucose test.
4. It is important not to use the test strips or control solution if the expiration date printed on the bottle label and carton has passed or if it has been six months (180 days) since you first opened the control solution bottle. It will help to write the six month **discard date** on the label in the area provided when you first open the control solution.
5. **Before testing, always wash your hands thoroughly with warm soapy water and dry them well.**

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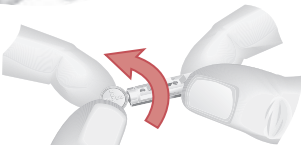
Getting Ready to Test:

Read the insert for the MICROLET2 lancing device for complete instructions.

Before testing, always wash your hands thoroughly with warm soapy water and dry them well.



Remove the endcap from the MICROLET2 lancing device.



Rotate (do not remove) the protective cap on a lancet 1/4 turn.



Insert the lancet firmly until it comes to a full stop. This will "cock" the device.

NOTE: You can also pull and release the cocking end to "cock" the device.



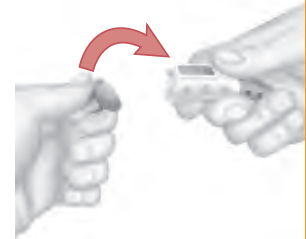
Twist off the lancet cap. Be sure to save it for disposing of the used lancet.

Need Help? Bayer Diabetes Care: 1-800-348-8100



Replace the device endcap.

Remove a test strip from the bottle. **Tightly close the bottle lid immediately after you have removed the test strip.**



NOTE: Check the expiration date. Make sure the test strip does not appear torn or damaged.

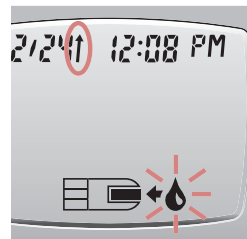
Tightly close the bottle lid immediately after you have removed the test strip. Excess moisture could damage the test strip.



Hold the test strip with the gray end facing up.

Insert the gray end into the test strip port on the meter. *No need to enter a code!*

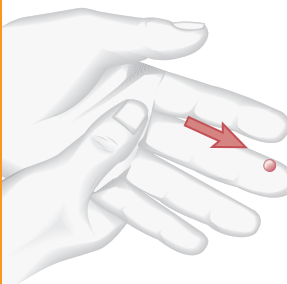
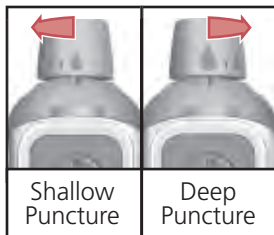
Check battery status. If battery shows low, see page 42.



The meter will turn on. A test strip with a flashing blood drop will appear, letting you know the meter is ready to test, and the *Send* arrow (↑) will show that the meter is set to send the result to your compatible Medtronic device.

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Getting the Blood Drop:

Fingertip Testing—

The depth of the puncture depends upon the adjustable endcap setting you choose and the amount of pressure applied to the puncture site. You should determine which combination works best.

Press the endcap firmly against the puncture site and press the blue release button.

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

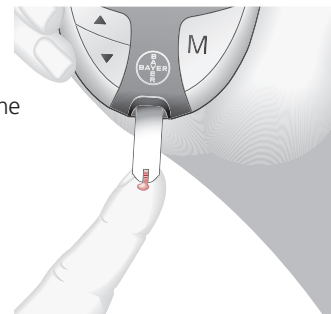
Test immediately after you have formed a blood drop.

Need Help? Bayer Diabetes Care: 1-800-348-8100

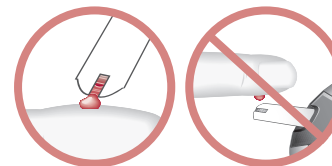


Testing Your Blood:

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



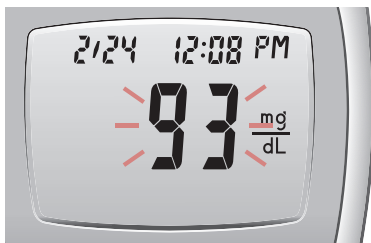
Do not press the tip against the skin or place the blood on top of the test strip.



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

After the beep, you will see the meter count down the five seconds until the test is complete and your result is displayed.





Your test result will begin flashing to indicate that it is being sent to your Medtronic device. It will continue to flash for at least 5 seconds (up to 60 seconds), until the

meter receives a message from the Medtronic device that the result has been received. If your result does not flash, check to be sure the *Send* option is turned on (see page 26).

The test result will also be automatically stored in the meter memory.

If you have set your meter to use the special marker options (see page 29), the markers must be selected while the result is still being displayed, before removing the strip or turning the meter off.

NOTES:

1. A result of “LO” or “HI” will not be sent to the Medtronic device, even when the *Send* option is on. Results of 10-19 mg/dL will be sent to the Medtronic device; however the device will ignore these results (they will not be displayed).
2. **Important:** Always check the display on your Medtronic device to ensure that the glucose result shown agrees with the meter display.
3. Do not attempt to insert a new test strip until the display stops flashing. Doing so will cause the transmission to be stopped.

Need Help? Bayer Diabetes Care: 1-800-348-8100

Stopping a Result While it is Being Sent

If you want to stop the transmission of a result (if it has not been accepted by the Medtronic device in 5 seconds), press **M**. The transmission will be cancelled. Be aware that the result **cannot** be resent later.

Turning off the *Send* option for a Single Test Result

If you do NOT want to send a blood test result to your Medtronic device, you can turn off the *Send* option for a single test. You may want to do this 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).

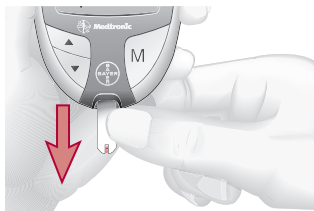
1. Insert a test strip into the meter to turn the meter on. **Before you begin your test**, press and hold the ▲ or ▼ key until “OFF” is displayed. The ↑ displayed next to the date will disappear, indicating that the *Send* option is temporarily turned off.
2. Test your blood as usual. The result will not flash, indicating that it is not being sent.
3. When you turn the meter on to perform another test, the *Send* option will again be on (the ↑ will be displayed).



Expected Values: Blood sugar values will vary depending on food intake, medication dosages, health, stress, or activity. Non diabetic expected values are 75 to 110 mg/dL fasting.¹ **You should consult with your healthcare provider for expected values specific to your needs.**

WARNING

- Test your blood again if your test result is below 50 mg/dL, above 250 mg/dL, or if you see “LO” or “HI” on the meter display. If your glucose level is still below 50 mg/dL, above 250 mg/dL, or shows as “LO” or “HI”, call your physician or healthcare professional immediately.
- Do not change your medication based on *CONTOUR LINK* blood glucose results without the advice of your physician or healthcare professional.



To turn your meter off, simply remove the test strip. Carefully dispose of the used test strip in an appropriate waste container. (The meter will automatically turn off after three minutes if you do not remove the test strip.)

NOTE: If the glucose result is still being sent to your Medtronic device, the meter will not turn off until the transmission is complete.

Need Help? Bayer Diabetes Care: 1-800-348-8100

Removing the used lancet:

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.



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

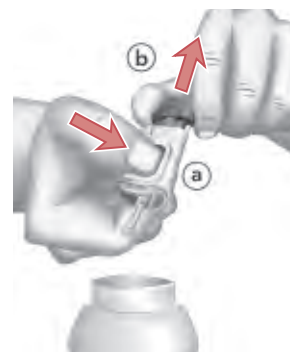
With the used lancet still in the lancing device, push the lancet needle completely into the middle of the exposed side of the cap.



While (a) pressing the blue release button, (b) pull the blue cocking handle, and the lancet will drop into the container you have selected.

Dispose of the used lancet carefully to prevent injury or contamination to others.

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



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Cleaning and Disinfection

Your *CONTOUR® 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® 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>

Need Help? Bayer Diabetes Care: 1-800-348-8100

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.

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 above in CLEANING YOUR METER.

DO NOT SPRAY BLEACH DIRECTLY ON YOUR METER

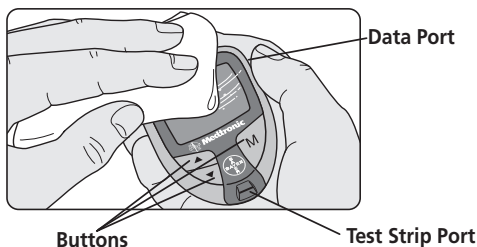
2. To disinfect, spray a clean and dry paper towel with bleach spray until wet but not dripping.

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Disinfecting Your Meter (cont'd)

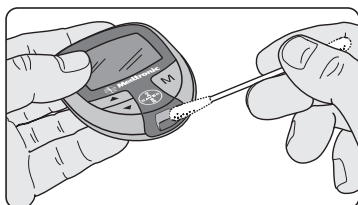
- Wipe all exposed surfaces of the meter until wet. *Do not allow disinfecting solution to run into the meter through areas such as the data or strip ports or around the buttons.*

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



- 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.



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

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Cleaning Your Lancing Device

Supplies Necessary for Cleaning:

- > Mild detergent
- > Paper towels

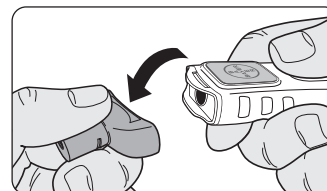
- If the *MICROLET*®2 is soiled, clean with a drop of mild detergent on a moist (not wet) paper towel. Wipe away any detergent residue and dry as necessary with a clean paper towel.

Disinfecting Your Lancing Device

Supplies Necessary for Disinfecting:

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

- Before disinfecting, if the lancing device is soiled it must be cleaned as described above in **CLEANING YOUR LANCING DEVICE**.
- To disinfect, spray a clean and dry paper towel with bleach spray until wet but not dripping.
- Remove the end cap and lancet if present.

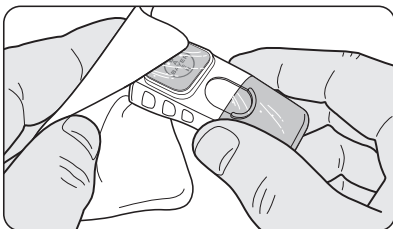


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Disinfecting Your Lancing Device (cont'd)

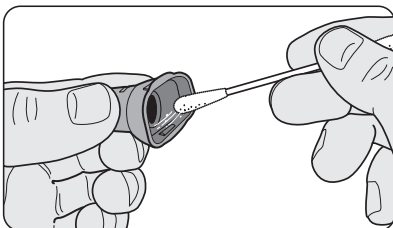
- Wipe all exposed surfaces of the lancing device until wet.

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



- 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.



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

Need Help? Bayer Diabetes Care: 1-800-348-8100

Control Solution Testing:

Use only Bayer's *CONTOUR*® control solutions (Normal, Low, or High) with your *CONTOUR* meter. Using anything other than *CONTOUR* control solution could present incorrect results.

Run a control test:

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

Remove a test strip from the bottle.

Tightly close the bottle lid immediately after you have removed the test strip. Excess moisture could damage the test strip.

NOTE: Check the expiration and discard date. Make sure the test strip does not appear torn or damaged.

Hold the test strip with the gray end facing up.

Insert the gray end into the test strip port on the meter.



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The meter will turn on. A test strip with a flashing blood drop will appear, letting you know the meter is ready to test.



Gently rock the control bottle before opening to ensure it is mixed well. Squeeze a small drop of control solution on a clean nonabsorbent surface (such as a piece of wax paper).

Do not apply the control solution to your finger nor directly to the test strip from the bottle. Recap the bottle immediately.

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



Hold the test strip in the drop until the meter beeps.

After the beep, you will see the meter count down five seconds until the test is complete and your control test result is displayed.



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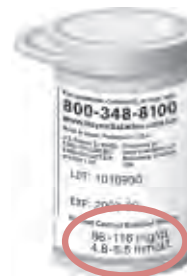
The meter will automatically recognize and mark (✓) the control result for you.

NOTE: The ✓ does not indicate the control test result is within the specified range.



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.

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



If your control test result is out of range, do not use your meter for blood glucose testing until you resolve the issue. See "What You Should Do" on page 40.

To turn your meter off, simply remove the test strip. The result will automatically be marked with a ✓ and stored in the meter memory. **Control results will not be included in your 14 day blood glucose average or in the 7 day total. They are also not sent to your Medtronic device (the result does not flash).**



Carefully dispose of the used test strip.

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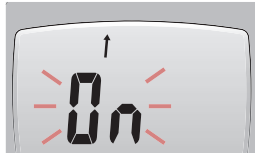


Setting Your Options:

You can set your meter to display different options.

To get into the Setup mode, press and hold **M** for three seconds. A complete display will briefly appear, then the *Send* option will be displayed.

NOTE: You can exit the Setup mode at any time by pressing and holding **M** for 3 seconds. All selections you have made up to that point will be saved.



Setting the Send Option:

The *Send* arrow (↑) will be displayed at the top of the display and the word "On" will be flashing.

This option controls whether you want to send your test results to your Medtronic device.

Press ▲ or ▼ to choose whether to turn the *Send* option on or off. (If you are not using the link functionality on your Medtronic device, you may want to turn the *Send* option off to save battery power.)

Press **M** to set.

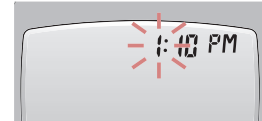


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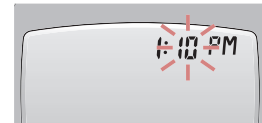
Setting the Time:

The time will now appear on the display. The number in the **hour** position will be flashing. Press ▲ or ▼ until you reach the correct time.



Press **M** to set.

The number in the **minute** position will now flash. Press ▲ or ▼ until you reach the correct minute.



Press **M** to set.

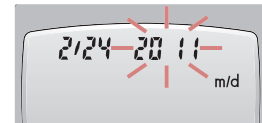
The **AM** or **PM** will now flash. Press ▲ or ▼ to choose AM or PM.



Press **M** to set.

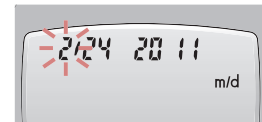
Setting the Date:

The date will now appear on the display. The **year** will be flashing. Press ▲ or ▼ to reach the current year.



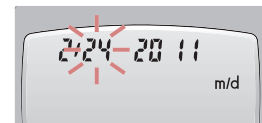
Press **M** to set.

The **month** will now flash. Press ▲ or ▼ to reach the current month.



Press **M** to set.

The **day** will now flash. Press ▲ or ▼ to set the day.



Press **M** to set.

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