

Contour. next link

Wireless Blood Glucose
Monitoring System



Medtronic

Uses only CONTOUR[®]NEXT blood glucose test strips

USER GUIDE

Indications for 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 quantitative measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The system is intended for self-testing outside the body (in vitro diagnostic use) and is to be used as an aid to monitor the effectiveness of diabetes control. The CONTOUR NEXT LINK wireless blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. Alternative site testing should be done only during steady state times (when glucose is not changing rapidly). The system consists of a CONTOUR®NEXT LINK wireless blood glucose meter, CONTOUR®NEXT test strips and CONTOUR®NEXT control solutions.


CONTOUR NEXT test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples.

The CONTOUR NEXT control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check to verify that the CONTOUR NEXT LINK system is working properly.

The CONTOUR®NEXT LINK wireless blood glucose monitoring system is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm® Insulin Pumps or Medtronic MiniMed Paradigm® REAL-Time Revel™ Insulin Pumps or Medtronic MiniMed 530G Insulin Pumps and facilitate transfer of information to Medtronic MiniMed 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 meter user guide, the 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.

WARNING

- The meter, lancing device and lancets are for single patient use. Do not share them with anyone including other family members. Do not use on multiple persons.^{1,2}
- Used test strips and lancets are possible biohazards and must be disposed of as medical waste.
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Always wash your hands well with soap and water and dry them well before and after testing, handling the meter, lancing device or test strips.

For complete instructions on cleaning and disinfecting your meter and lancing device, please see page 28.

Important: Examine product for missing, damaged, or broken parts. If the test strip bottle is open inside a new box of strips, do not use those strips. Contact Customer Service for replacement parts. See the back cover for contact information.

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

Your CONTOUR[®]NEXT LINK meter automatically transmits blood glucose results using a wireless, radio frequency transmission to your compatible MiniMed[®] insulin pump. (Hereafter, referred to as MiniMed insulin pump.)

Your CONTOUR NEXT LINK meter will work with GLUCOFACETS[®]DELUXE diabetes management software and Medtronic's Carelink Personal Therapy management software.

Your Meter Features

Easy: The CONTOUR NEXT LINK wireless 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. Your 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.



Programmed: Your 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 Customer Service. See the back cover for contact information.

Customizable: Your CONTOUR[®]NEXT LINK meter allows you to set personal choices for some features. For more information, please see the Setup and Testing sections in this user guide.

“Talks” to Your Compatible MiniMed Insulin Pump

Your CONTOUR NEXT LINK meter can automatically send your blood glucose result directly to your compatible MiniMed insulin pump. 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. Your CONTOUR NEXT LINK meter can also transmit your fingertip blood glucose result directly to your compatible MiniMed insulin pump, eliminating the need to manually enter the result when calibrating the system. See page 5 for initial setup options. Your compatible MiniMed insulin pump 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 5 in “Initial Setup.” If you have entered your meter's ID number into your compatible MiniMed insulin pump, 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 MiniMed insulin pump when the *Send* option is set to **Always** or **Ask Me**. See page 7 of this user guide. Your CONTOUR NEXT LINK meter and compatible MiniMed insulin pump must be within 4 feet of each other. If you are not using the meter link feature on your compatible MiniMed insulin pump, you may want to set the *Send* option to **Never** on your CONTOUR NEXT LINK meter and MiniMed insulin pump to save battery power.

Rechargeable Battery

Your 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 66.



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 64–66.



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GETTING
STARTED

TESTING

REMINDERS
AND NOTES

MAIN MENU
FUNCTIONS

TECHNICAL,
SERVICE & CARE

Your CONTOUR®NEXT LINK Wireless Blood Glucose Monitoring System

The CONTOUR NEXT LINK wireless blood glucose monitoring system works with CONTOUR®NEXT test strips.

CONTOUR NEXT Test Strip

Gray Square End:

Insert this end into test strip port with gray end face up.

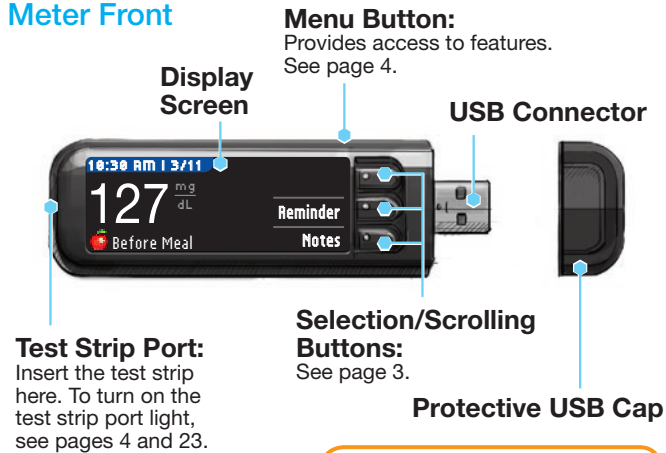
Sample Tip

Blood is drawn in here.



CAUTION: Your CONTOUR®NEXT LINK meter only works with CONTOUR NEXT test strips!

Meter Front



Menu Button:

Provides access to features. See page 4.

Display Screen

USB Connector

Selection/Scrolling Buttons:

See page 3.

Protective USB Cap

Test Strip Port:

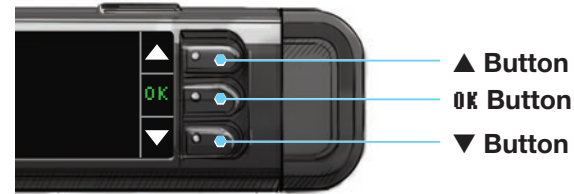
Insert the test strip here. To turn on the test strip port light, see pages 4 and 23.

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

Meter Overview

Using the Buttons

Your 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.

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 MiniMed insulin pump. Your compatible MiniMed insulin pump 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.



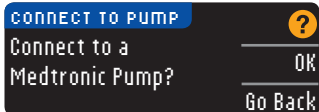
2. Press the ▲ or ▼ button to select your desired language. When highlighted, press the **OK** button.



✓ Language Selected:
English

A screen confirms your language.

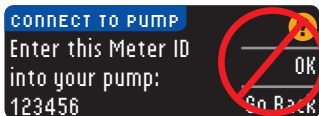
These meter screen images are for illustration purposes only.



3. Press **OK** on the next screen to start the connection process.

NOTE: Pump on meter screen refers to your compatible MiniMed insulin pump.

4. **STOP.** Do **NOT** press **ANY** buttons.



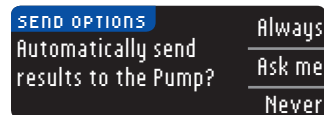
This screen displays the meter ID number (in the bottom left corner).

This ID is needed to complete the connection process. To **Go Back**, press the Menu button. Put down your meter. Pick up the MiniMed insulin pump and continue the connection process.

IMPORTANT: Refer to the compatible MiniMed insulin pump user guide for instructions on connecting your CONTOUR[®]NEXT LINK meter to your compatible MiniMed insulin pump.

Meter Send Options

5. After the meter and compatible MiniMed insulin pump are connected, you will set your **Send Options**. This controls how your meter will send blood glucose readings to your compatible MiniMed insulin pump.

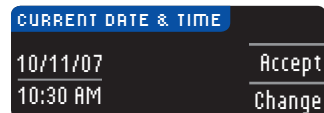


Choose the **Send Option** that is best for you.

A screen message will confirm the choice made (**Always** = Meter will always send results, **Ask Me** = Meter will ask you before sending 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.

Additional Meter Settings

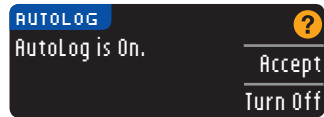
AutoLog Feature

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.

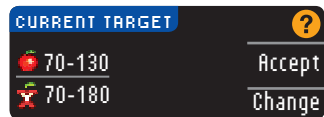
Your meter comes with **AutoLog** turned on. We recommend that you keep this feature turned on to get the most benefit from your meter features. AutoLog can be turned off in Setup if you choose to do so at a later time (see page 56).



7. Accept or turn off the AutoLog feature. See pages 23–25 for details about testing with AutoLog on or off.

Targets

NOTE: Targets can only be set inside your selected High and Low Limit(s). For additional information, you may contact Customer Service. See the back cover for contact information.



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

WARNING

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

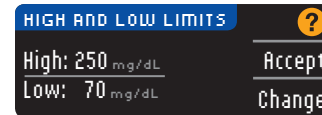
High and Low Limits

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).

NOTE: High and Low Limits can only be set outside your selected Target range(s). For additional information, you may contact Customer Service. See the back cover for contact information.

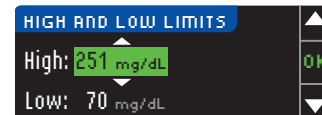
WARNING

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

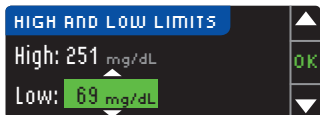


9. Choose **Accept** to use the default settings for high and low limits. The default high limit is 250 mg/dL and the default low limit is 70 mg/dL.

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

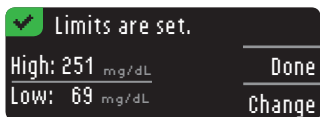


11. Press the ▲ or ▼ button to select your high limit. Press **OK**.



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 sugar.

Information for Safety



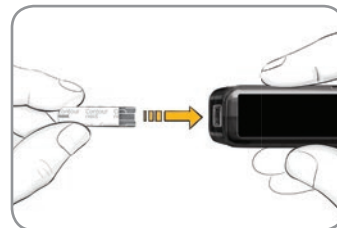
- **Always keep the test strips in the original bottle. Tightly close the bottle immediately after removing a test strip.** The bottle is designed to keep the test strips dry. Exposure to room humidity from leaving the bottle open or not storing them in the original bottle can damage your test strips. This could lead to inaccurate results.
- **Always wash your hands well with soap and water and dry them well before and after testing, handling the meter, lancing device, or test strips.**
- **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 and test strip bottle are 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[®]NEXT test strips, and the lancing device and lancets. You will also need control solution to perform a quality control check.
- **The 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 lancet each time you test because it is no longer sterile after use.**
- See pages 28–32 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.
- Your CONTOUR NEXT LINK meter only works with CONTOUR NEXT test strips and CONTOUR[®]NEXT control solution.

The following steps are shown in the proper order for performing a blood glucose test (pages 13–27).

Preparing Your Test Strip

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



3. Hold the test strip with the gray square end facing up.
4. Insert the gray square 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 lancing device insert for complete instructions. For Alternative Site Testing instructions, see page 20.

The lancing device graphics are for illustration purposes only. Your lancing device may look different. Refer to your lancing device insert for detailed instructions on preparing the lancing device.

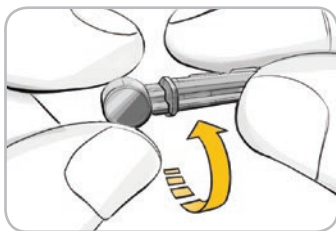
WARNING: Potential Biohazard

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

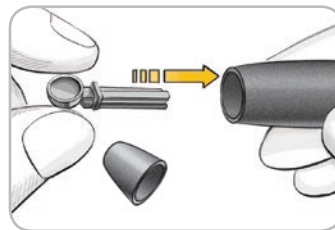
WARNING

- Dispose of the used lancet as medical waste.
-  Do not reuse lancets. Use a new lancet each time you test.

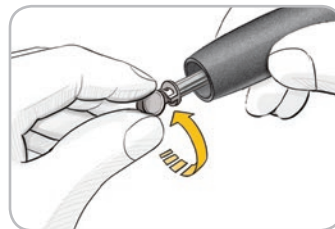
1. Remove the endcap from the lancing device.



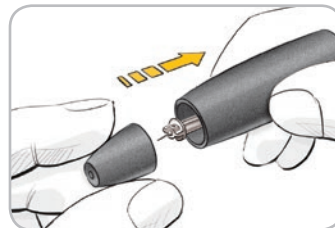
2. Loosen the round protective cap on a lancet by rotating it $\frac{1}{4}$ turn, but do not remove the cap.



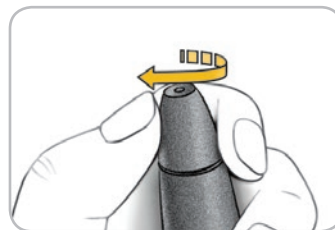
3. Insert the lancet firmly into the lancing device until the lancet comes to a full stop.



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



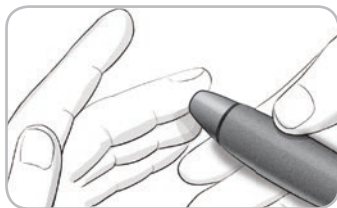
5. Replace the endcap.



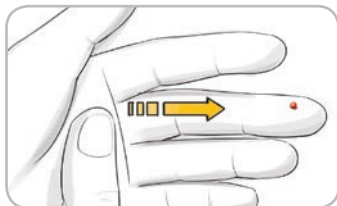
6. Rotate the endcap dial to adjust the puncture depth. The amount of pressure applied to the puncture site also affects puncture depth.

Getting the Blood Drop

For fingertip testing



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



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 a good blood drop has formed.

If the first blood drop is not enough, the meter will beep twice and display **STRIP UNDERFILLED**. You have about 30 seconds to apply more blood to the same strip.

WARNING

- The meter, lancing device and lancets are for single patient use. Do not share them with anyone including other family members. Do not use on multiple persons.^{1,2}
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Always wash your hands well with soap and water and dry them well before and after testing, handling the meter, lancing device or test strips.

For complete instructions on cleaning and disinfecting your meter and lancing device, please see page 28.



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.**



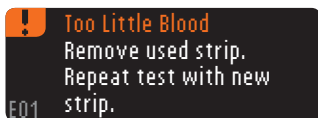
Press any button and the **Apply Blood** screen will become active again.

After a total of 3 minutes of inactivity the meter turns off.



If the first blood drop is not enough, the meter will beep twice and display a **STRIP UNDERFILLED** screen image.

You have about 30 seconds to apply more blood to the same strip.



If you are not able to apply enough blood within that time, discard that strip and start over with a new strip.


Follow the instructions on the meter screen.

Ejecting and Disposing of the Used Lancet



1. Do not use your fingers to remove the lancet from the lancing device. Your device has an automatic lancet ejection feature.
2. Refer to the separate **lancing device insert provided with your kit for instructions on automatic ejection of the lancet.**

WARNING

- Dispose of the used lancet as medical waste or as advised by your health care professional.
-  Do not reuse lancets. Use a new lancet each time you test.

WARNING: Potential Biohazard

- Always dispose of test strip and lancet as medical waste or as advised by your health care professional. All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.
- Please refer to your lancing device package insert for instructions on how to properly remove and dispose of the lancet.

For Alternative Site Testing on the Palm of the Hand with CONTOUR®NEXT Test Strips

IMPORTANT: Do not use Alternative Site Testing (AST) under the following conditions.

Use fingertip testing in any of these cases:

- If you think your blood sugar is low (hypoglycemia).
- When blood sugar 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.

Alternative Site Testing should not be used for Bolus Wizard, to calibrate a device or verify a low blood glucose level.

Consult your health care professional to determine if AST is right for you.

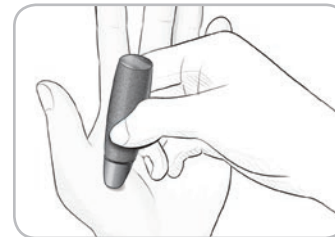
Alternative Site Testing with the CONTOUR®NEXT test strip can be performed on the palm of the hand. Alternative Site Testing is recommended only when it is more than two hours after a meal, diabetes medication, or exercise.



1. Wash your hands and the puncture site with soap and warm water. Rinse and dry well.
2. Attach the clear AST endcap to the lancing device provided with your kit. **Refer to the lancing device insert for detailed instructions.**



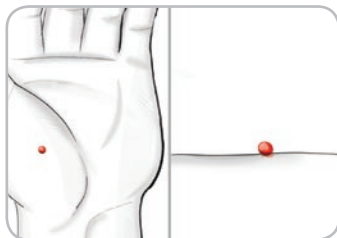
3. Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones and tendons.



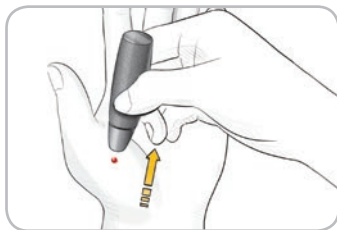
4. Press the lancing device firmly against the puncture site and then press the release button.

For Alternative Site Testing (cont'd)

The lancing device graphics are for illustration purposes only.



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.

7. Test immediately after you have formed a small, round blood drop.

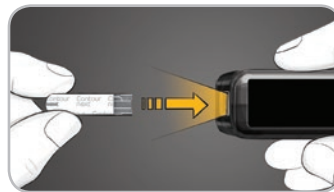
Immediately touch the tip of the test strip to the drop of blood. The blood is pulled into the test strip through the tip.

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

To continue testing, see page 17.

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 sugar 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 countdown timer. If you make your selection very quickly, you may see the remainder of the testing countdown.



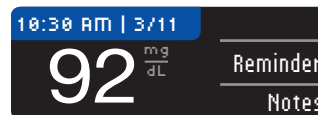
Your test result shows as large numbers and then changes to the normal test result screen.

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 56).



You may now set a Reminder or add a Note.



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 40) or add a **Note** (see page 46).

Remove the test strip from the meter. Hold down the Menu button for 2 seconds to turn the meter off, or press the Menu button once to go to the Main Menu.

WARNING

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

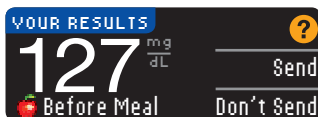
Please refer to your lancing device package insert for instructions on how to properly remove and dispose of the lancet.

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 **Risk Me**, you can always send or not send to your compatible MiniMed insulin pump.



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



You can change your **Send Options** at any time using the Setup Menu, **Pump Options**.

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 MiniMed insulin pump 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 should be < 100 mg/dL in the fasting state and < 140 mg/dL in the post-prandial state.³ **You should consult with your health care professional for glucose values specific to your needs.**

Cleaning and Disinfection

Your CONTOUR®NEXT LINK meter should be cleaned and disinfected once a week. For the meter, use only Clorox® Germicidal Wipes containing 0.55% sodium hypochlorite (bleach), which has been proven to be safe to use with the CONTOUR NEXT LINK meter.

Refer to the lancing device insert provided with your kit for detailed instructions for cleaning and disinfecting the lancing device.

Cleaning is the removal of visible dirt and debris, but does not reduce the risk for transmission of infectious diseases. Your CONTOUR NEXT LINK meter should be cleaned of dirt and debris once a week.

Disinfecting (if performed properly) reduces the risk of transmitting infectious diseases. Your meter should be disinfected once a week.

WARNING

Always wash your hands well with soap and water and dry them well before and after testing and handling the meter, lancing device, or test strips.

NOTE: If your meter is being operated by a second person who is providing testing assistance to you, the meter should be disinfected prior to use by the second person.

Signs of Deterioration

The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons or display. Your CONTOUR®NEXT LINK meter has been tested for 260 cycles of cleaning and disinfection (one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of cleaning and disinfection without damage. You should contact Customer Service for assistance if your device malfunctions for any cause or if you notice any changes in the meter case or display. Clorox® Germicidal Wipes are available for purchase online at <http://www.officedepot.com> or <http://www.amazon.com> or for more information contact Customer Service. See the back cover for contact information.

For more information see:

US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
Centers for Disease Control and Prevention. CDC clinical reminder: use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens. US Department of Health and Human Services; 8/23/2010. <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>

Cleaning Your Meter

Supplies Needed for Cleaning:

- Clorox® Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
 - Paper towels
1. Carefully clean the meter with Clorox Germicidal Wipes until all soil is removed. *Do not allow cleaning solution to run into the meter through areas such as around the buttons or the meter's test strip or data ports.*
 2. Dry as necessary with a clean paper towel.

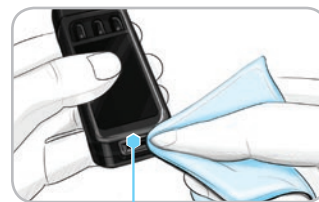
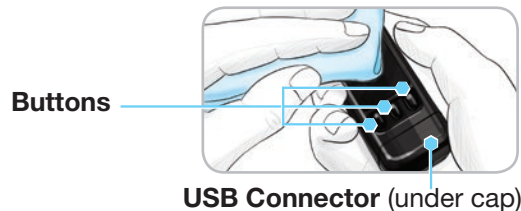
Disinfecting Your Meter

Supplies Needed for Disinfecting:

- Clorox Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
 - Paper towels
 - Timing device
1. Before disinfecting, clean the meter as described above in **Cleaning Your Meter**.

For proper disinfection, you must keep all meter surfaces wet for 60 seconds.

Using a new Clorox Germicidal Wipe, carefully wipe all outer surfaces of your meter until wet. *Do not allow cleaning solution to run into the meter through areas such as around the buttons or the meter's test strip or data ports.*



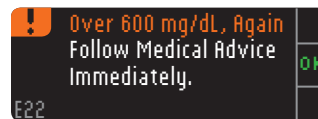
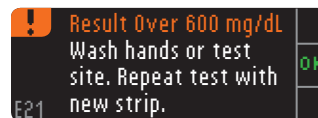
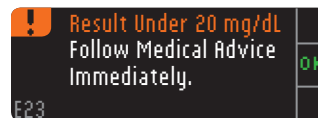
2. Dry all meter surfaces and test strip port using a clean paper towel if needed.

Cleaning and Disinfecting Your Lancing Device

Refer to the lancing device insert provided with your kit for detailed instructions for cleaning and disinfecting the lancing device.

Measuring Range

Your meter's measuring range is 20–600 mg/dL.



- 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 health care 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.

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 health care professional as soon as possible.
- Always consult your health care professional before changing your medication based on CONTOUR®NEXT LINK test results.

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 health care 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

WARNING

Shake the control solution well before testing.

CAUTION: Use only CONTOUR[®]NEXT control solutions (Level 1 and Level 2) with your CONTOUR[®]NEXT LINK blood glucose monitoring system. Using anything other than CONTOUR NEXT control solutions can cause inaccurate results.

*Control solution may not be included in all meter kits. Contact Customer Service for information about obtaining control solution. See the back cover for contact information.

Quality Control



- Shake the control solution bottle well, about 15 times before every use.
- Unmixed control solution may cause inaccurate results.

You should perform a control test when:

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

WARNING

- Do not calibrate your continuous glucose monitoring device from a control result
- Do not calculate a bolus based on a control result

CAUTION: Check the expiration date on the test strip bottle and the expiration date and discard date on the control solution bottle. **DO NOT** use expired materials.

Level 1 and Level 2 control solutions are available separately if not included in the meter kit. You can test your CONTOUR[®]NEXT LINK meter with control solution when the temperature is 59°F–95°F. Always use CONTOUR[®]NEXT control solutions. Other brands could present incorrect results. If you need help locating CONTOUR NEXT control solutions, contact Customer Service. See the back cover for contact information.



1. Remove the test strip from the bottle and firmly snap the lid closed.



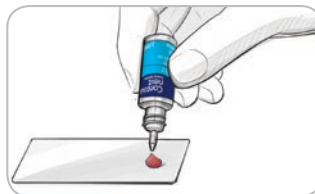
2. Hold the test strip with the gray square end facing up.
3. Insert the gray square end of the test strip into the test strip port until the meter beeps.



4. You will see the **Apply Blood** screen. The meter is now ready for you to test.



5. Shake the control solution bottle well, about 15 times before every use.



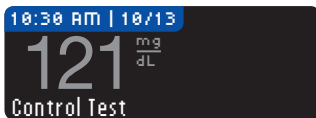
6. Remove bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.

7. Squeeze a small drop of control solution on a clean non-absorbent surface.

Do not apply control solution to your finger or to the test strip directly from the bottle.



8. Immediately touch the tip of the test strip to the drop of control solution.
9. **Hold the tip in the drop until the meter beeps.**



10. The meter shows the AutoLog screen (if AutoLog is ON) but will sense control solution. The meter will count

down for 5 seconds and the control test result will display on the meter. It automatically marks the result as a “Control Test” and stores it in memory. Control test results are not included in your blood sugar averages.



11. Compare your control test result to the ranges printed on the test strip bottle.
12. Remove test strip. To turn the meter off, press and hold the **Menu** button, OR, after three minutes of inactivity, the meter turns off. Dispose of the used test strip as medical waste or as advised by your health care professional.

NOTE: Control test results that are marked as “Control Test” are not transmitted to the pump.

WARNING

- If the control solution test result is out of range, the result may be transmitted to your pump when in “Always” send mode (see page 26).
- Do not send an out of range control result to your pump.

CAUTION: If your control solution test result is out of range, contact Customer Service. See the back cover for contact information. Do not use the meter or test strips for blood glucose testing until the issue is resolved.

Setting a Reminder

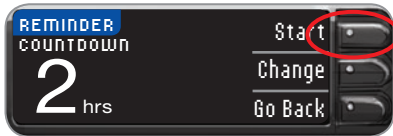
A Reminder for your next test can be set after testing or from the Setup menu.

After Testing

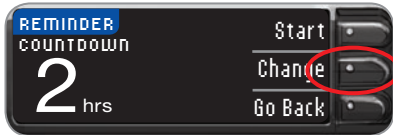
1. Press the **Reminder** button.



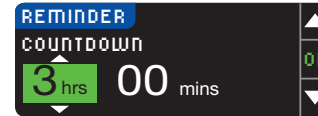
2. Press the **Start** button to begin the Countdown. The default time is 2 hours or the last reminder time that was set.



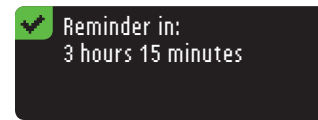
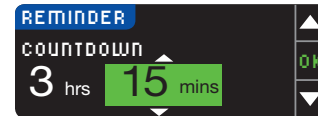
You can change the Reminder Countdown time to the time you wish by pressing the **Change** button.



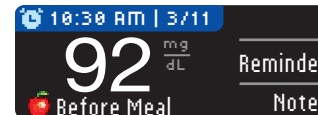
1. Press the **▲** or **▼** button to select the correct hours. Press the **OK** button.




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.

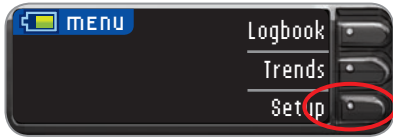


When the Reminder feature is on, the clock symbol  is in the blue header.

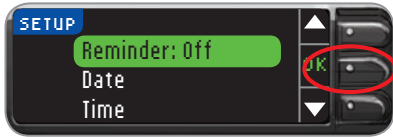
3. Remove the test strip from the meter. The meter retains the Reminder time that you set as the default.

From the Setup Menu

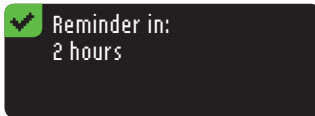
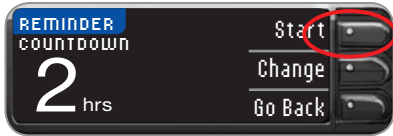
1. Go to the Main Menu. Press the **Setup** button.



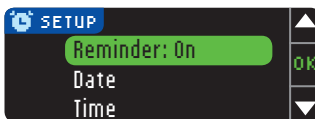
2. If Reminder is set to off, press the **OK** button to change the Reminder settings.




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.



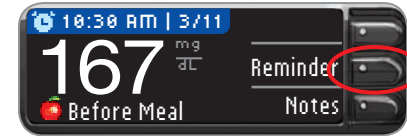
When the Reminder feature is on, the clock symbol  is in the blue header.

Turning Off a Reminder

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

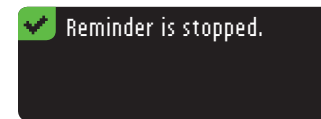
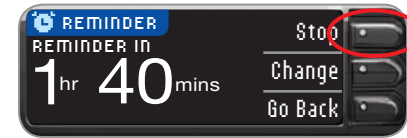
After Testing

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.

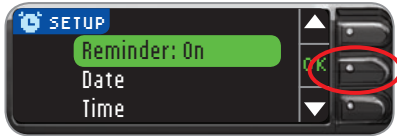


A screen confirms your choice.

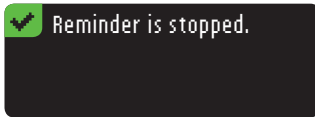
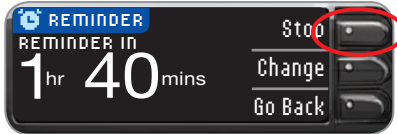
The Countdown is now stopped and the clock symbol  will no longer appear on the screen.

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.

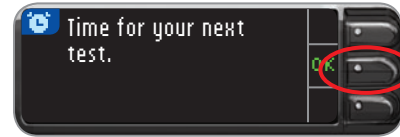


A screen confirms your choice.

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 13).

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

Adding Notes

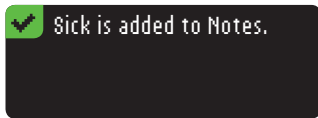
You may add Notes to your test result that may help explain results. Your notes will be saved in the **Logbook**.



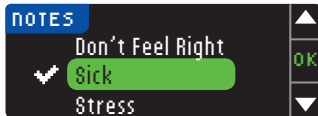
1. From the test result screen, press the **Notes** button.



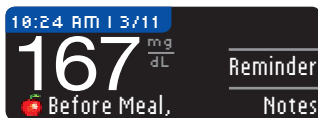
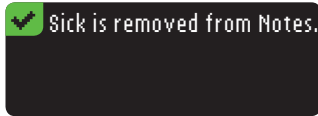
2. Press the ▲ or ▼ button to scroll through the choices. Some may not be visible until you scroll up or down. Press the **OK** button when your choice is highlighted.



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.



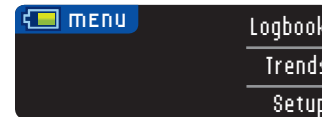
Menu Button

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



TOP VIEW

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.

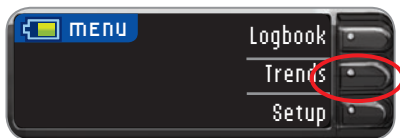


The most recent result is shown first and the oldest result last. When you reach the oldest entry you will see the **End of Logbook** screen. Your meter will store 1000 test results.

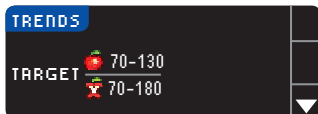
Trends

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 58).

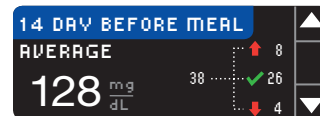


If AutoLog is on, the 🍎 (Before Meal) and 🍷 (After Meal) target ranges will appear. To set personalized target ranges, see page 57.

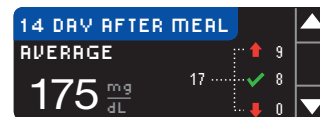
If AutoLog is off, you will only see one target range (no 🍎 Before Meal/ 🍷 After Meal).

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.

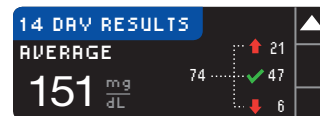
2. Press the **▼** button to display the 14 Day Before Meal Average.



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.

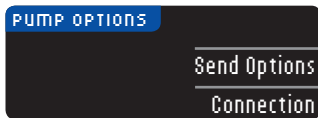
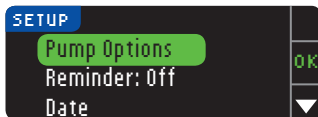
Setup

Pump Options

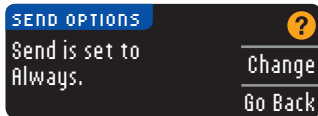
Go to the **Pump Options** in the Setup menu if you want to change your original choices.

1. Make your selection: Send Options or Connection.

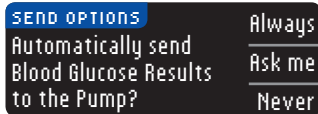
Send Options controls when your blood glucose readings are sent to your compatible MiniMed insulin pump. Choosing **Connection** will display steps to connect your CONTOUR®NEXT LINK meter to your compatible MiniMed insulin pump. (Go to Step 6.)



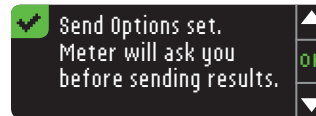
2. Press **Send Options to change your current setting.**



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

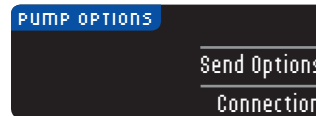


4. Choose the setting that is best for you. The choices are: **Always, **Ask Me**, or **Never**.**

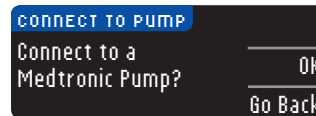


5. The next screen confirms your choice. Press **OK.**

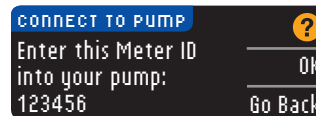
6. Choose **Connection from the **Pump Options** menu to connect your CONTOUR®NEXT LINK meter to your compatible MiniMed insulin pump.**



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 MiniMed insulin pump to connect with your meter (refer to the compatible MiniMed insulin pump user guide). Do not press **OK on your meter screen until connection process is complete.**



NOTE: Pump on meter screen refers to your compatible MiniMed insulin pump.

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.

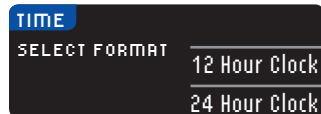
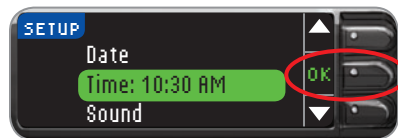


A screen confirms the date you entered. If correct, press the **Done** button and the Setup menu will appear.

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

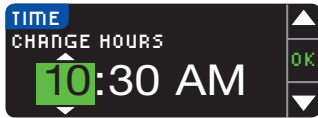
Setting the Time

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.

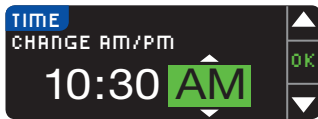
5. Select either the **12 hour clock** or **24 hour clock** button.



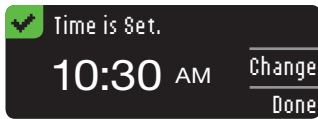
6. Press the ▲ or ▼ button to select the correct hour. Press the **OK** button.



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.



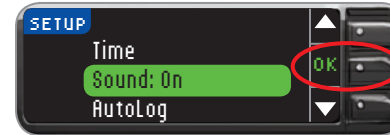
A screen confirms the time you entered. If correct, press the **Done** button and the Setup menu will appear.

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

Turning the Sound On/Off

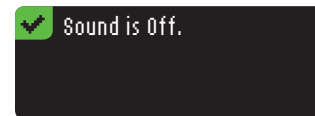
Sound is turned ON when you receive your meter. It can be turned off using the Setup menu. Some error messages and the Reminder bell will override the **Sound: Off** setting. One long beep indicates a confirmation. Two beeps indicate an error or situation that requires your attention.

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**.



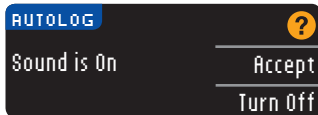
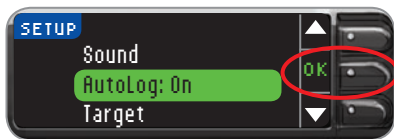
A screen confirms your choice. The Setup menu will appear.

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.



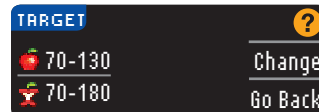
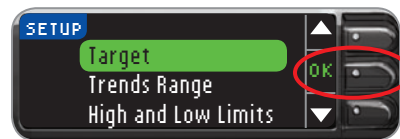
A screen confirms your choice. The Setup menu will appear.

Changing the Blood Glucose Target Range

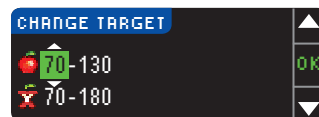
NOTE: Targets can only be set inside your selected High and Low Limit(s). For additional information, you may contact Customer Service. See the back cover for contact information.

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 health care 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.



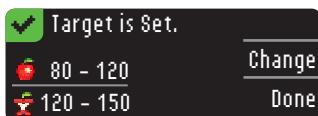
4. To make changes to your target range, press the **Change** button, otherwise **Go Back**. Press ? for **Help**.



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

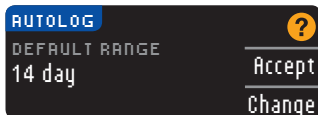
Repeat this process to set your personal 🍏 (**Before Meal**) high target and 🍷 (**After Meal**) low and high targets. Press the **OK** button after each selection.

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

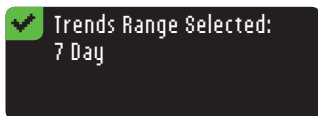


To make changes, press the **Change** button and repeat the process.

Setting Trends Range



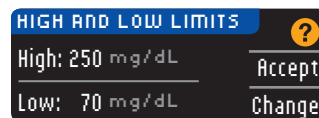
1. The default setting for the Trends Range is 14 days. To choose another Trends Range, press **Change**. The other Trends Range options are 7 or 30 days.



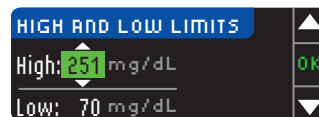
2. The next screen will confirm your selection.

High and Low Limits

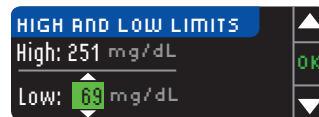
1. Choose **Accept** to use the default settings. The default high limit is 250 mg/dL and the default low limit is 70 mg/dL.



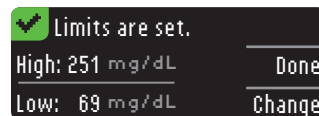
Choose **Change** if you wish to use different limits.



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



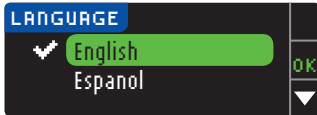
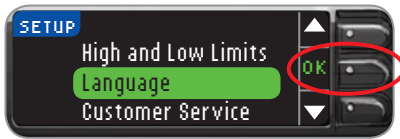
3. Press the ▲ or ▼ button to select your low limit. Press **OK**.



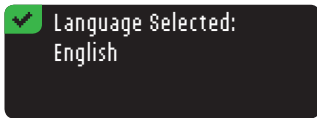
4. The next screen confirms your choices. Press **Done**.

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.

These meter screen images are for illustration purposes only.

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 MiniMed insulin pump 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 GLUCOFACETS®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 MiniMed insulin pump.

Your CONTOUR NEXT LINK meter is also compatible with GLUCOFACETS DELUXE diabetes management software.

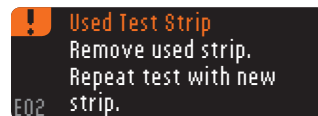
IMPORTANT:

The CONTOUR®NEXT LINK meter has only been tested for use with GLUCOFACTS®DELUXE diabetes management software and Medtronic's Carelink® Personal Therapy management software. Ascensia Diabetes Care is not responsible for any erroneous results from the use of other software.

For more information, contact Customer Service. See the back cover for contact information.

Error Detection Displays

An error screen will always have an “E” with a number in the lower left 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 MiniMed insulin pump. Make sure your CONTOUR®NEXT LINK meter is within 4 feet of your compatible MiniMed insulin pump 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 Customer Service. See the back cover for contact information.

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.



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 carrying case 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 test 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 test 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.

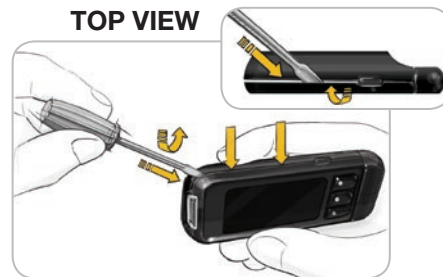
Wall Charger

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

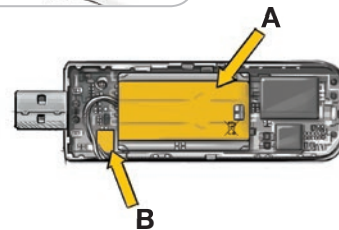
End of Meter Life/Battery Removal

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):	High blood sugar (Hyperglycemia):	Ketones (Ketoacidosis):
<ul style="list-style-type: none"> • shakiness • sweating • fast heartbeat • blurred vision • confusion • passing out • irritability • seizure • extreme hunger • dizziness 	<ul style="list-style-type: none"> • frequent urination • excessive thirst • blurred vision • increased fatigue • hunger 	<ul style="list-style-type: none"> • shortness of breath • nausea or vomiting • very dry mouth

WARNING

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 health care professional immediately.

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

System Performance Information

Capillary samples may be drawn from the fingertip and palm of the hand. 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.diabetes.ascensia.com

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. Capillary samples should be applied directly to the CONTOUR[®]NEXT test strip. 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).⁴

Limitations

Altitude:

This system has not been tested at altitudes higher than 20,674 feet (6301 meters).

Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference leading to inaccurate test results.

Contraindications: The system should not be used to test critically ill patients and should not be used by persons with reduced peripheral blood flow. Shock, severe hypotension, and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.⁵

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 Customer Service. See the back cover for contact information.

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.

Technical Information

Accuracy

The CONTOUR[®]NEXT LINK wireless blood glucose monitoring system was tested by 110 lay users using capillary blood samples and three CONTOUR[®]NEXT test strip lots. The results were compared to the YSI[®] Glucose Analyzer laboratory reference method, traceable to the CDC hexokinase method. The tables below show how well the two methods compare.

Table 1 — System accuracy results in lay users 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
8 of 8 (100%)	8 of 8 (100%)	8 of 8 (100%)

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

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
82 of 102 (80.4%)	101 of 102 (99.0%)	101 of 102 (99.0%)	102 of 102 (100%)

Precision

Ten CONTOUR[®]NEXT LINK instruments were tested with 10 replicates at each glucose level, for a total of 500 replicates. The grand means, pooled standard deviations (SD), and coefficient of variation (CV) were calculated and are presented here.

Mean glucose level, mg/dL	SD, mg/dL	CV
41.0	0.6	1.6%
79.3	1.0	1.3%
121.1	1.5	1.2%
205.3	4.1	2.0%
332.0	4.9	1.5%

Service Information


If you have a problem and none of the problem solving messages on the meter help, contact Customer Service. See the back cover for contact information. We have trained specialists to help you.

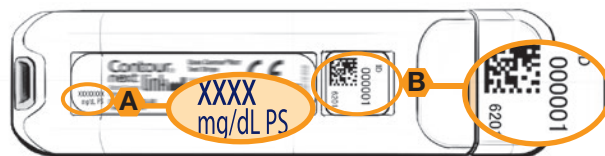
Important:

Speak to a 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[®]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 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 64, Battery Status Displays.)



METER BACK VIEW

Symbols Used

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

Symbol	What it Means
	Batch code
	Consult instructions for use
	<i>In Vitro</i> 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: 500 mA

Strip Storage Temperature Range: 41° – 86°F

Strip Humidity Storage Range: 10% – 80% Relative Humidity (RH)

Control Storage Temperature Range: 48° – 86°F

Control Solution Operating Temperature

Range: 59°F – 95°F

Meter Operating Temperature Range: 41° – 113°F

Meter Operating Humidity Range: 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.

Radio Transmitter Frequency: 916.5 MHz

Maximum Radio Transmitter Power: 0 dBi EIRP

Electromagnetic Compatibility (EMC): The CONTOUR®NEXT LINK meter complies with

the electromagnetic requirement specified in ISO 15197:2013. 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 meter. The CONTOUR NEXT LINK meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. Avoid use of electronic devices in very dry environments, especially if synthetic materials are present. The CONTOUR NEXT LINK meter meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference, do not use the CONTOUR NEXT LINK meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

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 mA 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 pages 28–32 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, contact Customer Service for a replacement. See the back cover for contact information.

Supplies

Replacement Parts

Item

CONTOUR NEXT LINK user guide

CONTOUR NEXT LINK quick reference guide

USB extension cable

USB cap

Wall charger

CONTOUR®NEXT test strips

CONTOUR®NEXT control solution

References

1. US Food and Drug Administration. Use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens: initial communication. US Department of Health and Human Services; update 11/29/2010. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>
2. Centers for Disease Control and Prevention. CDC clinical reminder: use of fingerstick devices on more than one person poses risk for transmitting bloodborne pathogens. US Department of Health and Human Services; 8/23/2010. <http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>
3. American Diabetes Association. Standards of medical care in diabetes—2015. *Diabetes Care*. 2015;38(supplement 1):S10.
4. Burtis CA, Ashwood ER, editors. *Tietz Fundamentals of Clinical Chemistry*. 5th edition. Philadelphia, PA: WB Saunders Co; 2001;444.
5. Atkin SH, et al. Fingerstick glucose determination in shock. *Annals of Internal Medicine*. 1991;114(12): 1020-1024.

Warranty

Manufacturer's Warranty: Ascensia 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, Ascensia 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. Ascensia Diabetes Care shall not be required to replace any units that malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Ascensia Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Ascensia Diabetes Care assumes no liability for malfunction of or damage to Ascensia Diabetes Care instruments caused by the use of test strips or control solution other than the appropriate products recommended by Ascensia Diabetes Care (i.e., CONTOUR®NEXT test strips and CONTOUR®NEXT control solutions).
3. Ascensia Diabetes Care reserves the right to make changes in the design of this instrument without obligation to incorporate such changes into previously manufactured instruments.
4. Ascensia Diabetes Care has not validated the performance of the CONTOUR®NEXT LINK blood glucose meter when used with any test strips other than CONTOUR NEXT test strips, and therefore does not

warrant the performance of the CONTOUR®NEXT LINK meter when used with any test strips other than CONTOUR®NEXT test strips or when the CONTOUR NEXT test strip is altered or modified in any manner.

5. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT LINK meter or test results when used with any control solution other than CONTOUR®NEXT control solution.
6. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT LINK meter or test results when used with any software other than the CONTOUR™ DIABETES app (where supported) or the GLUCOFACTS®DELUXE diabetes management software (where supported) from Ascensia Diabetes Care.

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