

Monitoring System



minde





Uses only CONTOUR®NEXT blood glucose test strips from Bayer 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 measurement of glucose in whole blood, and is for single-patient use only and should not be shared. 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. The system consists of a CONTOUR NEXT LINK wireless blood glucose meter, CONTOUR®NEXT test strips and CONTOUR®NEXT control solutions.

CONTOUR<sup>®</sup>NEXT test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL.

The CONTOUR®NEXT control solutions are aqueous glucose solutions intended for use in self-testing by people with diabetes as a quality control check.

The CONTOUR®NEXT LINK wireless blood glucose monitoring system is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm® REAL-Time Insulin Pumps or Guardian® REAL-Time Monitor 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

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

### <u>/!</u> WARNINGS:

- 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.<sup>1,2</sup>
- 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 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 Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week) for replacement parts. 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 from Bayer automatically transmits blood alucose results using a wireless, radio frequency transmission to your compatible Medtronic MiniMed devices. (Hereafter, referred to as Medtronic MiniMed device.)

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

### 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 from Bayer 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 from Bayer has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter). In some countries, the meters are preset to display units in mmol/L (millimoles of glucose per liter);

Results in mg/dL will never have a decimal point;

• Results in mmol/L will always have a decimal point.

Example:

93 mg/dL or 5.2 mmol/L

Check your display to ensure that results are displayed in mg/dL. If they are not, contact Bayer Diabetes Care Customer Service, 1-800-348-8100 (available 24 hours a day, 7 days a week).

Customizable: Your CONTOUR®NEXT LINK meter from Baver 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 Medtronic MiniMed Device

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

See page 5 for initial setup options. Your compatible Medtronic MiniMed device will only accept the glucose result if the Meter Option in your device's Utility Menu is set to On and you have programmed the device with the meter's ID (serial) number. Up to three different meter ID numbers can be accepted. See page 5 in "Initial Setup." If you have entered your meter's ID number into your compatible Medtronic MiniMed device, it can receive your blood glucose result. No one else's insulin pump or continuous glucose monitoring system can receive your glucose result, unless your meter ID number has been entered into that device. The meter uses a wireless signal to send the blood glucose result to the compatible Medtronic MiniMed device when the Send option is set to fisk Me. See page 7 of this user guide. Your CONTOUR NEXT LINK meter and compatible Medtronic MiniMed device must be within 4 feet of each other. If you are not using the meter link feature on your compatible Medtronic MiniMed device, you may want to set the Send option to Never on your CONTOUR NEXT LINK meter and Medtronic MiniMed device to save battery power.

# GETTING STARTED

# **REMINDERS** AND NOTES

# MAIN MENU FUNCTIONS

# TECHNICAL, SERVICE & CARE

### **Rechargeable Battery**

Your CONTOUR®NEXT LINK meter from Baver 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.





### **Table of Contents**

"Talks" to Your Compatible Medtronic	
MiniMed Device	iv
Meter Overview	3
Initial Setup	5
1	

11
16
20
28
35

Setting a Reminder	40
Turning Off a Reminder	43
Getting a Reminder	45
Adding Notes	46

Menu Button	.47
Trends	.48
Setup	.50
Transferring Data to Medtronic's CareLink® Personal	
Therapy Management Software	.61

Error Detection and Battery Status/	
Charging/Removal	.63
Symptoms of High and Low Blood Sugar	.68
Symbols Used	.75
Caring for Your Meter	.77
Supplies/References/Warranty	.78

**Blood** Bayer

Your ConTOUR®NEXT LINK Wireless Glucose Monitoring System From

### Your CONTOUR®NEXT LINK Wireless Blood Glucose Monitoring System From Bayer

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

### **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 from Bayer only works with CONTOUR NEXT test strips!



# **Meter Overview**

### Using the Buttons

Your CONTOUR®NEXT LINK meter from Bayer 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  $\blacktriangle$  or  $\blacktriangledown$  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  $\blacktriangle$  or  $\blacktriangledown$  buttons will scroll through the list faster.

3

### **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, Irends and Setup.

	-	
	Logbook	
	Trends -	
	Setup 🗧	
6		and the second se

- 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 guick 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 vou through the steps for meter setup and allows your meter to connect to your compatible Medtronic MiniMed device, Your compatible Medtronic MiniMed device must be nearby.

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

Language screen.



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



Language Selected: English

A screen confirms your language.

Initial Setup

Contour

**GETTING STARTED** 

Meter Send Options

**GETTING STARTED** 



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

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

### 4. STOP. Do <u>NOT</u> press <u>ANY</u> buttons.

CONNECT TO PUMP Enter this Meter ID into your pump: 123456

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 Medtronic MiniMed device and continue the connection process.

**IMPORTANT:** Refer to the compatible Medtronic MiniMed device user guide for instructions on connecting your CONTOUR®NEXT LINK meter from Bayer to your compatible Medtronic MiniMed device.

### **Meter Send Options**

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

SEND OPTIONS	
Automatically send results to the Pump?	As
	1

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

A screen message will confirm the choice made (fisk 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.

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ever

### **Date and Time Should Match**

6. The date and time on the meter should match your pump. If they match, press ficcept. If they do not match, press Change.

CURRENT DATE & TIME	
10/11/07	Ассер
10:30 AM	Chang

Follow the meter instructions to change the date and time.

6

# GETTING STARTED

# **Additional Meter Settings**

### AutoLog Feature

Your meter comes with a simple AutoLog feature that lets you mark your test result as **Gefore Meal** or  $\frac{1}{2}$  **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 Bayer Diabetes Care Customer Service at 1-800-348-8100.

CURRENT TARGET	?
<u>é</u> 70-130	Accept
🛫 70-180	Change

 8. The next screen displays the default blood sugar target range for <sup>™</sup> (Before Meal) and <sup>™</sup> (After Meal) blood sugar.

# 

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 Bayer Diabetes Care Customer Service at 1-800-348-8100.

# 🕂 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.

HIGH AND LOW LIMITS	?
High: 250 mg/dL	Accept
Low: 70 mg/dL	Change

9. Choose ficcept 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 0K. **High and Low Limits** 



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

NOTE: Pressing and holding the  $\blacktriangle$  or  $\checkmark$  buttons will scroll through the list faster.

🗹 Limits are set. 👘	
High: 251 mg/dL	Done
LOW: 69 mg/dL	Change

13. The next screen confirms vour choices. Press Done

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

# Information for Safety

after testing.

- 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 drv. Exposure to room humidity from leaving the bottle open or not storing them in the original bottle can damage your test strips. This could lead to inaccurate results.
- · Wash and drv your hands well before and
- 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 selfpowered 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 <u>not</u> 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 MICROLET®2 lancing device and MICROLET® lancets. You will also need control solution to perform a quality control check.
- The MICROLET 2 lancing device is intended for self testing by a single patient. It must not be used on more than one person due to the risk of infection.
- Use a new MICROLET lancet each time you test because it is no longer sterile after use.
- See pages 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 from Bayer 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.



**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.

**TESTING** 

Information for Safety

12

# **Preparing Your Lancing Device**

Read the MICROLET<sup>®</sup>2 lancing device insert for complete instructions. For Alternative Site Testing instructions, see page 20.

WARNING: Potential Biohazard The MICROLET 2 lancing device is intended for single patient use only. The MICROLET 2 device should not be used for assisted blood draws by 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 MICROLET<sup>®</sup> lancet each time you test because it is no longer sterile after use.



- 1. To remove the endcap, hold the device with your thumb on the grip indent and hold the endcap dial in the other hand. Snap the endcap off from top to bottom.
- - 2. Loosen the round protective cap on a lancet by rotating it <sup>1</sup>/<sub>4</sub> turn, but do not remove it.



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





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

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

TESTING

Contour

www.baverdiabetes.com/us Need Help? Call toll free: 1.800.348.8100 (available 24 hours a day. 7 days a week) TESTING

**Getting the Blood Drop – Fingertip Testing** 

# Getting the Blood Drop

### For fingertip testing







not squeeze around the puncture site. 3. Test immediately after

firmly against the puncture site and

release button with

finger towards the

puncture site to form

a drop of blood. Do

press the blue

vour thumb.

vou have formed a small, round blood drop (0.6 µl).

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.

## 

- 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.<sup>1,2</sup>
- 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 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.

TESTING





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.

### **Removing the Used Lancet**





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

1. In one hand, hold the

lancing device with

your thumb on the

grip indent, with your other hand, hold the

gray endcap dial as

shown, and gently snap off the endcap.

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



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

**5.** Dispose of the used lancet as medical waste. Do not reuse lancets. Use a new MICROLET<sup>®</sup> lancet each time you test.



**Getting the Blood Drop – Fingertip Testing** 

# TESTING

# 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. Attach the clear AST endcap to the MICROLET<sup>®</sup>2 lancing device



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



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



**TESTING** 

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



# TESTING

### For Alternative Site Testing (cont'd)



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



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



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

**Do not test the blood sample from palm if you get:** Smeared blood • Clotted blood • Runny blood • Clear fluid mixed with the blood. 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 Sefore Meal, \$\frac{1}{2}\$ After Meal or No Mark by pressing the button next to it. Your test result will not display until you make a selection.



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

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.

TESTING

**Testing in the Dark** 

# **Test Results**

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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 MICROLET<sup>®</sup>2 package insert for instructions on how to properly remove and dispose of the lancet.

### Stopping a Result While it Is Being Sent

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

### **Sending Test Results**

Depending on how you have set up your options, you can send your test results or not. If you have selected Ask Me, you can always send or not send to your compatible Medtronic MiniMed device.



If you have selected Never, your test result will never be sent to your compatible Medtronic MiniMed device.

Ιок



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 Medtronic MiniMed device to ensure that the glucose result shown agrees with the meter display.

### Test Results

Expected Values: Blood sugar values will varv depending on food intake, medication dosages, health, stress, or activity. Non diabetic plasma glucose concentrations are normally maintained within a relatively narrow range, roughly 70-110 mg/dL in the fasting state.<sup>3</sup> You should consult with your health care professional for glucose values specific to your needs.



*TESTING* 

Sent

Stopping a Result While it Is Being

# TESTING

### **Cleaning and Disinfection**

Your CONTOUR®NEXT LINK system should be cleaned and disinfected once a week. 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 and MICROLET<sup>®</sup>2 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 system should be cleaned of dirt and debris once a week.

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

### WARNING

Always wash your hands well with soap and water 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 and lancing device should be disinfected prior to use by the second person.

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 and MICROLET 2 lancing device have been tested for 260 cycles of cleaning and disinfection (one cycle per week for 5 years). These devices have been demonstrated to withstand 5 years of cleaning and disinfection without damage. You should call Bayer Diabetes Care 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 call Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week).

For more information see:

"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

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

"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

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



TESTING

**Cleaning and Disinfection** 

### **Cleaning Your Meter**

### **Supplies Needed for Cleaning:**

- Clorox<sup>®</sup> 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. Drv all meter surfaces and test strip port using a clean paper towel if needed.

Strip Port

### **Cleaning Your Lancing Device**

### **Supplies Needed for Cleaning:**

- Clorox<sup>®</sup> Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
- Paper towels
- 1. Clean the MICROLET<sup>®</sup>2 lancing device with Clorox Germicidal Wipes until all soil is removed.
- 2. Dry as necessary with a clean paper towel.

### **Disinfecting Your Lancing Device**

### **Supplies Needed for Disinfecting:**

- Clorox<sup>®</sup> Germicidal Wipes containing 0.55% sodium hypochlorite (bleach)
- Paper towels
- Timing device
- 1. Before disinfecting, clean the lancing device as described above in Cleaning Your Lancing Device.



2. Remove the endcap and lancet, if present.

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

*TESTING* 

**Cleaning and Disinfection** 





3. Using a new Clorox<sup>®</sup> Germicidal Wipe, carefully wipe all external and internal surfaces of the endcap until wet.

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



- 4. Use Clorox Germicidal Wipes to disinfect all exposed surfaces of your lancing device until wet.
- **5.** Dry all lancing device surfaces and endcap with a clean paper towel if needed.

#### Signs of Deterioration

Your MICROLET<sup>®</sup>2 lancing device has been tested for 260 cycles of the cleaning and disinfection procedure (one cycle per week for 5 years). The MICROLET 2 lancing device has been demonstrated to withstand 5 years of cleaning and disinfection without damage. However if your device malfunctions for any cause, contact Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week) to troubleshoot the issue and provide a solution.

### Warranty

Your MICROLET 2 lancing device is warranted for 5 years.

### **Measuring Range**

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

Result Under 20 mg/dL Follow Medical Advice Immediately.





- If your blood sugar reading is under 20 mg/dL, the Follow Medical fidvice 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.



**Cleaning and Disinfection** 

# TESTING

### 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, \$\frac{2}{5}\$ After Meal or No Mark by pressing the button next to it.

# **Control Solution\* Testing**

Shake the control solution well before testing.

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

\*Control solution may not be included in all meter kits. Contact Bayer Diabetes Care Customer Service at 1-800-348-8100 for information about obtaining control solution.

### **Quality Control**

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

### 

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

TESTING

**High and Low Blood Sugar Readings** 



**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. Always use CONTOUR®NEXT control solutions from Bayer. Other brands could present incorrect results. If you need help locating CONTOUR NEXT control solutions from Bayer, contact Bayer Diabetes Care Customer Service at 1-800-348-8100.



**TESTING** 

**Control Solution Testing** 

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.



- **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.

### 

#### Do not send an out of range control result to your pump

**CAUTION:** If your control solution test result is out of range, contact Bayer Diabetes Care Customer Service at 1-800-348-8100. Do not use the meter or test strips for blood glucose testing until the issue is resolved.



3

# 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.



 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.



Reminder in: 3 hours 15 minutes 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.

Setting a Reminder

**Setting a Reminder** 

REMINDERS AND NOTES



# REMINDERS AND NOTES

### 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.



Contour

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 is 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.



# Neminder is stopped.

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.

REMINDERS AND NOTES



MAIN MENU FUNCTIONS

### **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.

button to scroll through

the choices. Some may

scroll up or down. Press

the **OK** button when your

not be visible until vou

choice is highlighted.

A screen confirms your choice.



Sick is added to Notes.



Sick is removed from Notes.





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.



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 guick presses. Two guick presses of the Menu button will also turn off the light.

### Loabook

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  $\blacktriangle$  or  $\blacktriangledown$ button.

REMINDERS AND NOTES

**Adding Notes** 

47





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 Irends button to view averages.



14 days is the default. You can change the **Irends** time range to 7 or 30 days in **Setup** (see page 58).

TRENDS	
TARGET 🥌 70-130	
💢 /U-18U	

If AutoLog is on, the  $\stackrel{\bullet}{\bullet}$  (Before Meal) and  $\frac{1}{2}$  (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 o Before Meal/  $\frac{1}{2}$  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.

 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.

14 DAV AFTER	MEAL	
AVERAGE	🕇 9	F
	17 8	┡
	i 🖡 🛛	

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



 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.

.

Trends

# Setup

### **Pump Options**

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

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

SETUP Pump Options Reminder: Off Date	ОК	
PUMP OPTIONS	Send Options Connection	2.
SEND OPTIONS Send is set to Ask me.	<b>?</b> Change Go Back	3.
SEND OPTIONS Automatically send Blood Glucose Resu to the Pump?	l Its Ask me Never	4.

- 2. Press Send Options to change your current setting.
- 3. Then press Change. Or press 60 Back if you do not wish to change Send Options.
- 4. Choose the setting that is best for you. The choices are: fisk Me, or Never.



- 5. The next screen confirms your choice. Press 0K.
- 6. Choose Connection from the Pump Options menu to connect your CONTOUR®NEXT LINK meter to your compatible Medtronic MiniMed device.



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

CONNECT TO PUMP	
Connect to a Medtronic Pumn?	OK
	Go Back

8. Follow the instructions on your compatible Medtronic MiniMed device to connect with your meter (refer to the compatible Medtronic MiniMed device user guide). Do not press **0K** on your meter screen until connection process is complete.

CONNECT TO PUMP	?
Enter this Meter IU into your numn:	0K
123456	Go Back

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



Setup

### **Setting the Date**

- 1. Press the Menu button to go to the Main Menu.
- 2. Press the Setup button.
- **3.** Press the  $\blacktriangle$  or  $\checkmark$  button to select Date. Press the **IK** button.



4. To change the date, press the Change button.

DATE SELECT Month/Dau/Year Dau.Month.Year DATE CHANGE VEAR 10/13/ DRIE CHANGE MONTH /13/10 DATE CHANGE DAV οк 10/13/10

Contour

- 5. Select either the Month/ Day/Year or Day.Month. Year button.
- 6. Press the ▲ or ▼ button to select the correct year. Press the **IK** button.
- 7. Press the ▲ or ▼ button to select the correct month. Press the **OK** button.
- 8. Press the  $\blacktriangle$  or  $\blacktriangledown$ button to select the correct day. Press the **IIK** button.



A screen confirms the date vou 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  $\blacktriangle$  or  $\blacktriangledown$  button to select Time. Press the **IK** button.



- SELECT FORMAT **12 Hour Clock** 24 Hour Clock
  - 4. To change the time, press the Change button.

www.baverdiabetes.com/us

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

53

TIME

Setting the Date







- 6. Press the ▲ or ▼ button to select the correct hour. Press the 0K button.
- 7. Press the ▲ or ▼ button to select the correct minute. Press the **0K** button.
- 8. Press the ▲ or ▼ button to select the correct AM/PM. Press the 0K 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.



sound	
Sound is On	Accept
	Turn Off

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

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

### 🕗 Sound is Off. 👘

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

MAIN MENU FUNCTIONS



Setting the Time

MAIN MENU FUNCTIONS

### 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 **IK** button.



2. To turn the AutoLog off, press the Iurn Off button.

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

Accept

Turn Off



Sound is On

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 Bayer Diabetes Care Customer Service at 1-800-348-8100.

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  $\blacktriangle$  or  $\checkmark$  button to select **Larget**. Press the OK button.

SETUP	
Target	lov -
Trends Range	
High and Low Limits	

TARGET	?
<u>ó</u> 70-130	Change
蛇 70-180	Go Back

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

CHANGE TARGET	
e 70-130	ок
😴 70-180	

- 5. Press the  $\blacktriangle$  or  $\blacktriangledown$ button to select your
  - desired **(Before Meal**) low target. Press the OK button.

**High and Low Limits** 

MAIN MENU FUNCTIONS

**Setting Trends Range** 

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.

🗸 Target is Set. 👘	
<b>6</b> 80 - 120	Change
<del>2</del> 120 - 150	Done

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

### **Setting Trends Range**



AUTOLOG DEFAULT RANGE 14 dau	?
	Accept
-	Change

- 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.
- Irends Range Selected: 7 Day
- 2. The next screen will confirm your selection.

### **High and Low Limits**

NOTE: High and Low Limits can only be set outside your selected Target range(s). For additional information, you may contact Bayer Diabetes Care Customer Service at 1-800-348-8100.

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

HIGH AND LOW LIMITS	2
High: 250 mg/dL	Accept
Low: 70 mg/dL	Change

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

HIGH AND LOW LIMITS	
High: <mark>251</mark> mg/dL	
Low: 70 mg/dL	

 Press the ▲ or ▼ button to select your high limit. Press 0K.

HIGH AND LOW LIMITS	Ľ
High: 251 mg/dL	0
Low: 69 mg/dL	k

- ✓ Limits are set. High: 251 mg/dL Done Low: 69 mg/dL Change
- 3. Press the ▲ or ▼ button to select your low limit. Press 0K.
- 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  $\blacktriangle$  or  $\checkmark$  button to select Language. Press the **IK** button.





- 4. Press the ▲ or ▼ button to select the language you prefer. Press the **IK** button.
- Language Selected: English
- A screen confirms your choice. The Setup menu will appear in the language you selected.

### Transferring Data to Medtronic's CareLink<sup>®</sup> Personal Therapy **Management Software**



You can easily transfer blood alucose results from the CONTOUR®NEXT LINK meter to CareLink Personal Therapy Management software.

You can also wirelessly transfer data from your compatible Medtronic MiniMed device to CareLink Personal Therapy Management Software using your CONTOUR NEXT LINK meter

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

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



Setting the Language

MAIN MENU FUNCTIONS

### **IMPORTANT:**

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

For more information, call Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week) or visit our website at www.bayerdiabetes.com/us.

### **Error Detection Displays**

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

!	Used Test Strip	J
	Remove used strip.	
	Repeat test with new	
02	strip.	

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 **0K** shown, press the button next to it to continue.

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

Check the device display to see if your meter's glucose result has been received. If it has not, you can enter the test result manually. If you continue to have problems, contact Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week).

63

## **Battery Status Displays**

The battery status will be displayed with a battery symbol in 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 Status Displays** 



**SERVICE & C** 

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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 highpower 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 highpower 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.



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

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**Battery Charging** 

TECHNICAL, SERVICE & CARE

SERVICE & (

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> <li>shakiness</li> <li>sweating</li> <li>fast heartbeat</li> <li>blurred vision</li> <li>confusion</li> <li>passing out</li> <li>irritability</li> <li>seizure</li> <li>extreme hunger</li> <li>dizziness</li> </ul>	<ul> <li>frequent urination</li> <li>excessive thirst</li> <li>blurred vision</li> <li>increased fatigue</li> <li>hunger</li> </ul>	<ul> <li>shortness of breath</li> <li>nausea or vomiting</li> <li>very dry mouth</li> </ul>

### /!\ 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.

# 68

# 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.bayerdiabetes.com/us

### Principles of the Procedure: The

CONTOUR®NEXT LINK blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with FAD glucose dehydrogenase (FAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation is required.

**Comparison Options:** The CONTOUR NEXT LINK system is designed for use with capillary whole blood. Comparison to a laboratory method must be done simultaneously with aliquots of the same sample. **NOTE:** Glucose concentrations drop rapidly due to glycolysis (approximately 5–7% per hour).<sup>4</sup>

### Limitations

#### **Altitude:**

Up to 20,674 feet (6301 meters) does not significantly affect results.

### Lipemic Specimen:

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

Peritoneal dialysis solutions: Icodextrin does not interfere with CONTOUR®NEXT test strips.

**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:** Capillary blood glucose testing may not be clinically appropriate for 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.<sup>5</sup> **Interference:** Certain substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect results. The limiting concentrations of these compounds are listed on your test strip insert.



Limitations

**SERVICE & C** 

# Federal Communications Commission (FCC) Certified Device

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

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

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

If you have questions, please contact Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week).

## <u>()</u> 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 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.

 $\begin{array}{l} \textbf{Table 1} - \text{System accuracy results in lay users for} \\ \text{CONTOUR NEXT LINK meter using CONTOUR NEXT} \\ \text{test strips at glucose concentration} < 75 \text{ mg/dL} \\ \end{array}$ 

Within	Within	Within
± 5 mg/dL	± 10 mg/dL	± 15 mg/dL
8 of 8	8 of 8	8 of 8
(100%)	(100%)	(100%)

**Table 2** — System accuracy results in lay users forCONTOUR NEXT LINK meter using CONTOUR NEXTtest strips at glucose concentration  $\geq$  75 mg/dL

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

Acceptance criteria in ISO 15197: 2003 are that 95% of all differences in glucose values (i.e., between reference method and meter) should be within 15 mg/dL for glucose values less than 75 mg/dL, and within 20% for glucose values greater than or equal to 75 mg/dL.

TECHNICAL, SERVICE & CARE

73

### 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, call Bayer Diabetes Care Customer Service. In the USA, call toll free: 1-800-348-8100 (available 24 hours a day, 7 days a week). We have trained specialists to help you.

### Important:

Speak to a Baver Diabetes Care Customer Service Representative before returning your meter for any reason. He/she will give you the information needed to handle your problem correctly and efficiently. Have your CONTOUR NEXT LINK blood glucose meter and CONTOUR®NEXT test strips available when you phone. It would also be helpful to have a bottle of control solution suitable for your test strips nearby.

### Check List:

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

- **1.** Locate the model number (A) and serial number (B) on the back of the meter
- 2. Locate the test strips' expiration date on the bottle
- 3. Check the battery symbol **[**] on the screen. (See page 64, Battery Status Displays.)



### **Symbols Used**

### **METER BACK VIEW**

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

Symbol	What it Means
LOT	Batch code
Ţ	Consult instructions for use
IVD	In Vitro Diagnostic Medical Device

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Check List

Precision

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**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 **Control Storage Temperature Range:** 41° – 113°F **Meter Operating Temperature Range:** 41° – 113°F **Humidity:** 10–93% RH **Dimensions:** 3.8 in (H) x 1.2 in (W) x 0.8 in (T)

### Weight: 48 grams

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

Electromagnetic Compatibility (EMC): The

CONTOUR®NEXT LINK meter complies with the electromagnetic requirements specified in ISO 15197. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the CONTOUR®NEXT LINK. Immunity to electrostatic discharge meets the requirements of IEC

61000-4-2. It is advisable to avoid use of electronic devices in very dry environments especially if synthetic materials are present.

The CONTOUR NEXT LINK meter has been tested for radio frequency interference at the frequency range and test levels specified by ISO 15197. Immunity to Radio Frequency meets the requirements of IEC 61000-4-3. To avoid radio frequency interference do not use the CONTOUR NEXT LINK meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters or other electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

# **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.

**System Specifications** 

77

- 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, call 1-800-348-8100 (available 24 hours a day, 7 days a week) for a replacement.

# **Supplies**

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

### **Replacement Parts**

Part Number*	Item
84548072	CONTOUR NEXT LINK user guide
81548021	CONTOUR NEXT LINK quick
	reference guide
81363014	USB extension cable from Bayer
81675369	USB cap
81675377	wall charger
83624796	CONTOUR <sup>®</sup> NEXT test strips
83624818	CONTOUR NEXT control solution
*Part numbers a	are subject to change without notice.

These parts are available in the United States from: Bayer HealthCare LLC Customer Service Department Order Entry P.O. Box 2004 Mishawaka, Indiana 46546 or call 1-800-348-8100 (available 24 hours a day, 7 days a week) to order

## References

- <sup>1</sup> FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication: Update 11/29/2010. http:// www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ ucm224025.htm
- <sup>2</sup> CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens (2010). http://www.cdc.gov/ injectionsafety/Fingerstick-DevicesBGM.html
- <sup>3</sup> Longo D.L. et al. *Harrison's Principles of Internal Medicine*, 18th Edition, 2011. http://www.accessmedicine.com
- <sup>4</sup> *Tietz Fundamentals of Clinical Chemistry*, 5th Edition, Edited by Burtis CA and Ashwood ER, W. B. Saunders Co., Philadelphia, PA, 2001, p. 444.
- <sup>5</sup> Atkin, S. *et al.*: Fingerstick Glucose Determination in Shock. *Ann. Int. Med.* 114:1020-24; 1991.

79

Supplies

TECHNICAL, SERVICE & CARE



# Warranty

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

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

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

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

- **5.** Bayer Diabetes Care makes no warranty of the performance of the CONTOUR NEXT LINK meter or test results when used with any control solution other than CONTOUR NEXT control solution.
- 6. Bayer Diabetes Care makes no warranty of the performance of the CONTOUR NEXT LINK meter or test results when used with any software other than GLUCOFACTS®DELUXE diabetes management software from Bayer and Medtronic's MiniMed CareLink® Therapy Management software.

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

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

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

**For warranty service:** Purchaser must contact the Customer Service Department of Bayer Diabetes Care, by calling toll free 1-800-348-8100 (available 24 hours a day, 7 days a week), for assistance and/or instructions for the use of this instrument.

Warranty

### Index

After Meal marker	8
Alternative Site Testing (AST)	20
AutoLog (Meal Markers)	8
Averages (Trends)	
Batteries	64
Charging	66
Low Batteries	64
Removal	67
Before Meal Marker	8
Blood Sugar Readings	34
Care and Maintenance	77
Cleaning and Disinfection	28
Control Solution Testing	35
Error Detection Displays	63
Lancing	14
Limits (High and Low) Settings	9
Care and Maintenance Cleaning and Disinfection Control Solution Testing Error Detection Displays Lancing Limits (High and Low) Settings.	

Logbook	
Meal Markers (AutoLog)	8
Menu Button	
Measuring Range	
Notes	
Pump Options	50
Reminders	
Setup	50
Date	
Language	60
Sound	55
Time	
System Performance Information	69
System Specifications	76
Target Range	57
Transferring Data	61





Bayer HealthCare LLC Mishawaka, IN 46544 USA

www.bayerdiabetes.com/us

Call Toll Free: 1-800-348-8100 (available 24 hours a day, 7 days a week)

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