



Uses only Bayer's CONTOUR®NEXT blood glucose test strips



INTENDED USE

The CONTOUR®NEXT USB 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 consists of a CONTOUR NEXT USB blood glucose meter, CONTOUR®NEXT test strips and CONTOUR NEXT control solutions. The CONTOUR NEXT USB blood glucose monitoring system is

indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. The CONTOUR NEXT USB blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The CONTOUR®NEXT Test Strips are for use with the CONTOUR NEXT USB blood glucose monitoring system for the quantitative measurement of glucose in whole blood.

The CONTOUR NEXT Control Solutions are for use with the CONTOUR NEXT USB blood glucose monitoring system to check that the meter and test strips are working properly.

IMPORTANT SAFETY INFORMATION

A WARNINGS

Serious Illness

 Capillary (fingerstick or Alternative Site) blood glucose testing may not be clinically appropriate when peripheral flow is decreased. Shock, severe hypotension, hyperosmolar hyperglycemia, diabetic ketoacidosis, and occurrence of severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.¹⁻³

Talk to Your Health Care Professional

- Before setting any Target Ranges or High or Low Alerts on your meter.
- Before changing your medication based on test results.

- 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.
- About whether Alternative Site Testing (AST) is appropriate for you.

Potential Biohazard

- Always wash your hands well with soap and water before and after testing, handling the meter, lancing device or test strips.
- 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 patients!^{4,5}
- All parts of this kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection. For complete instructions on cleaning and disinfecting your meter and lancing device, please see pages 26 29.
- Use a new MICROLET[®] lancet each time you test because it is no longer sterile after use.
- Always dispose of 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.
- Keep out of reach of children. This kit contains small parts which could cause suffocation if accidentally swallowed.

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PRECAUTIONS

- Read your CONTOUR®NEXT USB user guide, the MICROLET®2 lancing device package 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.
- · 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 Baver Diabetes Care Customer Service 24 hours a day, 7 days a week, at 1-800-348-8100 for replacement parts.
- Bayer's CONTOUR NEXT USB meter only works with CONTOUR®NEXT test strips and CONTOUR NEXT control solution.
- Always keep the CONTOUR NEXT test strips in their original bottle. Tightly close the bottle immediately after removing a test strip. The bottle is designed to keep the test strips dry. Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt. Exposure to room humidity by leaving the bottle open or not storing the strips in their original bottle can damage your test strips. This could lead to inaccurate results. Do not use a test strip that appears damaged or has been used.
- Check the expiration dates on your test strips and control solution. Do not use the test strips or control solution if the expiration date printed on the bottle label and carton has passed. This can cause inaccurate results. 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.
- If your control solution test result is out of range, call Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week). Do not use the meter for blood glucose testing until you resolve this issue.
- The meter has been designed to give accurate results at temperatures between 41°F and 113°F. If you are outside this range, you should not test. Whenever the meter is moved from one location to another, allow approximately 20 minutes for the meter to adjust to the temperature of the new location before

performing a blood glucose test. The products have been designed to give accurate results at temperatures between 41°F and 113°E.

- Do not perform a blood glucose test when the CONTOUR®NEXT USB meter is connected to a computer.
- Use only approved equipment from the manufacturer or certified body such as UL or TUV.
- It is advisable to avoid use of electronic devices in very dry environments, especially if synthetic materials are present.
- · Bayer's CONTOUR NEXT USB meter has been preset and locked to display results in mg/dL (milligrams of glucose per deciliter of blood).
 - * Results in mg/dL will never have a decimal point;
 - * Results in mmol/L will always have a decimal point. or
 - 93 Example:
 - Check your display screen to be sure the results are shown the right way. If not, contact Bayer Diabetes Care Customer Service 24 hours a day, 7 days a week, at 1-800-348-8100.

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- Bayer's CONTOUR NEXT USB blood glucose monitoring system has a measuring range of 20 mg/dL to 600 mg/dL.
 - * For results over 600 mg/dL or under 20 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.
- Please be aware that USB ports in some computers and selfpowered USB hubs can become much warmer than the room. A USB extension cable has been provided for your convenience. If you wish to test immediately after disconnecting from your computer, please use the USB cable. iv

Rechargeable Battery

Bayer's CONTOUR®NEXT USB meter has a rechargeable battery. You must charge your battery before you can use your meter and you cannot do a blood sugar test while the battery is charging.

To Charge

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.

The meter is fully charged when the test strip port light stops flashing and turns off. Unplug your CONTOUR NEXT USB meter to test.

HINT: After one minute of charging, you can run one blood sugar test if needed.

A USB extension cable is included for your convenience.



Please be aware that USB ports in some computers and selfpower USB hubs can become much warmer than the room. If you wish to test immediately after disconnecting from your computer, please use the USB cable.

You must unplug your CONTOUR NEXT USB meter to test.

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GETTING STARTED

TESTING

FEATURES

Blood Glucose Monitoring System

Bayer's CONTOUR®NEXT USB

Bayer's **CONTOUR®NEXT** USB Blood Glucose Monitoring System



Gray Square End

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

Sample Tip

Blood is drawn in here.

CAUTION: Bayer'S CONTOUR NEXT USB meter ONLY works with CONTOUR NEXT test strips and CONTOUR NEXT control solutions!

Your MICROLET®2 Lancing Device



*Available on request from Bayer Diabetes Care Customer Service, Call 1-800-348-8100. GETTING



Meter Overview

Turning the Meter On or Off

- Press and hold the top Menu button to turn the meter on or off.
- Insert a test strip to turn the meter on and remove the test strip to turn the meter off.

Using the Top Menu Button



The top Menu button has 3 functions:

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- To turn the meter on/off, press and hold the top **Menu** button until the meter turns on/off
- From most screens, press the top Menu button once to go back a screen.
- With the meter off, 2 quick presses of the Menu button will turn the test strip port light on or off.

Using the Selection/Scrolling Buttons



- The three buttons next to the screen allow you to make your selection by pressing the button next to your choice.
- You can scroll up or down for additional choices when the ▲ or ▼ arrows appear on the meter screen.
- When your choice is highlighted, make a selection by pressing the **OK** button.

HINT: Press and hold the \blacktriangle or \blacktriangledown buttons to scroll through the list faster.

Using the Main Menu



• The Main Menu has 3 choices: Logbook, Trends and Setup. Select one by pressing the button next to your choice. See page 49 for more details on "Setup".



GETTING STARTED



Initial Setup

Before use, charge your meter. See page 68.

HINT: Your meter comes with GLUCOFACTS®DELUXE diabetes management software on board. You do not need to set this up to charge your meter or perform a blood sugar test. Please see page 63 for more information on GLUCOFACTS DELUXE.

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 \blacktriangle or \checkmark button to select your desired language. Press the ▼ button to scroll down to see more language choices.

When your language is highlighted, press the **OK** button. A screen confirms your language.





3. The date and time will appear and you can Accept or Change.

When you accept the date and time as they appear, you are also accepting the date format and time format. After pressing **Accept**, you will see the High and Low Alert settings.

1. If you want to change date, time, date format or time format, select Change.



2. Use the \blacktriangle or \blacktriangledown buttons to make any changes. When the desired choice is highlighted, press the OK button.

- 3. Continue this process until the date is set the way you want. Select Accept.
- 4. The 12 hour or 24 hour clock screen will appear.



5. Follow the same steps to get to the time you want.



A screen confirms your choice. Press ficcept. After pressing Accept, you will see the High and Low Alert settings.

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GETTING

High and Low Alerts

High and Low Alerts

The High and Low Alert feature tells you when your test result is above or below the settings you choose. Alerts appear as large orange numbers.

HINT: Alerts can only be set outside your selected Target Range(s). For more information, call Bayer Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week), or visit our website at www.bayercontour.com.

Discuss your High and Low Alert settings with your health care professional.

Your meter comes preset with a High Alert level of 250 mg/dL and a Low Alert level of 70 mg/dL. You can **Accept** or **Change** these levels.

1. Select Accept to keep the preset Alert levels and move on to Targets. If you wish to change these Alert levels, choose Change.

HIGH AND	LOW ALERTS	?
High: 25	() mg/dL	Accept
Low: 7	() mg/dL	Change

HINT: Your Target Ranges must be within your High and Low Alert levels. You will set your target ranges next. If you selected Change, press the ▲ or ▼ button to select your High Alert level. This can be set between 126 - 360 mg/dL. Press 0K.

HIGH	AND LOW ALERTS	Z
High:	251 mg/dL	0
Low:	70 mg/dL	

 Press the ▲ or ▼ button to select your Low Alert level. This can be set between 54 - 99 mg/dL. Press 0K.

HIGH AND LOW ALERTS	
High: 251 mg/dL	0
Low: 70 mg/dL	

HINT: Pressing and holding the \blacktriangle or \blacktriangledown buttons will scroll through the numbers more quickly.

4. The next screen confirms your choices. Press ficcept to confirm your Alert settings.

🖌 Al	erts	are set.	
High:	251	mg/dL	Accept
Low:	69	mg/dL	Change



Target Ranges

The next screen displays the preset blood sugar Target ranges for Fasting, Before Meal and After Meal blood sugar.

HINT: Targets can only be set inside your selected Alert level(s). For more information, call Baver Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week), or visit our website at www.bayercontour.com.



Discuss your Target ranges with your health care professional.

You can accept or change these ranges.

Each Target will have an option to Accept or Change.

1. To change the Targets press the \blacktriangle or \checkmark buttons until the desired Target is reached and then press **OK**. The preset value for Fasting and Before Meal is 70 - 130 mg/dL and for After Meal is 70 - 180 mg/dL.

TARGET	?
Before Meal:	Accept
🍻 70 - 130	Change
✓ Targets are set. ○ 70 - 130 ● 70 - 130 ▼ 70 - 180 	Accept Change

A screen confirms your choice for each Target.

Initial Setup is complete. Insert strip to start a test.

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

You can also change these settings by going to the Main Menu and selecting Setup. See page 49.

Getting Ready to Test

Read vour CONTOUR®NEXT USB user quide, 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.

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.

CAUTION: Your CONTOUR®NEXT USB meter only works with CONTOUR NEXT test strips and CONTOUR NEXT control solutions.

Have all the materials you will need ready before you begin testing. This includes your CONTOUR NEXT USB meter, CONTOUR®NEXT test strips, and the MICROLET2 lancing device and MICROLET[®] lancets. You may also need CONTOUR NEXT control solution to perform a quality control check. CONTOUR NEXT control solutions are sold separately if not included in the meter kit.

WARNING

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

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

TESTING

AutoLog

- **2.** Hold the test strip with the gray end facing toward the meter.
- **3.** Insert the gray square end firmly into the test strip port until the meter beeps.





You will see the Apply Blood screen. The meter is now ready to test a blood drop.

HINT: After test strip is inserted, if you do not apply blood to the test strip within 1 minute, the meter screen will dim and the meter will beep. Press any button and the Apply Blood screen will become bright again. After a total of 3 minutes of inactivity the meter will turn off.

AutoLog

Your meter comes with an AutoLog feature that lets you mark your test result as Fasting, Before Meal, After Meal and No Mark.

O Fasting – The Fasting marker can be used when testing blood sugar levels after going without food or drink for at least 8 hours.

Before Meal – The Before Meal marker can be used when testing blood sugar levels within 1 hour before a meal.

After Meal – The After Meal marker can be used when testing blood sugar levels within 2 hours after a meal.

No Mark –You can select No Mark if you are testing at times other than before or after a meal or fasting.

Your meter comes with AutoLog turned on. To get the most from your meter, we recommend that you keep this feature turned on.





Getting Ready to Test

Preparing the Lancing Device

Read the MICROLET[®]2 lancing device insert for complete instructions. For Alternative Site Testing instructions, see page 20.

/ WARNING: Potential Biohazard

The MICROLET2 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.



1. Remove the endcap from the MICROLET[®]2 lancing device with your thumb on the grip indent as shown. Snap the endcap off from top to bottom.



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2. Loosen the round protective cap on a lancet by rotating it ¹/₄ turn, but do not remove it.







- 3. Insert the lancet firmly into the lancing device until it comes to a full stop. This will re-set the device. You can also pull and release the re-setting handle.
- 4. Twist off the round protective lancet cap. Save it for disposing of the used lancet.

TESTING

Preparing the

Lancing Device

5. Replace the gray endcap.

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

Getting the Blood Drop for Fingertip Testing

TESTING

Getting the Blood Drop for Fingertip Testing

- 1. Press the endcap firmly against the puncture site and press the blue 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 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.

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 16 or errors.

- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!^{4,5}
- 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 26.

Apply More Blood If Necessary

If the first blood drop is not enough, the meter may beep twice and display "\$TRIP UNDERFILLED" and "APPLY MORE BLOOD NOW." You have about 30 seconds to apply more blood onto the same strip. Follow the instructions on the meter display screen.

Test Results with AutoLog On

Before your test result is displayed, the AutoLog screen appears.

Select Fasting, Before Meal, After Meal, or No Mark by pressing the OK button when the selection is highlighted.

(Scroll down to see No Mark.) Your test result will not display until you make a selection.

However, if your result is above or below your High and Low Alerts settings, you will see your result in 5 seconds without pushing a button.

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

Your test result appears as a large-sized number and then changes to the usual test result screen.

You can now set a Reminder for your next test (see page 34), log insulin or carbs information (see page 38), or add a Note (see page 43).

HINT: LEAVE the test strip in the meter to add a note related to this result or set a reminder. For information about adding a note or setting a reminder, see pages 34 – 43.

Test Results with AutoLog Off

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

You can now set an optional Reminder for your next test (see page 34), log insulin or carbs information (see page 38), or add a Note (see page 43).

Remove the test strip from the meter to turn it off.

HINT: LEAVE the test strip in the meter to add a note related to this result or set a reminder. For information about adding a note or setting a reminder, see pages 34 – 43.

TESTING

For Alternative Site Testing (AST) - Palm

- Ask your health care professional if Alternative Site Testing is right for you.
- Do not calibrate your continuous glucose monitoring device from an AST result.
- Do not calculate an insulin dose based on an AST result.

IMPORTANT: For Alternative Site Testing, use the clear endcap. Your CONTOUR®NEXT USB meter can be used for fingertip or palm testing. See the MICROLET®2 insert for complete instructions in Alternative Site Testing.

IMPORTANT: Do not use AST under the following conditions:

- If you think your blood sugar is low
- When blood sugar is changing rapidly (after a meal, insulin dose, or exercise)
- If you are unable to feel symptoms of low blood sugar (hypoglycemic unawareness)
- If you get alternative site blood sugar 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

Alternative Site results may be different from fingertip results when glucose levels are changing rapidly (e.g., after a meal, after taking insulin, or during or after exercise). Additionally, glucose levels may not rise as high or fall as low as levels in the fingertip. As such, fingertip results may identify hypoglycemic levels sooner than alternate site results. Alternative Site Testing is recommended only when it is more than 2 hours after a meal, diabetes medication, or exercise.

If you do not have a clear end cap to perform AST, call Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week).

Getting a Blood Drop for Alternative Site Testing

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- 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 MICROLET[®]2 lancing device.
- **3.** Select a puncture site from a fleshy area on the palm. Avoid veins, moles, bones, and tendons.
- 4. Press the clear endcap firmly against the puncture site and then press the blue release button.

Getting a

Blood Drop for Alternative

Site Testing

TESTING

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:

- Smeared blood
- Clotted blood
- Runny blood
- Clear fluid mixed with the blood.
- 8. 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.

Apply More Blood if Necessary

If the first blood drop is not enough, the meter may beep twice and display "STRIP UNDERFILLED" and "APPLY MORE BLOOD NOW". You have about 30 seconds to apply more blood onto the same strip.

Follow the instructions on the meter screen. If you do not apply more blood within about 30 seconds, remove the strip and start over with a new strip.

9. If you have the AutoLog feature turned on, the AutoLog screen appears. Your test result will not display until you make a selection. Select Fasting, Before Meal, After Meal, or No Mark by pressing the OK button when the selection is highlighted. Scroll down to see No Mark.

CAUTION: If your result is below 70 mg/dL or above 250 mg/dL, you will always see your result without pushing a button. (If you changed your settings, your below and above readings will be based on those settings.)

Please go to Test Results with AutoLog On, page 18, or Test Results with AutoLog Off, page 19.

Removing the Used Lancet

- 1. In one hand, hold the lancing device with your thumb on the grip indent, with your other hand, hold the endcap as shown, and gently snap off the endcap.
- 2. Place the round protective lancet cap on a flat surface with the Bayer logo facing down.
- 3. With the used lancet still in the lancing device, push the lancet needle completely into the middle of the cap.
- 4. While pressing the release button (a), pull the re-setting handle (b), and the lancet will drop into the container you have selected.

WARNING: Potential Biohazard

- The meter, lancing device, lancets, and test strips are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients! 4,5
- Always dispose of test strip and lancet as medical waste. All products that come in contact with human blood should be handled as if capable of transmitting infectious diseases.
- Please refer to your MICROLET[®]2 package insert for instructions on how to properly remove and dispose of the lancet.

Test Results

Expected Values: Blood sugar values will vary depending on food intake, medication dosages, health, stress, or activity. Non diabetic plasma glucose concentrations are normally maintained within a relatively narrow range, roughly 70 - 110 mg/dL in the fasting state.6

You should consult with your health care professional for glucose values specific to your needs.

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

TESTING

Cleaning and Disinfection

Your CONTOUR®NEXT USB 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 USB meter and MICROLET®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 USB 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.

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 USB meter and MICROLET2 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

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

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.*

and **Disinfection**

Cleaning

Disinfecting Your Meter

USB Connector (under cap)

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

Cleaning Your Lancing Device

Supplies Needed for Cleaning:

- Clorox[®] Germicidal Wipes containing 0.55% sodium hypochlorite (bleach) • Paper towels
- 1. Clean the MICROLET[®]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:

Contour

- Clorox[®] 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.

3. Using a new Clorox 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[®]2 lancing device has been tested for 260 cycles of the cleaning and disinfection procedure (one cycle per week for 5 years). The MICROLET2 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

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Cleaning and Disinfection

TESTING

Your MICROLET2 lancing device is warranted for 5 years.

TESTING

High and Low Blood Sugar Alert Screens

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

If your blood sugar reading is under your low blood sugar alert level:

• A screen with largesized orange numbers will alert you that your blood sugar is low.

If your blood sugar reading is over your high blood sugar alert level:

- A screen with largesized 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, select Options and then Notes. You may now select Fasting, Before Meal, After Meal, or No Mark by pressing the button next to it.

- 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, follow medical advice immediately.
- Always consult your health care professional before changing your medication based on test results.

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.

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Test Results

TESTING

Control Solution Testing

Use only Bayer's CONTOUR®NEXT control solutions with vour CONTOUR®NEXT USB meter and CONTOUR NEXT test strips. Using any other control solution or any other combination of control solution and strips can cause incorrect results.

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 right
- you have repeated, unexpected blood glucose results

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. If you need help locating Bayer's CONTOUR NEXT control solutions, call Bayer Diabetes Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week).

- 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 toward the meter.
- 3. Insert the test strip into the test strip port on the meter.
- 4. The meter will turn on and show a test strip with a flashing blood drop.
- 5. Gently rock the control solution bottle to mix it well.

6. Squeeze a small drop of control solution on a clean nonabsorbent surface. Do not apply control solution to your fingertip or to the test strip directly from the bottle.

- 7. Immediately touch the tip of the test strip to the drop of control solution.
- TESTING

- 8. Hold the tip in the drop until the meter beeps.
- 9. The meter will show the AutoLog screen, but will sense control solution and switch to count down for 5 seconds and the control test result will be automatically marked

with "Control Test" on the screen and stored in memory. Control test results will not be included in your blood sugar averages.

- 10. Compare your control test result with the range printed on the test strip bottle or the bottom of the test strip box.
- 11. Remove the test strip to turn the meter off.

If your control solution test result is out of range, call Baver Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week). Do not use the meter or test strips for blood glucose testing until you resolve this issue.

TESTING

Setting a Test Reminder After Testing

A Reminder for your next test can be set after testing or from the Setup menu. A Reminder can be set in 15 minute increments from 15 minutes to 23 hours, 45 minutes.

1. With the test strip still in the meter, press the **Reminder** button.

2. Press the **Start** button to begin the Countdown. The preset 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.

- 3. Press the ▲ or ▼ button to select the correct hours. Press the 0K button.
- Press the ▲ or ▼ button to select the minutes (in 15 minute increments). Press the 0K button.

A screen confirms the Reminder Countdown time.

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

Remove the test strip from the meter. The meter retains the Reminder time that you set until you change it. To set a test Reminder at other times, see page 49.

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FEATURES

Turning Off a Test Reminder After Testing

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

HINT: If you do a blood sugar test within 15 minutes of when a Reminder is set, the Reminder will turn off.

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 and the Countdown is now stopped.

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 in two ways:

- 1. Press the ${\tt 0K}$ button, insert a test strip and proceed with testing, ${\sf OR}$
- 2. Insert a test strip and proceed with testing (see page 11).

HINT: If you decide to test within 15 minutes before the Reminder time, the Countdown will be stopped with the insertion of the test strip. Proceed with testing.

FEATURES

Logbook – Adding Carbs, Insulin and Notes Information

Log Carbs Information

You can log carbohydrates (carbs) information after testing or from the Logbook menu. Your CONTOUR®NEXT USB meter will store this information for you and display it in the Logbook.

Log Carbs Information after Testing

- 1. Press the Options button. The Options screen appears.
- 2. Press the Log Carbs button.

If you are using this option for the first time, you will need to select one of the carb units of measurement: Grams, Points, or Choices. Ask your health care professional whether you should be tracking your carbs in grams, points, or choices.

3. You can enter carbs you are eating right now, or anytime today or yesterday.

If you have just eaten and want to use the current time and date of your meter, press **Now**.

If you would like to enter carbs for a different time, choose **Other Time**.

Select Today or Yesterday.

Then, press the ▲ and ▼ buttons to enter the hour, minutes, and AM/PM. Press **0K** after each selection.

4. Enter the amount of carbs in the meal.

Press the \blacktriangle or \checkmark button to select the value. Press the **OK** button. When you are finished, a screen confirms your choice, and you can select **Accept** or **Change** to change your entry.

CONFIRM	
Carbs: 11 grams	Change
7/25/10 6:54PM	Accept

FEATURES

Carbs Information

-ogbook - Log

5. The meter will then ask if you want to log insulin information.

Select the Yes or No button to enter insulin information.

If you select No, you will be returned to the Main Menu screen. If you select Yes, see steps 2 to 5 in the following section on Logging Insulin Information.

Log Insulin Information

You can record your insulin dosage after testing or from the Logbook menu. Your CONTOUR®NEXT USB meter will store this information for you and display it in the Logbook.

Log Insulin Information after Testing

1. Press the Options button from your test results screen and press Log Insulin.

2. You can enter insulin you are taking right now, or from another time today or yesterday.

INSULIN		?	
When did you insulin?	i take	Now	If you are taking insulin now, select Now .
	0	ther Time	

If you would like to enter insulin for a different time, choose $\ensuremath{\texttt{0ther Time}}.$

Then, press the \blacktriangle and \blacktriangledown buttons to enter the hour, minutes, and AM/PM. Press **0K** after each selection.

FEATURES

3. Select your insulin type.

INSULIN	Fast-Acting
Select insulin	Long-Acting
type.	Mixed

4. Enter the amount of insulin in units using the \blacktriangle or \checkmark button.

Press **IK**.

5. A screen confirms your choice and you can select Change or Accept. If you select Accept you will see an option to log carbs information.

οк

6. Press the Yes or No button. If you select No, you will be returned to the Main Menu screen. If you select Yes, see steps 2 to 4 in the previous section on logging carbs information.

HINT: You can log insulin units in 0.5 unit increments from 0.5 to 200 units. Remember you can press and hold the \blacktriangle or \checkmark button to scroll faster.

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 **Options** button.

3. Press the \blacktriangle or \checkmark button to scroll through the choices. Some may not be visible until you scroll down. Press the **OK** button when your choice is highlighted.

A screen confirms your choice.

HINT: When you choose After Meal, Time After Meal will show and you will be prompted to enter a time. You can enter time in 15 minute increments from 15 minutes to 3 hours.

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

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FEATURES

Logbook – Log Insulin Information

Log Carbs Information from the Logbook Menu

- 1. Press and hold the Menu button until the meter turns on.
- 2. Go to the Main Menu by pressing the Menu button on the top of the meter.

5. Then follow steps 2 to 5 in the previous instructions to log carbs information.

Log Insulin from the Logbook Menu

- 1. Press and hold the Menu button until the meter turns on.
- 2. Go to the Main Menu by pressing the Menu button on the top of the meter.

5. Then follow steps 2 to 5 in the previous instructions for logging an insulin dose.

BAYER

Reviewing the Logbook

The Logbook menu contains Log Carbs, Log Insulin and Yiew Logbook.

To review entries in the Logbook:

1. Press and hold the **Menu** button on the top of the meter until it turns on.

 You can select All, Blood Sugar, Carbs or scroll down using the ▼ button to view Insulin options.

VIEW LOGBOOK	
All	01
Blood Sugar	F
Carbs	
Insulin	

The entries will be shown in chronological order beginning with the most recent. Your meter will store 2000 entries and delete the oldest when you have reached 2000.

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Log Carbs Information from the Logbook Menu

Trends

The Trends feature displays your averages and your results as they compare to your targets, over a period of time that you select. The options available are 7, 14, 30 and 90-day average. Your meter has been preset to 14-day averages, but you can change this in Setup.

HINT: Your 90-day average is not intended to be reflective of your HbA1c result.

Viewing Trends with AutoLog On

1. Press and hold the Menu button to turn the meter on and select Irends.

You will see this summary screen.

 Press the ▼ button to display the 14 Day Fasting Average. If you have marked any test results as Fasting, you will see your Fasting Average first.

Your screen will display the total number of test results included in the average and the number of tests above ↑, within ✓ and below ↓ target.

 Press the ▼ button to go to 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 within ✓ the target range, 8 above ↑ the target range and 4 below ↓ the target range.

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

Trends

Viewing Trends with AutoLog Off

1. Press and hold the Menu button to turn the meter on.

From the Main Menu. select Trends.

Your meter has been preset to 14-day averages. You can change the Trends time range to 7, 30, or 90 days in Setup.

2. Press the ▼ button to display the 14 Day Results screen.

You can change options on your meter and personalise it from the Setup menu. The Setup menu displays the current settings in the meter. By scrolling through the items, you can view each setting.

Setting a Reminder

1. Press and hold the Menu button to turn the meter on.

- 2. Reminder: Aff is highlighted. Press **OK** to
- 3. To accept the preset time of 2 hours, select Start. To change the time, select Change, and you can change the reminder time in 15 minute increments from 15 minutes to 23 hours 45 minutes.

- **Turning Off a Reminder**
- MAIN MENU FUNCTIONS

4. Once you have selected hours and minutes, press 0K. When you have selected the time for your Reminder, select 0K.

You will see a confirmation screen and can select Change or Accept.

HINT: If you do a blood sugar test within 15 minutes of when a Reminder is set, the Reminder will turn off.

Turning Off a Reminder

To turn off a reminder, you can use the Setup menu, or do a blood sugar test within 15 minutes of the Reminder time. To use the Setup menu:

1. Press and hold the Menu button to turn the meter on.

2. Reminder: On is highlighted. Press OK to turn it off.

C SETUP	
Reminder: On	
Date	
Time	
	the second se

3. Select Stop.

Reminder is now off.

SETUP	
Reminder: Off	οκ
Date	<u> </u>
Time	

MAIN MENU FUNCTIONS

Setting the Date

- 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 **Date**.

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

5. Select either the Month/Day/Year or Day.Month.Year button.

6. Press the \blacktriangle or \blacktriangledown button to select the correct year.

Setting the Date

MAIN MENU FUNCTIONS Press the OK button.

- 7. Press the ▲ or ▼ button to select the correct month. Press the 0K 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 **Accept** button and the Setup menu will appear.

Setting the Time

- 1. Press and hold the Menu button to turn the meter on.
- 2. Press the Setup button.
- 3. Press the ▲ or ▼ button to select Time. Press the **UK** 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.
- Press the ▲ or ▼ button to select the correct minute. Press the OK button.
- If you have selected the 12 hour clock format, press the ▲ or ▼ button to select AM or PM.

Time is set. A screen confirms your choice. Press Accept.

Turning the Sound On/Off

Sound is turned ON when you receive your meter. Some error messages and the Reminder bell will override the Sound Off setting.

- 1. Press the Menu button to go to the Main Menu.
- 2. Press the Setup button.
- 3. Press the ▼ button to select \$ound.

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

Your meter comes with AutoLog turned on. We recommend that you keep this feature turned on.

HINT: When AutoLog is ON, a result will not appear unless marked as Fasting, Before Meal, After Meal, or No Mark. If your test result is above the High Alert setting or below the Low Alert setting, you will see your result without pushing a button.

To Turn AutoLog Off:

1. Press and hold the Menu button to turn the meter on. Select **AutoLog** from the setup list, using the ▼ button.

OK button.

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

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

Carbs Settings

You can set your Carbs Units to Grams, Points, or Choices. You can also set these the first time you enter carbs information. You will <u>not</u> need to set these each time you use this feature, but can change them in the Setup menu.

CARBS	Grams
Select units:	Points
	Choices

1. Use the \blacktriangle or \blacktriangledown buttons to highlight your choice.

2. Select OK.

Changing the Blood Sugar Target Range with AutoLog On

When AutoLog is on, your CONTOUR®NEXT USB meter comes preset with the following target ranges for testing:

- 70 130 mg/dL: Before Meal
- 70 180 mg/dL: After Meal
- 70 130 mg/dL: Fasting

Ranges can be changed to personal targets decided upon by you and/or your health care professional.

HINT: Targets can only be set inside your selected Alert level(s). For more information, call Bayer Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week), or visit our website at www.bayercontour.com.

Talk to your health care professional before setting any target ranges on your meter.

- 1. Press and hold the Menu button to turn the meter on.
- 2. Press the Setup button.
- **3.** Press the $\mathbf{\nabla}$ button to select Target. Press **OK**.

MAIN MENU FUNCTIONS

Carbs Settings

4. To make changes to your Fasting target range, press the Change button, otherwise Accept.

TARGET	?
Fasting:	Accept
○ 70 - 130	Change

5

Blood Sugar Target Range with AutoLog

Changing

MAIN MENU FUNCTIONS

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Press the ▲ or ▼ button to select your desired Fasting targets. Press 0K.

Repeat this process to set your personal Before Meal targets and After Meal targets.

Press the **OK** button after each selection.

\star Targets are set. 🛛	
	Change
1 70 − 130 1 70 − 180	Accept

A screen confirms that all target ranges are set.

If correct, press the ficcept button. You will be returned to the Setup menu.

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

Changing Blood Sugar Target Range with AutoLog Off

- 1. Press the Menu button to go to the Main Menu.
- 2. Select Setup.

 Use your ▲ or ▼ buttons to change each value of the Target.

6. Press 0K. A screen confirms your choice.

Setting Trends Range

The Trends feature displays your averages and your results as they compare to your targets, over a period of time that you select. The options available are 7, 14, 30 and 90-day average. Your meter has been preset to 14-day averages, but you can change this in Setup.

- 1. Press and hold the Menu button to turn the meter on.
- 2. Press Setup.

Setting Trends Range

MAIN MENU FUNCTIONS

3. Press the ▼ button to select Irends Range.

Press 0K.

HINT: Your 90-day average is not intended to be reflective of your HbA1c result.

4. Select 7, 14, 30 or 90 Day by using the ▼ button and then press OK.

5. A screen confirms your choice.

High and Low Alerts

The High and Low Alerts tell you that your test result is above or below the setting you choose. Alerts appear as large orange numbers.

HINT: Alerts can only be set outside your selected Target Range(s). For more information, call Bayer Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week), or visit our website at www.bavercontour.com.

Discuss with your health care professional what Alert settings are best for you.

1. Choose **Accept** to use the preset value for high and low alerts. The preset high alert is 250 mg/dL and the preset low alert is 70 mg/dL.

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

- 2. Choose Change if you wish to use different alert levels.
- **3.** Press the \blacktriangle or \blacktriangledown button to select your high alert. Press 0K.
- **4.** Press the \blacktriangle or \blacktriangledown button to select your low alert. Press **OK**.
- 5. The next screen confirms your choices. Press Accept.

MAIN MENU FUNCTIONS

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 0K button.
- 4. Press the ▲ or ▼ button to select the language you prefer.
 Press ▼ to see more choices. Press the 0K button.

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

Customer Service

This option is to be used if you are speaking to a Customer Service representative. They will give you a code that enables them to verify certain settings. It is not for use any other time. Bayer Diabetes Care Customer Service is available 24 hours a day, 7 days a week at 1-800-348-8100.

GLUCOFACTS®DELUXE Diabetes Management Software

With GLUCOFACTS DELUXE software, you can view, print, save or email reports to your health care professional. Your meter comes with GLUCOFACTS DELUXE diabetes management software installed. The first time you use GLUCOFACTS DELUXE, you will need to follow these steps.

For PC Users:

- Plug your meter into a high-power USB port on your computer. A window will open. In the window, select Open folder to view files and then click 0K.
- 2. The GLUCOFACTS window will open. Double click on the GLUCOFACTS DELUXE Smart Launch application and follow the installation prompts.

GLUCOFACTS DELUXE will start. GLUCOFACTS DELUXE works with Java software, and will verify your computer's version of Java. If needed, you will be directed to update your Java version from the Java website.

HINT: If you do not have an Internet connection and Java software, please go to the Java folder on your CONTOUR®NEXT USB meter and double-click the file in that folder to install the Java update. After updating Java, unplug your meter and reinsert it to re-start GLUCOFACTS DELUXE.

Your initial setup of GLUCOFACTS DELUXE is complete. Thereafter, GLUCOFACTS DELUXE will automatically start. Any test results on your meter will be transferred to your computer screen and you can view or print GLUCOFACTS DELUXE reports.

MAIN MENU FUNCTIONS

For Mac Users:

- Plug your meter into a high-power USB port on your computer.
- You will see a drive appear on your desktop.
- Click the drive (this will open a Finder window displaying drive contents/files).
- Click the 'GLUCOFACTS DELUXE Smart Launch.mpkg' file and follow the installation prompts. GLUCOFACTS®DELUXE will start. Your initial setup of GLUCOFACTS DELUXE is complete. Thereafter, GLUCOFACTS DELUXE will automatically start.

For PC and Mac Users:

HINT: To avoid potential problems with the files installed on the USB drive of the CONTOUR®NEXT USB meter, both PC and MAC users must safely eject the drive prior to removing the meter from the USB port of a computer.

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

GLUCOFACTS®DELUXE Features

A variety of report styles are available by using the links along the top of your GLUCOFACTS DELUXE screen. Highlights of the reports:

- In the Logbook report, you can see details by pointing your mouse to a specific test result.
- View Standard Day or Standard Week showing results for combined days or weeks.
- View the Trends report. This is the first report screen that appears for you. If you have carbs and/or insulin entries in your meter, they will appear on the Trends report.
- Additional data analysis appears at the bottom of each report. Test results are color coded by above, below and within target.
- You can add comments in the reports.

HINT: Click the 🕜 button on any screen in GLUCOFACTS DELUXE for more help and information.

A GLUCOFACTS DELUXE User Guide is also available at www.bayerglucofacts.com.

Bayer's CONTOUR®NEXT USB meter has only been tested for use with Bayer's GLUCOFACTS®DELUXE diabetes management software. Bayer is not responsible for any erroneous results from the use of other software.

For more information, call 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.bayercontour.com.

Error Detection Displays

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

Used Test Strip Remove used strip. Repeat test with new 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 the error. The next lines describe what you should do. When an error screen has an **OK** shown, press the button next to it to continue.
- If you do not resolve the problem, contact Bayer Diabetes Care Customer Service at 1-800-348-8100 (available 24 hours a day, 7 days a week).

Battery Status

Battery Status Displays

The battery status will be displayed with a battery symbol Image: 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.

💶 menu	Logbook
	Trends
	Setup

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

Error Detection Displays

TECHNICAL & CARE

If you do not charge the battery, a display will alert you: **"Shutting down, Battery is dead.**" You must 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. If you wish to test immediately after disconnecting from your computer, please use the USB cable that has been provided for your convenience.

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

Battery Charging

When you plug your meter into your wall charger or computer, it will start to charge immediately. While the battery charges, the 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 sugar test as soon as Rapid Charge is complete and you have unplugged the meter.

Normal Charging

When Rapid Charge ends, normal charging is expected to last up to 2 hours when plugged into a high-power USB port. When the battery is full, the test strip port light turns off.

HINT: If the charging status displays "Low Power Charging," your CONTOUR®NEXT USB meter may be plugged into a low-power USB port. Please try a different USB port on your computer. Only connect to a computer or charger that is certified to UL 60950-1, 5V minimum. A charging current of 300 mA minimum is required.

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

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Battery Charging

Symptoms of High and Low Blood Sugar

& CARE

End of Meter Life/Battery Removal

HINT: 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 prv 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).

Symptoms of High and Low Blood Sugar

You can better understand your blood sugar results by being aware of the symptoms of high or low blood sugar. Some of the most common symptoms are:

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High Blood Sugar

Frequent Urination

Excessive Thirst

Increased Fatigue

Blurred Vision

Hunger

(Hyperglycemia)

Low Blood Sugar (Hypoglycemia)

- Shakiness
- Sweating
- Fast Heartbeat
- Irritability
- Seizure
- Extreme Hunger
- Dizziness •

Ketones (Ketoacidosis)

- Shortness of breath
- Nausea or vomiting
- · Very dry mouth

WARNING

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.

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

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TECHNICAL & CARE

Technical Information

Principles of the Procedure

The CONTOUR®NEXT USB 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 USB 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).7

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.

!	Result Over 600 mg/dL	
	Wash hands or test site. Beneat test with	0
E21	new strip.	

 If results are still over 600 mg/dL, "Follow Medical Advice Immediatelu" is displayed.

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Fechnical Information

Accuracy

The CONTOUR®NEXT USB blood glucose monitoring system was tested on 204 lay users using capillary blood samples and three CONTOUR®NEXT test strip lots. Results were compared to the YSI® glucose analyzer, which is traceable to the CDC hexokinase method. The tables below compare the performance of the two methods.

Table 1 — System accuracy results for CONTOUR NEXT USBmeter using CONTOUR NEXT test strips at glucoseconcentration < 75 mg/dL.</td>

Difference range in values between YSI laboratory reference method and CONTOUR NEXT USB meter	±5 mg/dL or ±5%	±10 mg/dL or ±10%	±15 mg/dL or ±15%	±20 mg/dL or ±20%
Number (and percent) of samples within specified range	8/8 (100%)	8/8 (100%)	8/8 (100%)	8/8 (100%)

Table 2 — System accuracy results for CONTOUR NEXT USBmeter using CONTOUR NEXT test strips at glucoseconcentration \geq 75 mg/dL.

Difference range in values between YSI laboratory reference method and CONTOUR NEXT USB meter	±5 mg/dL or ±5%	±10 mg/dL or ±10%	±15 mg/dL or ±15%	±20 mg/dL or ±20%
Number (and percent) of samples within specified range	152/196 (77.55%)	188/196 (95.92%)	193/196 (98.47%)	195/196 (99.49%)

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.

Precision

A repeatability study was conducted with the CONTOUR®NEXT USB blood glucose monitoring system using 100 venous whole blood specimens with glucose levels from 47 to 331 mg/dL. Multiple replicates (n=300) were tested using multiple CONTOUR NEXT USB blood glucose meters and three lots of CONTOUR®NEXT blood glucose test strips. The following precision results were obtained.

System repeatability results for CONTOUR NEXT USB meter using CONTOUR NEXT test strips

Mean, mg/dL	Pooled Standard Deviation	Coefficient of Variation, %
46.8	0.8	1.8
86.7	1.3	1.5
131.0	1.9	1.5
211.1	2.8	1.3
341.8	6.4	1.9

Precision

Service Information

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

Important

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

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

Check List

Service Information

TECHNICAL & CARE 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 67, Battery Status.)

Symbols Used

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

Symbo	What it Means	Symbol	What it Means
41°F-	^{rF} Temperature limitations	Â	Caution
C	Recycle Packaging		Certified USB-IF

System Specifications

Test Sample: Capillary and venous 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 2000 entries

Battery Type: Non-serviceable, 250mAh rechargeable lithium polymer battery, 3.4v – 4.2v (5V input voltage)

Meter/Battery Life: 5 years

Charging Current: 300 mA ∩**∽86°F** Strip Storage Temperature Range: $_{48^{\circ}F}$ -86°F Normal Control Storage Temperature Range: 59°F |**∕~113°F** Meter Operating Temperature Range: 41°F-/ Humidity: 10-93% RH

Dimensions: 3.8 in (H) x 1.2 in (W) x 0.7 in (T)

Weight: 1.5 ounces

Sound Output: 45 to 80 dBA at a distance of 10 cm

Electromagnetic Compatibility (EMC): The

CONTOUR®NEXT USB meter complies with the electromagnetic requirements specified in ISO 15197: 2003. 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 USB meter. Immunity to electrostatic discharge meets the requirements of IEC 61000-4-2: 2008. It is advisable to avoid use of electronic devices in very dry environments especially if synthetic materials are present.

The CONTOUR®NEXT USB meter has been tested for radio frequency interference at the frequency range and test levels specified by ISO 15197: 2003. To avoid radio frequency interference, do not use the CONTOUR NEXT USB 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.

System Requirements

Windows XP SP3, Windows Vista SP3 and Windows 7 SP1 MAC OS X 10.7.1 Java 1.6 update 17 or higher For latest compatibility - www.BayerContourNextUSB.com

References

- 1. Wickham NWR, Achar KN, Cove DH. Unreliability of capillary blood glucose in peripheral vascular disease. Practical Diabetes. 1986;3(2):100.
- 2. Atkin, S. et al. Fingerstick Glucose Determination in Shock. Ann Intern Med. 1991:114:1020-1024.
- 3. Desachy A, Vuagnat AC, et al. Accuracy of bedside glucometry in critically ill patients: influence of clinical characteristics and perfusion index. Mayo Clin Proc. 2008;83(4):400-405.
- 4. 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
- 5. 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
- 6. Longo D.L. et al. Harrison's Principles of Internal Medicine, 18th Edition. 2011. http://www.accessmedicine.com
- 7. Tietz Fundamentals of Clinical Chemistry, 5th Edition, Edited by Burtis CA and Ashwood ER, W. B. Saunders Co., Philadelphia, PA, 2001, p. 444.

& CARE

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System Specifications

Caring for Your Meter

CAUTION: Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.

- 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 water, oils and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- The USB cap of your CONTOUR®NEXT USB 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

Replacement Parts

Item

CONTOUR®NEXT USB user guide CONTOUR NEXT USB quick reference guide Bayer's USB extension cable USB cap Wall charger CONTOUR®NEXT test strips CONTOUR NEXT control solution

Check the website www.bayerdiabetes.com for any meter updates or GLUCOFACTS®DELUXE software updates. *Part numbers are subject to change without notice. To order parts, please call Bayer Diabetes Care Customer Service at 1-800-348-8100, 24 hours a day, 7 days a week.

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 USB 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 USB 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 USB 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 USB meter or test results when used with any software other than Bayer's GLUCOFACTS®DELUXE diabetes 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 CONSEQUENTIAL DAMAGES, EVEN IF BAYER DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

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

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

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Narranty

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