

# Contour USD

**BLOOD GLUCOSE MONITORING SYSTEM** 





#### **USER GUIDE**

USES BAYER'S CONTOUR® BLOOD GLUCOSE TEST STRIPS www.bayerdiabetes.ca



Bayer is committed to providing tools and services to make life simpler for people with diabetes. GLUCOFACTS® DELUXE software is installed on your CONTOUR® USB meter. Plug your meter into your computer for access to helpful reports of your stored data. You can change your meter settings to personalize the way you test, record and view your blood glucose results. Easy accuracy and helpful reports provided by Bayer with the CONTOUR USB meter and GLUCOFACTS® DELUXE software are simple. With diabetes, simple wins.

Please keep this User Guide for your reference.

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#### Your CONTOUR® USB Blood Glucose

The CONTOUR® USB blood glucose monitoring system (meter, test strips and controls) is intended for self-testing by people with diabetes and by healthcare professionals to monitor glucose concentrations in whole blood. Capillary samples may be drawn from alternative site testing locations. The CONTOUR USB system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The MICROLET®2 lancing device included in the kit is not suitable for use by healthcare professionals. It must not be used on more than one person due to the risk of infection. Used test strips and lancets are possible biohazard and must be disposed of properly.

#### **Rechargeable Battery:**

see page 52.

Your meter has a permanent rechargeable battery. Before you do anything else, charge your battery by plugging your CONTOUR USB meter into your computer. Be sure your 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

#### Test Strip

Grey Electrode End: Insert this end into test strip port with grey end face up.

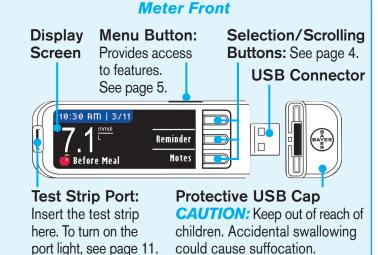
#### Sample

drawn in here. **CAUTION:** Your

CONTOUR USB meter **only** works with CONTOUR test strips!



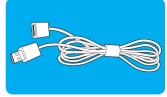
#### **Monitoring System:**



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

A USB extension cable is included for your convenience.

For more information on Battery Status Displays and Charging see pages 50-52.



**Getting Started** 

System

Monitoring

Glucose

Blood

SB

CONTOUR

# Setting

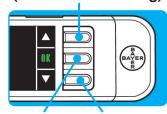
Meter Overview

#### **Meter Overview:**

#### **Using the Buttons -**

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





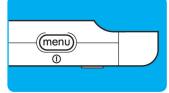
OK Button ▼ Button (Selection/ Scrolling)

#### Using the Selection/Scrolling Buttons -

When the ▲ or ▼ arrows appear on the screen, the buttons are used for scrolling. When your choice is highlighted, make a selection by pressing the OK button. Pressing and holding the ▲ or ▼ buttons will scroll through the list faster.

#### **Using the Menu Button -**

 To turn on the meter and access the main menu, press and hold the Menu button until the meter turns on.



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

 Select one by pressing the button next to your choice.



 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 on the test strip port light with the meter off, press the Menu button twice with one second between each press. Press the Menu button twice to turn the light off.

#### Introducing AutoLog -

Your meter comes with a simple AutoLog feature that lets you mark your test result as **© Before** 



Meal or  $\widehat{T}$  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.

#### To Run a Blood Sugar Test -

Read user guide and all instructional materials provided in your meter kit before testing.

To test, insert a CONTOUR® test strip and the meter will turn on.

Follow the on-screen prompts.

Remove the test strip to turn the meter off.

#### Extra Memory -

Your meter contains 500 MB extra memory.

Extra memory and GLUCOFACTS® DELUXE software require a high-power USB port. For more details see page 53.

We encourage you to plug your meter into computers with current anti-virus software installed and running.

**NOTE:** Computer viruses cannot affect the blood sugar data on your CONTOUR® USB meter.

## **GLUCOFACTS® DELUXE Data Management Software:**

When you plug your CONTOUR® USB meter into your computer's USB port, follow your computer specific prompts to initiate GLUCOFACTS® DELUXE software.



For more information see the GLUCOFACTS® DELUXE User Guide or Quick Start Guide.

# Initial Startup Using Quickstart

**Getting Started** 

#### **Initial Startup:**

First charge your meter. Your computer can be used to perform initial startup while your meter is charging. You can also initiate setup directly on your meter once it is fully charged. When you first turn on your CONTOUR® USB meter, a setup sequence begins.

- Press and hold the Menu button until the meter turns on. After a welcome screen, you will see the Select Language screen.
- Press the ▲ or ▼ button to select your desired language. When highlighted, press the 0K button.



A screen confirms your language.



On the next screen choose: Quickstart (see page 9), Customize (see page 10), or ? Help.



**Quickstart** – is set to the default settings. You will need to confirm the date and time, then you can immediately begin testing. You can also change these settings later.

Customize – allows you to adjust settings.

By default:

AutoLog is on;

Target is set to: Before Meal, 3.9-7.2 mmol/L After Meal, 3.9-10.0 mmol/L

Targets have been preset according to American Diabetes Association Clinical Practice Guidelines, 2009.

These settings can be changed in Setup.

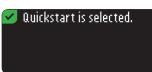
? Help – provides additional information.

#### **Initial Startup Using Quickstart:**

Press the Quickstart button.



A screen confirms your choice.



• The next screen has the current date and time. If it is correct press the **Accept** button. If incorrect, press the **Change** button (see pages 43–45).



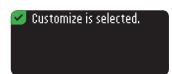
Setup is complete. You may now check your blood sugar.

#### **Initial Startup Using Customize:**

 Press the Customize button to change the default settings.



A screen confirms your choice.



 The next screen has the current date and time. If it is correct press the Accept button. If incorrect, press the Change button (see pages 43-45).



A screen confirms the date and time are set.

 The next screen shows that AutoLog is on. AutoLog lets you mark a test as Before Meal or After Meal during the 5 second test time.



To turn AutoLog off, see page 47.

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



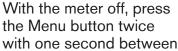
These values can be changed to the range you and/or your healthcare professional decide are your personal target ranges. You can accept the default ranges or change them by pressing the Change button (see page 48).

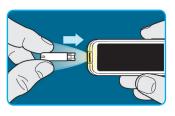
A screen confirms your target is set.

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

#### **Testing in the Dark:**

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





each press 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 guick presses of the Menu button will turn the light off.

**Getting Started** 

**Customize** 

Using

Initial Startup

Important Things

Ö

Know

**Getting Started** 

#### **Important Things to Know:**

- ► Always keep the test strips in the original bottle. Tightly close the bottle immediately after **removing a test strip.** The bottle is designed to keep the test strips dry. Exposure to room humidity from leaving the bottle open or not storing them in the original bottle can damage your test strips.
- Do not drop blood directly on the flat surface of the test strip. Your test strip is designed to easily "sip" the blood into the sample tip.
- Do not press the test strip against your finger. This may block the sample tip.
- Test strips are for single use only.
- Do not use a test strip that appears damaged or has been used.
- Let the meter and test strips adjust to the temperature of the location where you are testing. Allow 20 minutes for the meter to adjust to the temperature of that new location before performing a blood glucose test. The products have been designed to give accurate results at temperatures between 5°C and 45°C. Please be aware that USB ports in some computers and self-powered USB hubs can become much warmer than the room. A USB cable has been provided for your convenience. If you wish to test immediately after disconnecting from your computer, please use the USB cable.
- Check the expiration dates on your test strips and control solution.

#### **Important Note:**

- Your meter has been preset and locked to display results in mmol/L (millimoles of glucose per liter). In some countries, the meters are preset to display units in mg/dL (milligrams of glucose per deciliter);
- Results in mmol/L will always have a decimal point;
- Results in mg/dL will never have a decimal point.

**Example:**  $5.2^{\frac{mm}{L}}$  or  $93^{\frac{mq}{L}}$ 

Check your screen to ensure that results are being displayed in mmol/L. If they are not, contact Bayer Diabetes Care Helpline, 1-800-268-7200.

#### **Before You Begin Testing:**

- 1. Have your testing materials ready, including your CONTOUR® USB meter, CONTOUR® test strips, and the MICROLET®2 lancing device with MICROLET® lancets. You may also need CONTOUR® control solution to run a quality control check.
- 2. Wash your hands and "puncture site" thoroughly with warm soapy water and dry them well before testing.

# Getti

#### **Getting Ready to Test:**

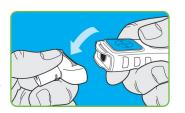
Read the MICROLET®2 insert for complete instructions. If you are using a different lancing device, refer to those instructions.

For fingertip testing, you will use the solid colour endcap. For Alternative Site Testing, you will use the clear endcap. For Alternative Site Testing instructions, see page 18.

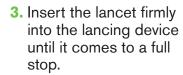
#### **Potential Biohazard**

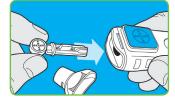
The MICROLET®2 lancing device is designed for self testing by a single patient. It must not be used on more than one person due to the risk of infection. Use a new MICROLET® lancet each time you test because it is no longer sterile after use.

1. 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.

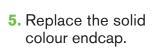


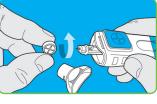
2. Loosen the round protective cap on a lancet by rotating it 1/4 turn, but do not remove it.

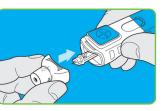




**4.** Twist off the round protective lancet cap. Save it for disposing of the used lancet.







Ready to Test

Getting

# NO

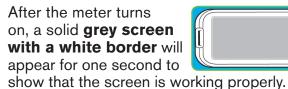
**NOTE:** Your CONTOUR® USB meter codes itself every time you insert a test strip, so you do not have to worry about CODING m getting inaccurate results due to miscoding or forgetting to code your meter.

6. Remove a test strip from the bottle. Tightly close the bottle lid immediately after vou have removed the test strip.

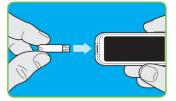


**NOTE:** Check the expiration date. Make sure the test strip does not appear torn or damaged.

- 7. Hold the test strip with the grey end facing up.
- 8. Insert the grey end into the test strip port on the meter.



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







#### **Getting the Blood Drop:**

#### For fingertip testing

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

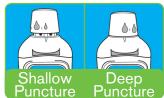




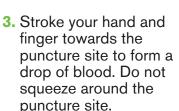
**Testing** 

**Getting the Blood Drop** 

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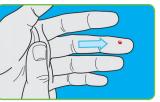


2. Press the endcap firmly against the puncture site and press the blue release button with the Bayer logo.



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







#### If you selected fingertip testing, turn to page 22 to continue reading testing instructions.

For Alternative Site Testing (AST)

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

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

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

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 alternative site results.

Need Help? Call toll free: 1-800-268-7200

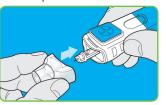
Alternative Site Testing (AST) is recommended only when it is more than two hours after a meal. diabetes medication, or exercise.

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

#### Use the Clear endcap



To receive a clear AST endcap, please call the Bayer Diabetes Care Helpline: 1-800-268-7200.



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



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



**Getting the Blood** 

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#### For forearm testing:

 Rub the testing area vigorously until it feels warm to increase blood flow.



2. Press the clear endcap firmly against the puncture site and then press the blue release button. Keep the device in constant



contact with the skin and pump (apply and release pressure) up and down 2-3 times without lifting the device away from the skin.

3. Maintain steady pressure until a small round blood drop forms.



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



For palm testing, it is not necessary to rub the skin or pump the device up and down.

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



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



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



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

**Getting the Blood Drop** 

Your Blood

Testing

#### **Collecting Your Blood Drop:**

- Immediately touch the tip of the test strip to the drop of blood.\* The blood is drawn into the test strip tip.
- 2. Hold the tip of the test strip in the blood drop until the meter beeps.

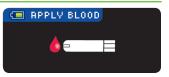


Do not press the tip against the skin or place the blood on top of the test strip.





\*NOTE: If you do not apply blood to the test strip in 1 minute, the meter screen will dim and



the meter beeps. Press any button and the **Apply Blood** screen will become active again. After a total of 3 minutes of inactivity the meter turns off.

#### **Testing with AutoLog On:**

Before your test result is displayed, the AutoLog screen appears. Select Before Meal, Rfter Meal or No Mark by pressing the button next to it. Your test result will not display until you make a selection. However, if your result is a low blood sugar result or high blood sugar result, you will always see your result in 5 seconds.



Your meter features a 5 second test time. If you make your selection in less than 5 seconds, you will see the remainder of the testing countdown.



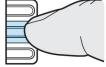
Your test result is displayed in large numbers for 2 seconds before changing to the normal test result screen. For results under



1.1 mmol/L or over 33.3 mmol/L, see page 26.

You can now set an optional Reminder (see page 32) or add a Note (see page 39).





Remove the test strip to turn the meter off.

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

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

#### **Testing with AutoLog Off:**

After applying blood to the test strip when AutoLog is turned off, the testing countdown screen appears for the 5 second countdown.



Your test result is displayed.



You may add a Note or Reminder. Please see pages 32 and 39 for further instructions.

**Testing Your Blood** 

#### **Test Results:**

**Expected Values:** Blood sugar values will vary depending on food intake, medication dosages, health, stress, or activity. Non diabetic expected values are 3.9 to 7.2 mmol/L fasting.<sup>1</sup> **You should consult with your healthcare provider for expected values specific to your needs.** 

#### **High and Low Blood Sugar Alert Screens:**

 If your blood sugar reading is under
 1.1 mmol/L, the normal screen sequence will appear for 5 seconds.



The "Follow Medical Advice Immediately" screen will then display and the meter will beep twice.

 If your blood sugar reading is over
 33.3 mmol/L the normal screen sequence will display for 5 seconds and the next screen will



and the next screen will tell you to retest. The meter will beep twice.

 If results are still over 33.3 mmol/L, "Follow Medical Advice Immediately" is displayed.



#### **CAUTION:**

- If your blood sugar reading is under 2.8 mmol/L, follow medical advice immediately.
- If your blood sugar reading is over 13.9 mmol/L repeat the test. If you get a similar result, call your healthcare professional immediately.
- Do not change your medication based on CONTOUR® USB blood sugar results without the advice of your healthcare professional.

**Testing** 

**Test Results** 

**Testing** 

#### **High and Low Blood Sugar Readings:**

Your meter has been preset with a hypoglycemic (low blood sugar) value of 3.9 mmol/L and a hyperglycemic (high blood sugar) value of 13.9 mmol/L. These are the default values, but can be customized by you and/or your healthcare professional using the **GLUCOFACTS® DELUXE software** on your computer. See the GLUCOFACTS® DELUXE User Guide for assistance.

#### Low Blood Sugar

If your blood sugar reading is under 3.9 mmol/L:

 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 13.9 mmol/L:

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



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

#### **Symptoms of High and Low Blood Sugar:**

You can better understand your test results by being aware of the symptoms of high or low blood sugar; this will also help you decide what to do if your results seem unusual.

Some of the most common symptoms are:2

## High blood sugar (Hyperglycemia):

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

#### **Ketones (Ketoacidosis):**

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

# Low blood sugar (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- seizure

CAUTION: Blood sugar levels below 2.8 mmol/L or above 13.9 mmol/L may indicate a potentially serious medical condition. If your test result is below 2.8 mmol/L or above 13.9 mmol/L, consult a healthcare professional immediately.

For additional information and a complete list of symptoms, contact your healthcare professional or refer to the website for the Canadian Diabetes Association: www.diabetes.ca **Performing** 

#### **Performing a Control Test:**

You should perform a control test:

- When using your meter for the first time
- To check if you are testing correctly
- © Contour
- When you open a new bottle of test strips
- If you leave the test strip bottle open for an extended period of time
- If you think your meter may not be working properly
- If your test results do not match how you feel.

Low, Normal and High control solutions are available. Always use CONTOUR® control solutions, as other brands could present incorrect results.

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

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

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

- 6. Immediately touch the tip of the test strip to the drop of control solution.
- **7.** Hold it in the drop until the meter beeps.

Even when AutoLog is on, there is no need to mark the control test. In 5 seconds the meter displays the control test result.



10:30 AM | 3/11

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



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

If your control test result falls out of the specified range, call the Bayer Diabetes Care Helpline, 1-800-268-7200. Do not perform any blood glucose tests until you resolve this issue.

The result will automatically be marked as a control test and stored in the meter memory. Control results will not be included in your blood sugar average. To turn your meter off, simply remove the test strip.

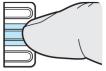
#### **Setting a Reminder:**

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

#### After Testina:

1. Press the Reminder button.





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



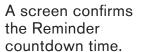


You can change the Reminder countdown time to the time you wish by pressing the **Change** button.



Need Help? Call toll free: 1-800-268-7200

- 1. Press the ▲ or ▼ button to select the correct hours. Press the OK button.
- 2. Press the ▲ or ▼ button to select the minutes. Minutes change in 15 minute increments. Press the OK button.



The meter will return to the test result screen.

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





Reminder

Setting





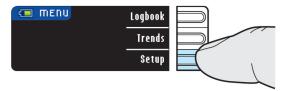
3. Remove the test strip from the meter.

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

# ninder

#### 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 **\$tart** button or press the **Change** button to scroll to a different countdown time. Follow the instructions on the previous page.



A screen confirms the Reminder time set.

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





Reminder

Setting

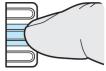
#### **Turning Off a Reminder:**

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

#### After Testina:

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.



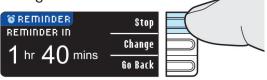
The Countdown is now stopped and the clock symbol i will disappear.

#### From the Setup Menu:

1. Press the OK button.



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



A screen confirms your choice.



Reminder

**Turning** 

37

#### **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 **0K** button.



2. Proceed with testing (see page 14).

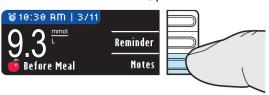


If you are testing when the Reminder countdown time is within 15 minutes of the reminder, neither screen will appear and the countdown will be stopped.

#### **Adding Notes:**

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

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



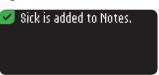
2. Press the ▲ or ▼
button to scroll through
the choices. Some
may not be visible until
you scroll up or down.
Press the OK button



Adding Notes

when your choice is highlighted.

A screen confirms your choice.



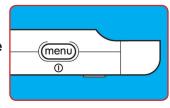
After the confirmation screen disappears, you may add additional Notes by repeating the steps above. The notes will scroll



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, press the Menu button twice with one second between each press. Press the Menu button twice to turn the light off.

#### Logbook:

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

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



The most recent result is shown first and the oldest result last. When you reach the oldest entry you will see the End of



Logbook screen. Your meter will store 2000 test results.

#### **Trends:**

1. Press the Irends button to view averages.



14 days is the default. To change the averages to 7 or 30 days, plug the meter into your computer and set using GLUCOFACTS® DELUXE software.

If AutoLog is on, the default (Gefore Meal) and (After Meal) target ranges will appear. To set personalized target ranges, see page 48.



**Trends** 

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
- 14 DRV BEFORE MEAL

  RUERRGE

  7.1 mmol

  38 mm/26

  ▼

average is 7.1 mmol/L and 38 test results are included in the Before Meal average with 26 in the  $\checkmark$  target range, 8  $\uparrow$  over your target range and 4  $\downarrow$  under the target range.

- Press the ▼ button to go to the 14 Day After Meal Average.
- 14 DRY RFTER MERL

  RVERRGE

  9.7 mmol

  17. 3

  T
- 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.

#### Setup:

#### **Setting the Date -**

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



- **4.** To change the date, press the **Change** button.
- DRTE
  SELECT
  Month/Day/Year
  Day.Month.Year
- 5. Select either the Month/Day/Year or Day.Month.Year button.
- 6. Press the ▲ or ▼ button to select the correct year. Press the OK button.
- 7. Press the ▲ or ▼ button to select the correct month. Press the OK button.
- 8. Press the ▲ or ▼ button to select the correct day. Press the **OK** button.







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



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

#### Setting the Time -

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



- **4.** To change the time, press the **Change** button.
- SELECT FORMAT

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

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

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









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

the

Setting

Setup: 3

#### Turning the Sound On/Off -

Sound is turned ON when you receive your meter. It can be turned off using the Setup menu. Certain 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.



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

To keep the sound on, press the **Go Back** button.

A screen confirms that sound is off. The Setup menu will appear.





#### Turning AutoLog On/Off -

The AutoLog feature lets you mark your test result as Before Meal or After Meal during the 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.

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 ranges.

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



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

To keep the AutoLog on, press the Accept button.

A screen confirms that AutoLog is off. The Setup menu will appear.





On/Off

**AutoLog** 

Setup: Turning

#### Changing the Blood Sugar Target Range -

Your CONTOUR® USB meter comes preset with 3.9–7.2 mmol/L for Before Meal testing and 3.9–10.0 mmol/L for After Meal testing. Ranges can be changed to personal targets decided by you and/or your healthcare professional. **Use GLUCOFACTS® DELUXE software to make such changes.** 

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



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



5. Press the ▲ or ▼ button to select your desired (Before Meal) low target.
Press the 0 button.



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

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



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

#### **Setting the Language -**

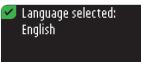
- 1. Press the Menu button to go to the Main Menu.
- 2. Press the **Setup** button.
- Press the ▲ or ▼ button to select Language.
   Press the OK button.



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

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





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the

Setting

Setup:

Status/Charging/Removal

Battery

and

**Detection** 

Error

#### **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 <sub>EO2</sub> strip.

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

#### **Battery Status Displays:**

The battery status will be displayed with a battery symbol on the Apply Blood screen and the Main Menu screen. It



shows how much battery life is left. This screen displays full battery.

As the battery is used, the battery symbol on the screen gradually shows less fill colour. The colour 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 computer. Be sure your computer is turned on and not in sleep, hibernate or power save mode. Please be aware that USB ports in some computers and



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

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

# lecnnical, Service & Care

Status/Charging/Removal

**Battery** 

and

Detection

Error

#### **Battery Charging:**

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

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

#### Rapid Charge

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



#### Normal Charging

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

NOTE: A high-power USB port will allow you to access GLUCOFACTS® DELUXE and your meter's extra memory. It also allows the shortest charging time. If the charging status displays "Low Power Charging," your CONTOUR USB meter may not be plugged into a high-power USB port. Please try a different USB port on your computer. If you are unsure whether your computer has a high-power USB port, please check with your computer user manual or the computer manufacturer.

#### **Extra Memory:**

Your meter contains 500 MB extra memory. It appears on your computer as a "Removable Disk" when you insert your meter into the USB port. You can use this memory while your battery is charging. When you read or write to the memory, the strip port light flashes quickly.

#### Wall Charger:

For information about a wall charger, please call the Bayer Diabetes Care Helpline at 1-800-268-7200 or visit www.bayerdiabetes.ca

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# Technical, Service & Care

Information

**Performance** 

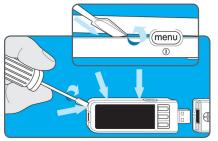
System

#### **End of Meter Life/Battery Removal:**

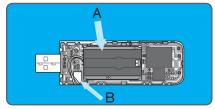
NOTE: Carry out this process only when you no longer intend to use the meter. Meter will not be functional once opened to remove the battery.

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

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



Pry off the black plastic cover over the battery (A). Disconnect the battery from the connector (B).



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

### **System Performance Information:** Intended Use:

The CONTOUR® USB system (meter, test strips and control) is intended for self-testing by people with diabetes to monitor glucose concentrations in whole blood. Capillary samples may be drawn from alternative site testing locations. The test provides a quantitative measurement of glucose in blood from 1.1 to 33.3 mmol/L.

The CONTOUR USB system is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

#### **CAUTION:**

- For in vitro diagnostic use only.
- Potential Biohazard:

The CONTOUR USB 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 viral diseases.<sup>3</sup>

#### **Principles of the Procedure:**

The CONTOUR® blood glucose test is based on measurement of electrical current caused by the reaction of 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 potassium ferricyanide. 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.

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#### **Limitations:**

- Preservatives: Blood may be collected by healthcare professionals into test tubes containing heparin. Do not use other anticoagulants or preservatives.
- Altitude: Up to 3048 meters (10,000 feet) does not significantly affect results.
- Lipemic Specimen: Cholesterol concentrations >12.9 mmol/L or triglyceride concentrations >34.3 mmol/L may produce elevated readings.
- Peritoneal dialysis solutions: Icodextrin does not interfere with CONTOUR® test strips.
- Xylose: Do not use during or soon after xylose absorption testing. Xylose in the blood will cause an interference.
- Contraindications: Capillary blood glucose testing may not be clinically appropriate for persons with reduced peripheral blood flow. Shock, severe hypotension, hyperosmolar hyperglycemia and severe dehydration are examples of clinical conditions that may adversely affect the measurement of glucose in peripheral blood.4
- Interference: Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect results. The limiting concentrations of these compounds are listed in your test strip insert.

#### System Requirements:

Windows®: XP SP3, Vista SP2

Mac: OS® X v10.5.2 (Intel® 64 bit processors only)

High-Power USB port Java 1.6.0 07 or higher

For latest compatibility: www.bayerdiabetes.ca

#### **Precision and Accuracy Summary:**

Accuracy: The accuracy of the CONTOUR® USB blood glucose monitoring system has been assessed in a correlation study conducted by healthcare professionals. In this study 100 fresh capillary blood specimens were tested with the CONTOUR USB blood glucose monitoring system by 100 untrained people with diabetes using three test strip lots. The reference measurement was done on the YSI<sup>™</sup> Glucose analyzer. CONTOUR USB data compare well with the results from the YSI method.

Regression Statistics (Plasma/Serum Reference): plasma reference glucose range: 3.2 mmol/L to 22.8 mmol/L

Lot	y =	Correlation Coefficient (r)
1	0.97x + 0.25 mmol/L	0.975
2	1.04x - 0.23 mmol/L	0.971
3	1.01x + 0.15 mmol/L	0.979

Precision: A study was conducted with the CONTOUR USB blood glucose monitoring system with five heparinized whole blood specimens with glucose levels from 2.3 mmol/L to 18.9 mmol/L. Multiple replicates (n=100) were tested using multiple CONTOUR® USB blood glucose meters and one lot of CONTOUR® blood glucose test strips. The following precision results were obtained.

#### Plasma/Serum:

Mean	SD	Coefficient of variation
2.4 mmol/L	0.06 mmol/L	2.4%
4.7 mmol/L	0.08 mmol/L	1.7%
7.3 mmol/L	0.10 mmol/L	1.3%
11.3 mmol/L	0.19 mmol/L	1.7%
18.4 mmol/L	0.21 mmol/L	1.2%

Information

**Performance** 

System

#### **Service Information:**

If you have a problem and none of the problem solving messages on the meter help, call Bayer Diabetes Care Helpline. In Canada, call toll free: 1-800-268-7200. We have trained specialists to help you.

#### Important:

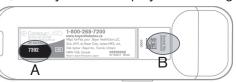
Speak to a Bayer Diabetes Care Helpline Representative before returning your meter for any reason. He/she will give you the information needed to get your problem handled correctly and efficiently.

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

#### **Check List:**

This check list may be helpful when speaking with Bayer Diabetes Care Helpline:

- 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 50, Battery Status Displays and Charging.)



#### **Specifications:**

Test Sample: Whole blood

Test Result: Referenced to plasma/serum glucose

Sample Volume: 0.6 µL

Measuring Range: 1.1-33.3 mmol/L

Measuring Time: 5 seconds

Memory: Stores most recent 2000 test results

Battery Type: Non-serviceable, 280mAh rechargeable lithium polymer battery, 3.4-4.2v (5V input voltage)

Meter / Battery Life: 5 years Charging Current: 500mAh Charging Temperature: 0°-35°C Shipping, Storage and Operating Temperature Range: 5°-45°C

Humidity: 10-93% RH

Dimensions: 97mm (H) x 30mm (W) x 16mm (T)

Weight: 43 grams (1.5 oz.)

**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.

Extra Memory: 1 GB portable flash drive with 500 MB user-accessible partition.

Emissions: CONTOUR® USB 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 CONTOUR USB. 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.

Specifications

Technical, Service & Care

Supplies/References

#### **Caring for Your Meter:**

- CAUTION: Only connect to a computer or charger that is certified to UL 60950-1, 5V maximum. A charging current of 500 mAh minimum is required.
- If you use a cable, use the one provided in your meter kit.
- Store your meter in the carrying case provided whenever possible.
- Wash hands and dry them thoroughly before handling to keep the meter and test strips free of oils and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing meter and test strips to excessive humidity, heat, cold, dust, or dirt.
- The exterior of the meter can be cleaned using a moist (not wet) lint-free tissue with a mild detergent or disinfectant solution, such as 1 part bleach mixed with 9 parts water. Wipe dry with lint-free tissue after cleaning. Do not insert anything into or attempt to clean inside the USB connection or test strip port.

**CAUTION:** Do not allow cleaning solution to run in or around the buttons, USB cap, or strip port. Doing so may cause a malfunction.

• The USB cap of your CONTOUR USB meter is designed to protect the USB port. Should you lose the cap, call 1-800-268-7200 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

81732893 CONTOUR® USB User Guide 81363014 Bayer's USB Extension Cable

81675369 USB Cap

7081C CONTOUR® Test Strips (box of 50)
7091C CONTOUR® Test Strips (box of 100)

7109BB CONTOUR® Normal Control Solution (2 vials)
7110BB CONTOUR® Low Control Solution (1 vial)
7111BB CONTOUR® High Control Solution (1 vial)

6611 MICROLET®2 Lancing Device 6546RC MICROLET® Lancets (box of 100's) 6550RC MICROLET® Lancets (box of 200's)

\*Part numbers are subject to change without notice.

These parts are available in Canada from:

Attention: Diabetes Care Customer Service

Bayer Inc.

Toronto, Ontario M9W 1G6

Canada

www.bayerdiabetes.ca

or call 1-800-268-7200 to order

#### **References:**

- <sup>1</sup> Fauci, A. et al.: Harrison's Principles of Internal Medicine-17th Edition, 2008.
- <sup>2</sup> Canadian Diabetes Association, www.diabetes.ca
- <sup>3</sup> Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline–Third Edition. Clinical and Laboratory Standards Institute (CLSI), document M29-A3, (ISBN 1-56238-567-4). CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2005.
- <sup>4</sup> Atkin, S. et al.: Fingerstick Glucose Determination in Shock. Ann. Int. Med. 114:1020-24; 1991.

# lechnical, service & Care

Warranty

#### **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, 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 reagents (i.e., CONTOUR® 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® USB blood glucose meter when used with any test strips other than CONTOUR® test strips, and therefore makes no warranty of the performance of the CONTOUR USB meter when used with any test strips other than CONTOUR test strips or when the CONTOUR test strip is altered or modified in any manner.

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.

For warranty service: Purchaser must contact Bayer Diabetes Care Helpline, by calling toll free 1-800-268-7200, for assistance and/or instructions for obtaining service of this instrument.

Patents: The system described herein is covered by one or more of the following US patents: 5,120,420; 5,266,179; 5,582,697; 5,620,579; 5,723,284; 5,954,738; 6,059,946; 6,451,040; 6,599,406; 6,827,829; 6,911,131; 7,232,510; as well as pending applications and international equivalents.



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81732893 Rev. 8/09